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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THEO ARNITZ

Appeal 2017-011477
Application 13/524,760
Technology Center 3700

Before JENNIFER D. BAHR, LISA M. GUIJT, and BRENT M. DOUGAL, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Theo Arnitz (Appellant)[1] appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1–5, 8, 11, 13–16, 19, 20, and 25–36.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

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[1] According to Appellant, the real party in interest is Roche Diabetes Care, Inc. Appeal Br. 3.

[2] Claims 6, 7, 17, 18, and 21–24 have been withdrawn from consideration. Appeal Br. 24–27 (Claims App.). No other claims are pending.

THE CLAIMED SUBJECT MATTER

Claim 1, reproduced below, is illustrative of the claimed subject matter.

> 1. A device for the dosed dispensing of a fluidic medium, the device comprising:
>
> a housing;
>
> at least one transporting and transferring container, wherein the transporting and transferring container has at least one reservoir for receiving the fluidic medium, the reservoir has at least one displaceable element, wherein the reservoir is movably mounted in relation to the at least one displaceable element, and wherein a relative positioning of the displaceable element in relation to the reservoir determines an interior space of the reservoir available for receiving the fluidic medium;
>
> at least one energy unit, wherein the at least one energy unit subjects the reservoir to a force so that the fluidic medium is under increased pressure, wherein the energy unit is configured to move the reservoir;
>
> at least one measuring element, wherein the measuring element is configured to sense the relative positioning of the displaceable element in relation to the reservoir and configured to sense a relative positioning of the reservoir in the housing; and
>
> at least one adjusting element for influencing the dispensing of the fluidic medium by way of at least one fluid connection to the interior space;
>
> wherein the measuring element and the adjusting element interact so that the dispensing of the fluidic medium is influenced by the relative positioning sensed by the measuring element; and
>
> wherein the reservoir is movably mounted in the housing and wherein the displaceable element is fixedly coupled to the housing.

REJECTIONS

I. Claims 31, 35, and 36 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

II. Claims 1–3, 5, 8, 11, 13–16, 19, 20, 25, 26, 28,[3] 29, and 31–36 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shekalim (US 2003/0216683 A1, published Nov. 20, 2003), Donovan (US 8,257,310 B2, issued Sept. 4, 2012), and Bochenko '972 (US 8,385,972 B2, issued Feb. 26, 2013).

III. Claim 4 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Shekalim, Donovan, Bochenko '972, and Sidler (US 2005/0159708 A1, published July 21, 2005).

IV. Claims 27 and 30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Shekalim, Donovan, Bochenko '972, and Bochenko '659 (US 2010/0204659 Al, published Aug. 12, 2010).

DISCUSSION

Rejection I—Indefiniteness

Appellant does not present any substantive arguments challenging the merits of the rejections of claims 31, 35, and 36 under 35 U.S.C. § 112, second paragraph, as indefinite. *See* Appeal Br. 11. Rather, Appellant states an intention to amend these claims to address the source of the indefiniteness after the appeals process concludes. *Id.* Thus, Appellant has waived any argument of error, and we summarily sustain the rejections of claims 31, 35,

[3] The Examiner inadvertently omitted claim 28 from the statement of this rejection, but expressly addressed claim 28 in the detailed explanation of the rejection. Final Act. 3.

and 36 under 35 U.S.C. § 112, second paragraph. *See In re Berger*, 279 F.3d 975, 984, 985 (Fed. Cir. 2002) (holding that the Board did not err in sustaining a rejection under 35 U.S.C. § 112, second paragraph, when the applicant failed to contest the rejection on appeal).

Rejection II—Obviousness

Claims 1–3, 5, 8, 11, 13–16, 19, 20, 25, 28, and 29

The Examiner found that Shekalim discloses a dosing device as claimed including, in pertinent part, structure (shown in Figure 4) corresponding to both the claimed "housing" and the claimed "transporting and transferring container," a reservoir within the housing/container structure, at least one energy unit (the spring shown in Figures 1 and 6), at least one measuring element (pressure measurement system 22) for calculating remaining volume in the reservoir, and at least one adjusting element (valve 16). Final Act. 3. The Examiner found that Shekalim does not disclose the reservoir being movable in relation to the housing or a volume measuring element that senses a relative positioning of the reservoir in the housing. *Id.*

The Examiner found that Donovan discloses a reservoir volume measuring element (optical sensor 140) that senses the positioning of a displaceable element in relation to the reservoir and determined it would have been obvious to use a position displacement sensor in Shekalim as an art-recognized alternative means of determining remaining volume. Final Act. 4. The Examiner also reasoned that Donovan's optical sensor would be a desirable means for determining remaining volume because it would yield more accurate results over a wide range of pressure environments. *Id.*

The Examiner also found that Bochenko '972 teaches, as an alternative to a syringe design having a displaceable plunger in a fixed reservoir, a reverse syringe design in which the reservoir (medication container 20B) is movably mounted in relation to plunger 25, which is fixedly coupled to housing 4 and pressed against an abutment (the rod on which plunger 25 is mounted) such that plunger 25 is pressed into the reservoir. *Id.* (citing Bochenko '972, Fig. 7A); *compare* Bochenko '972, Fig. 7A, *with id.*, Fig. 6A. The Examiner determined it would have been obvious to further modify Shekalim by incorporating a reverse syringe design as taught by Bochenko '972 as an obvious design choice and/or obvious reversal of parts. Final Act. 4. According to the Examiner, "[s]uch a fluid delivery design is an obvious art-recognized alternative, has the same structure, and performs the same function, with the reservoir moving instead of the plunger, absent any unexpected results." *Id.* The Examiner further explained:

> Once combined, the reservoir of Shekalim, Donovan, and Bochenko ['972] would be movabl[y] mounted in a housing and the measuring element would be capable of sensing a relative position of the reservoir in the housing since it already has been shown to sense the position of the reservoir relative to the displaceable element and in the combination, the displaceable element is fixed relative to the housing.

Id.

In summary, the Examiner's rejection proposes modifying Shekalim by providing a relative displacement sensor for determining the remaining volume in the reservoir and by reversing the arrangement of the plunger and the reservoir so that the reservoir is defined by a structure movably mounted

within the housing and the plunger is fixedly coupled to the housing via an abutment.

Appellant argues that Shekalim and Bochenko '972 teach using pressure sensors or other flow sensors to determine the volume of fluid dispensed and, thus, do not "disclose a measuring element 'configured to sense a relative positioning of the reservoir in the housing' and 'wherein the reservoir is movably mounted in the housing and wherein the displaceable element is fixedly coupled to the housing'" as recited in claim 1. Appeal Br. 15–16. Appellant also argues that Donovan's volume sensor 140 measures the relative position of a *movable plunger tip*, rather than the relative position of the reservoir in a housing, and, thus, does not remedy the asserted deficiency of Shekalim and Bochenko '972. *Id.* at 16. These arguments do not apprise us of error because they attack the references individually rather than as combined in the rejection. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (citing *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

Appellant also argues that Donovan teaches away from using spatial measurements in order to measure accurate volumes, and that Shekalim and Bochenko '972 also teach using pressure sensors. Appeal Br. 16. In particular, Appellant points out that Donovan teaches that the high pressures involved in Donovan's application deform the syringe and tubing, leading to inaccurate volume measurements by volume sensor 140 alone. *Id.* To overcome this deficiency, Donovan teaches using compensation circuit 160, which uses pressure measurements from pressure sensor 150 to compensate

for the measurement error of sensor 140. *Id.* at 16–17. Thus, Appellant contends that Shekalim, Bochenko '972, and Donovan, even when combined, teach away from using a spatial sensor (a sensor that senses relative positioning of a movable component) in order to determine volume remaining in the reservoir. *Id.* at 17. For the reasons set forth below, we do not agree with Appellant.

Prior art does not teach away from claimed subject matter merely by disclosing a different solution to a similar problem unless the prior art also criticizes, discredits or otherwise discourages the solution claimed. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Shekalim uses a differential pressure sensor for determining the remaining volume of liquid medicament in the reservoir. Shekalim ¶ 68. Bochenko '972 also uses a differential pressure sensor for determining the volume of fluid delivered. Bochenko '972 23:63–24:15. However, Appellant does not identify any disclosure in either Shekalim or Bochenko '972 that criticizes, discredits, or otherwise discourages using a measuring element configured to sense the positioning of the reservoir relative to fixed structure in the housing in order to determine volume remaining in the reservoir.

Donovan explicitly teaches using a volume sensor that measures the displacement of the plunger (i.e., the relative positioning of the plunger and the reservoir) and, thus, does not teach away from using such a sensor. Donovan 4:28–38. Donovan teaches that, for the particular system and application contemplated by Donovan, such as dispensing of relatively viscous bone cements, the higher pressures used to deliver the flowable material cause system components to expand. *Id.* 2:7–33; 5:45–47. Donovan also teaches that this system compliance can result in volume

measurement inaccuracy. *Id.* 5:45–56. Donovan provides compensation circuit 160, which adjusts the value read by volume sensor 140 based on a pressure reading from pressure sensor 150, in order to compensate for this measurement inaccuracy. *Id.* 5:57–67. Appellant does not direct our attention to any disclosure in Shekalim, Bochenko '972, or Donovan suggesting that system compliance presents such a problem in Shekalim's device, which is designed for delivery of liquid medicament, rather than a relatively viscous bone cement. *See* Shekalim ¶¶ 1, 10. Moreover, even if system compliance would negatively influence volume measurement accuracy in Shekalim's system, Donovan teaches a solution to this problem, namely, providing a compensation circuit to compensate for such inaccuracy. Further, as discussed above, Shekalim already includes a differential pressure sensor, which could be used with such a compensation circuit.

Appellant notes that Shekalim uses the differential pressure sensor to perform other functions, such as detecting valve leaks and the like, in addition to measuring fluid volumes, and, therefore, incorporating a different volume measurement technique would destroy these intended functions of the differential pressure sensor. Appeal Br. 21. This argument is not convincing because Shekalim's differential pressure sensor need not be eliminated in order to use a displacement sensor, such as taught by Donovan, to measure reservoir volume. Rather, a displacement sensor as taught by Donovan could be used in concert with the differential pressure sensor of Shekalim, with each sensor being used to verify or compensate for inaccuracies in the measurements of the other. *See* Final Act. 4 (the Examiner reasoning that use of Donovan's optical sensor design would be

desirable in that it would yield more accurate results under some pressure conditions). Merely by way of example, Shekalim teaches that a discrepancy between the expected remaining drug volume and the remaining drug volume as calculated from the differential pressure value indicates either an occlusion in the system (if the pressure differential is lower than expected) or a disconnected output connection (if the pressure differential is higher than expected). Shekalim ¶¶ 71, 72. A relative displacement sensor, as taught by Donovan, for measuring volume independently of the differential pressure measurement would be instrumental in identifying such an occurrence.

In the Reply Brief, Appellant takes issue with the Examiner's treatment of the claimed housing and container as being the same. Reply Br. 2; *see* Final Act. 3. Although the Examiner's statement that the two "appear to [be the] same" (Final Act. 3) may be a bit imprecise, we appreciate the Examiner's point. Appellant's illustration of transporting and transferring container 114 in Figures 1A and 1B, with the lead line for element 114 pointing to the assembly including reservoir 116, spring 130, abutment 132, and housing 124, suggests that housing 124 is part of transporting and transferring container 114. Moreover, given the ordinary and customary meaning of the term "container," it is reasonable for one to interpret Appellant's housing 124 to be the "container," or at least part of the "container," rather than a separate element discrete from the "container." Thus, to the extent that the Examiner's statement conflating the "housing" and the "container" may be inaccurate, we view this as harmless error.

Claim 1 recites "a housing," and also recites "at least one transporting and transferring container," thereby suggesting that the "housing" is distinct

from the "transporting and transferring container." Appeal Br. 23 (Claims App.). However, claim 1 cannot be read, consistent with Appellant's Specification and drawings, as requiring two distinct containers or housings.[4] To the extent that the "reservoir" in claim 1 requires a housing or container for defining an interior volume for receiving the fluidic medium, distinct from the claimed "housing," the structure resulting from the modification of Shekalim to incorporate a reverse syringe design as taught by Donovan, which includes a reservoir movably mounted within a housing, includes a reservoir housing/container structure distinct from the housing—that is, a reservoir housing/container structure movably mounted within reservoir 12 of Shekalim.

For the above reasons, Appellant does not apprise us of error in the rejection of claim 1 as unpatentable over Shekalim, Donovan, and Bochenko '972. Accordingly, we sustain the rejection of claim 1, as well as claims 2, 3, 5, 8, 11, 13–16, 19, 20, 25, 28, and 29, for which Appellant does not present any separate arguments. Appeal Br. 17–20.

Claim 31

Claim 31 is indefinite, for the reasons set forth by the Examiner on page 2 of the Final Action, which Appellant does not challenge (*see* Appeal Br. 11). Having sustained a determination that claim 31 is indefinite, we cannot sustain the rejection of this claim under 35 U.S.C. § 103(a) because to do so would require speculation as to the scope of the claims. *See In re Steele*, 305 F.2d 859, 862–63 (CCPA 1962) (holding that the Board erred in

[4] In the event of further prosecution of the claimed subject matter, Appellant may wish to consider amending claim 1 to more closely correspond to the underlying disclosure in the Specification and drawings of the present application by reciting the "housing" as a component of the "container."

affirming a rejection of indefinite claims under 35 U.S.C. § 103(a) because the rejection was based on speculative assumptions as to the meaning of the claims). It should be understood, however, that our decision in this regard is based solely on the indefiniteness of the claimed subject matter, and does not reflect on the adequacy of the prior art evidence applied in support of the rejection.

Claim 32

Appellant argues that Shekalim and Donovan fail to disclose measuring the relative position of a movable reservoir in a stationary housing and that Bochenko '972 never mentions measuring volume by measuring the relative position of the container. Appeal Br. 18. These arguments do not apprise us of error because they attack the references individually, rather than as combined in the rejection.

Appellant contends that modifying Donovan's volume sensor 140 to satisfy the limitations of claim 32 would change its principle of operation and "require significant and dramatic modifications in order to be incorporated into the system described in Shekalim." *Id.* at 18–19. Donovan's volume sensor 140 is used to determine the volume of fluid dispensed from the reservoir by measuring the displacement of a movable plunger relative to the reservoir. Donovan 4:28–38. Using sensor 140 to measure the displacement of a movable reservoir relative to a stationary plunger would not change its principle of operation. Whether the plunger is the moving part or the reservoir is the moving part, Donovan's sensor 140 measures the displacement of the moving part relative to the fixed part in order to determine the volume of fluid displaced. Further, Appellant does not offer any evidence or persuasive technical explanation to support the

contention that incorporation of Donovan's volume sensor 140 into Shekalim's system would "require significant and dramatic modifications." Shekalim's system, like that of Donovan, includes a plunger and a reservoir. Thus, incorporation of a sensor as taught by Donovan into Shekalim's system to measure the displacement of either of the plunger or the reservoir relative to the other to determine the volume of fluid displaced from the reservoir would seem to require nothing more than routine skill in the art.

Appellant also reiterates the argument that Donovan teaches away from using spatial measurements to determine volume. Appeal Br. 19. This argument does not apprise us of error, for the reasons discussed above.

Appellant's arguments do not apprise us of error in the rejection of claim 32 as unpatentable over Shekalim, Donovan, and Bochenko '972, which we, thus, sustain.

Claims 33 and 34

Claim 33 depends from claim 32 and further recites that "the reservoir includes a rim; and the measuring element is configured to sense the position of the rim relative to the housing." Appeal Br. 30 (Claims App.). In rejecting claim 33, the Examiner read the claimed "rim" on Donovan's volume sensor 140 because it is located around the reservoir. Final Act. 7. Donovan's sensor 140 is located on the outside of reservoir 120, which is the stationary component in Donovan's system, to measure displacement of the plunger, which is the movable component in Donovan's system. Donovan 4:28–38. Even if Donovan's sensor 140 were considered to be a "rim" around reservoir 120, as depicted, for example, in Donovan's Figure 2C, the Examiner does not adequately explain how Donovan's sensor 140 would be incorporated into Shekalim's system so as to be disposed on the reservoir

and sense its own position relative to the housing, as claimed.[5] Accordingly, we do not sustain the rejection of claim 33, or claim 34, which depends from claim 33, as unpatentable over Shekalim, Donovan, and Bochenko '972.

Claim 26

The Examiner's findings and reasoning in rejecting claim 26 are substantially similar to those set forth in rejecting claim 1. *See* Final Act. 6–7. Further, Appellant's arguments in contesting the rejection of claim 26 are substantially similar to those set forth in contesting the rejection of claims 1 and 32. *See* Appeal Br. 20–21. For the reasons discussed above, these arguments do not apprise us of error in the rejection of claims 1 and 32, and, likewise, do not apprise us of error in the rejection of claim 26. Accordingly, we sustain the rejection of claim 26 as unpatentable over Shekalim, Donovan, and Bochenko '972.

Claims 35 and 36

Normally, when substantial confusion exists as to the interpretation of a claim, and no reasonably definite meaning can be ascribed to the terms in a claim, a determination as to compliance with 35 U.S.C. § 103 is not made. *See In re Steele*, 305 F.2d at 862–63. However, in this instance, we consider it to be desirable to address the rejections of claims 35 and 36 to avoid the inefficiency of piecemeal appellate review. *See Ex parte Ionescu*, 222 USPQ 537, 540 (Bd. App. 1984) (expressing the view that, where a claim is subject to more than one interpretation, one of which would render the

[5] The Examiner, correctly, points out that "[a]n end of a cylindrical reservoir" is a "rim." Ans. 13. Thus, any cylindrical reservoir would have a "rim," with or without Donovan's sensor 140 disposed thereon. However, the Examiner persists in reading the claimed "rim" of the reservoir on sensor 140. *Id.*

claims unpatentable over the prior art, the USPTO should enter simultaneous rejections under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 102 or § 103, to avoid piecemeal appellate review). As discussed in more detail below, Appellant's arguments presented with respect to claims 35 and 36 are directed to other aspects of the claims not involving the indefinite language identified in the Examiner's rejection under 35 U.S.C. § 112, second paragraph, and, thus, unlike the rejection of claim 31, we need not speculate about the meaning of the indefinite language to consider the merits of the disputed aspects of the rejection of these claims.

Appellant argues that "[n]one of the cited references disclose 'loading the at least one transporting and transferring container into the medication device with the fluidic medium under the increased pressure before said using' as is required in claim 35, especially one in conjunction with claim 26's requirement that the reservoir moves." Appeal Br. 22. The Examiner responds that the step of loading is performed when the device of Shekalim, as modified by Donovan and Bochenko '972, is fully assembled. Ans. 15. The Examiner also construes the "loading . . . before said using" limitation of claim 35 as "simply requir[ing] a pressurized state before using," but not "requir[ing] that the reservoir be in a constantly pressurized state during loading." *Id.* Appellant does not dispute this claim construction. *See* Reply Br. *passim*. The Examiner finds that "the reservoir is inherently under some pressure by virtue of the cartridge being sealed since the parameters of this increased pressure have not been specified." Ans. 15.

Appellant does not present any persuasive argument explaining why the Examiner's findings are in error. When Shekalim's device is fully assembled, with the spring biasing the reservoir toward the plunger, in the

reverse syringe arrangement as taught by Bochenko '972, and outlet 14 sealed prior to use, and/or valves 16 and 20 closed, so that fluid cannot flow out of the reservoir, the fluidic medium in the reservoir will be under increased pressure from the force exerted by the spring.

For the above reasons, Appellant does not apprise us of error in the rejection of claim 35 as unpatentable over Shekalim, Donovan, and Bochenko '972, which we, thus, sustain.

Claim 36 depends from claim 35 and further recites "maintaining the fluidic medium under the increased pressure for at least one month." Appeal Br. 30 (Claims App.). In addressing this limitation, the Examiner reasoned that the duration of maintaining the increased pressure is an obvious matter of routine optimization. *See* Final Act. 8.

Appellant argues that none of the references discloses the "maintaining" step recited in claim 36. Appeal Br. 22. This argument is unavailing because it does not address the rejection set forth by the Examiner, which does not include a finding that any of the references discloses the recited "maintaining" step. In particular, Appellant does not specifically contest the Examiner's determination that the duration of maintaining the increased pressure is an obvious matter of routine optimization. Moreover, the Examiner explains that Shekalim's container is under pressure from the force of the displaceable element acting on a sealed reservoir and finds that one of ordinary skill in the art "would recognize that medical devices are often stored for various lengths of time" prior to use, with "one month simply being an example of any typical length of time, as would be readily understood by one of ordinary skill." Ans. 15. Appellant

does not contest the Examiner's findings or reasoning in this regard. *See* Reply Br. *passim*.

Appellant asserts that the reverse syringe design of Bochenko '972 "is incapable of holding the increased pressure for a prolonged period of time when stored away from its medication delivery apparatus." Appeal Br. 22. This argument does not apprise us of error because it attacks Bochenko '972 individually, rather than as combined with Shekalim and Donovan in the rejection.

For the above reasons, Appellant does not apprise us of error in the rejection of claim 36 as unpatentable over Shekalim, Donovan, and Bochenko '972, which we, thus, sustain.

Rejections III and IV—Obviousness

Appellant does not present any arguments specifically contesting the rejections of claims 4, 27, and 30. *See* Appeal Br. 11–22. Thus, for the reasons set forth above in addressing the rejection of claim 1, from which claims 4, 27, and 30 depend, we also sustain the rejections of claims 4, 27, and 30.

DECISION

The Examiner's decision rejecting claims 31, 35, and 36 under 35 U.S.C. § 112, second paragraph is AFFIRMED.

The Examiner's decision rejecting claims 1–3, 5, 8, 11, 13–16, 19, 20, 25, 26, 28, 29, and 31–36 under 35 U.S.C. § 103(a) is AFFIRMED as to claims 1–3, 5, 8, 11, 13–16, 19, 20, 25, 26, 28, 29, 32, 35, and 36, and is REVERSED as to claims 31, 33, and 34.

The Examiner's decision rejecting claim 4 under 35 U.S.C. § 103(a) is AFFIRMED.

The Examiner's decision rejecting claims 27 and 30 under 35 U.S.C. § 103(a) is AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART