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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/807,481	09/07/2010	Tara Chand Singhal	11195.177	9920

103550 7590 03/10/2020

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EXAMINER	
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ART UNIT	PAPER NUMBER
3783	

NOTIFICATION DATE	DELIVERY MODE
03/10/2020	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TARA CHAND SINGHAL

Appeal 2019-002426
Application 12/807,481
Technology Center 3700

Before MURRIEL E. CRAWFORD, NINA L. MEDLOCK, and KENNETH G. SCHOPFER, *Administrative Patent Judges*.

SCHOPFER, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 3, 5–17, and 21–23. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Tara Chand Singhal. Appeal Br. 4.

BACKGROUND

The Specification describes "apparatus and methods for preparing for reuse, single-use disposable syringes and needles for a home user, to reduce the cost of such disposables and to reduce the effort and the infrastructure cost of disposing sharp medical waste." Spec. 1, ll. 20–23.

CLAIMS

Claims 1, 8, 12, and 21 are the independent claims on appeal. Claim 1 is illustrative of the appealed claims and recites:

> 1. An injection needle apparatus, comprising:
>
> an injection syringe with a permanently attached injection needle, wherein the syringe has a needle cover, wherein the needle cover when positioned over the injection needle, cleans, disinfects and lubricates the injection needle for reuse for a same user;
>
> the needle cover has positioned inside, a first stack as a wicking medium, a second stack as a disinfecting agent, and a third stack as a lubricating agent, wherein the wicking medium, the disinfecting agent, and the lubricating agent are stacked on top of each other in heights for different needle lengths;
>
> a guide mechanism, wherein the guide mechanism has male and female parts attached to the syringe body and the needle cover, wherein the guide mechanism using the male and female parts guides the needle cover onto the injection needle for temporary storage of the injection needle inside the needle cover; and
>
> the injection needle, when moved inside the needle cover, first moves through the first stack, then the second and then the third stack, thereby the needle cover cleans, disinfects and lubricates the same injection needle for reuse by the same user.

Appeal Br. 44.

REJECTIONS

1. The Examiner rejects claims 1, 3, 5–7, and 21–23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
2. The Examiner rejects claims 1, 3, 5–17[2] under 35 U.S.C. § 112, second paragraph, as indefinite.
3. The Examiner rejects claims 1, 3, 5–7, and 21–23 under 35 U.S.C. § 103(a) as unpatentable over Swan[3] in view of Manganini[4] and Horvath.[5]
4. The Examiner rejects claims 8 –17 under 35 U.S.C. § 103(a) as unpatentable over Ashkenaz[6] in view of Manganini and Horvath.

DISCUSSION

Written Description

With respect to independent claims 1 and 21, the Examiner finds that written description support is lacking for the limitation "a permanently attached injection needle." Final Act. 4. The Examiner finds that the original Specification only discloses embodiments with non-permanent needles and that the only disclosure of needles with permanent needles is related to the state of the prior art. *Id.* at 4–5.

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[2] The Examiner did not list claim 6 in this rejection. *See* Final Act. 6. However, because claim 6 depends from rejected claim 1, we consider it to have been rejected by virtue of this dependence.
[3] Swan, US 2,400,722, iss. May 21, 1946.
[4] Manganini et al., US 5,876,380, iss. Mar. 2, 1999.
[5] Horvath et al., US 2012/0029469, pub. Feb. 2, 2012.
[6] Ashkenaz, US 2,828,742, iss. Apr. 1, 1958.

We find that there is adequate support for "a permanently attached injection needle" as recited in each of claims 1 and 21. We agree with the Examiner that permanently attached needles are described in the Specification with respect to the prior art. Specifically, the Specification discloses that Figure 1C depicts a prior art syringe "where the needle is permanently attached to the syringe." Spec. 5, ll. 8–9. Further, a review of Figures 1C and 2D shows that the syringe and needle have a similar structure. We also note that the Specification discloses that Figure 2C depicts a preferred embodiment of the present invention. *See id.* at 9, ll. 13–14. Thus, where the Specification discloses that "Figure 2D illustrates embodiment 30 used with syringes 8 with attached needles as in prior art Figure 2C," one would understand that the reference to Figure 2C is a typographical error and should have been a reference to Figure 1C. Under this understanding of the disclosure, we find that the Specification reasonably conveys that Appellant was in possession of the claimed invention at the time the Specification was filed.

Based on the foregoing, we do not sustain the written description rejection of independent claims 1 and 21 or dependent claims 3, 5–7, 22, and 23.

Indefiniteness

With respect to claim 1, the Examiner finds that the recitation of "the syringe body" lacks antecedent basis. Final Act. 6. We agree. The claim recites "a guide mechanism, wherein the guide mechanism has male and female parts attached to the syringe body and the needle cover." Appeal Br. 44. The claim earlier recites "an injection syringe with a permanently attached injection needle . . . [and] a needle cover." *Id.* The claim does not

provide any earlier indication such that one of ordinary skill in the art would understand what the later recited "syringe body" is, i.e., without first referencing a body portion of the syringe, one of ordinary skill in the art would not understand from the claim language where the claimed guide mechanism is attached. Thus, we sustain this rejection of claim 1. We also sustain this rejection of dependent claims 3 and 5–7 based on their dependency from claim 1. For the same reasons, we also sustain the Examiner's separate rejection of claim 7 based on the recitation of "a syringe body." *See* Final Act. 6.

With respect to independent claim 8, the Examiner finds that the limitations "the injection needle" and "the same injection needle" lack antecedent basis. We agree. Claim 8 first recites "[a]n injection needle apparatus," indicating that the entire claim is directed to an injection needle. Appeal Br. 45. Claim 8 further recites "a pen needle for injection." *Id.* Claim 8 later recites "the injection needle" and "the same injection needle." *Id.* However, it is unclear from the context of the claim whether these later recitations of "the injection needle" and "the same injection needle" are intended to refer to "a pen needle for injection" or the "injection needle apparatus" as a whole. For this reason, we sustain this rejection of claim 8. We also sustain the rejection of claims 9–11 based on their dependency from claim 8.

Similarly, the Examiner finds that claim 12 includes the limitation "the injection needle," which lacks antecedent basis. Final Act. 7. We agree. Claim 12 includes the limitations "a pen injection needle," "the pen injection needle," and "the injection needle." Appeal Br. 46–47. Given the inconsistency of language in the claim, it is unclear if "the injection needle"

is intended to refer to the same "pen injection needle" as the limitation "the pen injection needle." Accordingly, we sustain this rejection of claim 12. We also sustain the rejection of claims 13–17 based on their dependency from claim 12.

Obviousness

Each of independent claims 1, 8, 12, and 21 requires a first stack including a wicking medium. *See* Appeal Br. 44–46, 48. With respect to independent claims 1 and 21, the Examiner acknowledges that the combination of Swan, Manganini, and Horvath does not teach a first stack that includes a wicking medium. Final Act. 23, 27. Similarly, with respect to independent claims 8 and 12, the Examiner acknowledges that the combination Ashkenaz, Manganini, and Horvath does not teach a first stack that includes a wicking medium. *Id.* at 9, 16. For each claim, the Examiner determines that using a wicking medium in the first stack would have been an obvious design choice over the septum provided in Manganini's first stack. *See, e.g., id.* at 9. Specifically, the Examiner finds and determines:

> However, Ashkenaz in view of Manganini et al does not teach or suggest the first stack being a wicking medium. Rather, Manganini's first stack is a septum (col. 7, lns 18–21). However, Manganini does discloses a wicking medium (i.e. gauze; col. 7, ln 23).
>
> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first stack being a septum material as taught by Manganini et al with the cotton gauze material as taught by Manganini for the purpose of a simple substitution of one known stack element for another with a predictable and similar result. Here, using a cotton gauze instead of a septum as the first stack 94 would be an obvious design choice as a simple substitution of one stack material for another with a predictable and similar result.

Id.

We determine that the Examiner erred with respect to this reasoning. A so-called "design choice" rationale, such as the Examiner relies upon here, has been deemed appropriate where one prior art element or property is proposed to be substituted for another that achieves the same purpose. *See ACCO Brands Corp. v. Fellowes, Inc.*, 813 F.3d 1361, 1367 (Fed. Cir. 2016) ("The prior art consistently locates the two sensors at issue in the shredder's feed, and no party disputes that an ordinary artisan would have found this the obvious location for the combination of sensors. The ordinary artisan would then be left with two design choices."); *Ex parte Maeda*, Appeal 2010-009814, 2012 WL 5294326, at *3 (PTAB Oct. 23, 2012) (informative). *Cf. In re Gal*, 980 F.2d 717, 719 (Fed. Cir. 1992) ("The Board held that Gal had simply made an obvious design choice. However, the different structures of Gal and Matsumura achieve different purposes."). Our reviewing court has cautioned that "[m]erely stating that a particular [limitation] is a design choice does not make it obvious." *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n.4 (Fed. Cir. 2018) (quoting *Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App'x 575, 578 (Fed. Cir. 2016) (nonprecedential)).

Here, the Examiner does not adequately established the predicate finding for a design-choice position — i.e., that the prior art provides an alternative element that achieves the same purpose as what is claimed. *See ACCO Brands*, 813 F.3d at 1367. The Examiner states only that substituting a wicking material for Manganini's septum would be a design choice "as a simple substitution of one stack material for another with a predictable and similar result." Final Act. 9. Thus, the Examiner finds that the claimed

wicking material and Manganini's septum achieve the same result or purpose.

However, the Examiner does not cite to any evidence or provide any further explanation regarding this finding. The rejection seeks to replace Manganini's septum 94 with a wicking material. Notably, the Examiner has not provided evidence or explanation as to what the purpose of septum 94 is. Manganini discloses several septa that may be sterile and provide a seal around a needle, and thus, one might conclude that septum 94 is intended to provide a sterile seal. *See, e.g.,* Manganini col. 7, ll. 14–31. In contrast, the Specification describes the wicking medium as a material that absorbs excess fluid droplets from a needle head. *See* Spec. 8, ll. 11–12. Without further explanation, we fail to see how Manganini's septum and the claimed wicking material achieve the same purpose such that the Examiner may appropriately rely on a design choice rationale to show obviousness.

Based on the foregoing, we do not sustain the rejections of independent claims 1, 8, 12, and 21. For the same reasons, we do not sustain the rejections of dependent claims 3, 5–7, 9–11, 13–17, 22, and 23.

CONCLUSION

We AFFIRM the rejection of claims 1, 3, and 5–17 as indefinite. We REVERSE the remaining rejections of the claims on appeal.

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 3, 5–7, 21–23	112, first paragraph	Written description		1, 3, 5–7, 21–23
1, 3, 5–17	112, second paragraph	Indefiniteness	1, 3, 5–17	

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 3, 5–7, 21–23	103(a)	Swan, Manganini, Horvath		1, 3, 5–7, 21–23
8–17	103(a)	Ashkenaz, Manganini, Horvath		8–17
Overall Outcome			1, 3, 5–17	21–23

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)(l)(iv).

AFFIRMED-IN-PART