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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EUGENE PRAIS, ROBERT S. SAMS, and SIMIN YAO

Appeal 2018-003644
Application 14/204,190
Technology Center 3700

Before JENNIFER D. BAHR, EDWARD A. BROWN, and
RICHARD H. MARSCHALL, *Administrative Patent Judges*.

MARSCHALL, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant,¹ Bayer Healthcare LLC,
appeals from the Examiner’s decision to reject claims 1–4, 6–8, and 21–33.
We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word “Appellant” to refer to “Applicant” as defined in 37
C.F.R. § 1.42(a). Appellant identifies the real party in interest as Ascensia
Diabetes Care Holdings AG. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claims are directed to a lancing device. Claims 1 and 32 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A lancet device comprising:

a base having first external threads, a first opening and a second opening;

a lancet comprising a needle having a tip and having a position relative to the base, the lancet received in the base through the first opening and attached to the base via second threads at the first opening allowing the lancet to be adjustably positioned within the base, the tip of the needle protruding through the second opening; and

a flexible member having an aperture, the flexible member positioned over the second opening;

wherein the flexible member is arranged relative to the needle so that when a sufficient force is applied to the flexible member, the flexible member transitions from a first configuration to a second configuration, and wherein the tip of the needle protrudes from the aperture of the flexible member while the flexible member is in the second configuration.

REFERENCES

The prior art relied upon by the Examiner is:

Mohammad M.B.B.S.	US 6,379,337 B1	Apr. 30, 2002
Olson	US 2006/0184189 A1	Aug. 17, 2006
Brown	US 2011/0184448 A1	July 28, 2011
Allen	US 2012/0323142 A1	Dec. 20, 2012

REJECTIONS

Claims 1–4, 6, 7, and 25– 32 are rejected under pre–AIA 35 U.S.C. § 103(a) as being unpatentable over Olson in view of Mohammad. Final Act. 3.

Claims 8, 21–24, and 33 are rejected under pre–AIA 35 U.S.C. § 103(a) as being unpatentable over Olson in view of Mohammad, Brown, and Allen. Final Act. 8.

OPINION

Claim 1

In the rejection of claim 1, the Examiner finds that Olson teaches the majority of the limitations, including threaded portions 204, 206 and rear housing portion 208 that correspond to the claimed base, and “lancet mechanism 212” within that base. Final Act. 4; Olson ¶ 76, Fig. 12. The Examiner also finds that Olson “does not teach attaching the lancet mechanism to the base via second threads.” *Id.* The Examiner finds that Mohammad teaches a lancet attached to a base via second threads and “allowing the lancet to be adjustably positioned within the base.” *Id.* The Examiner determined that it would have been obvious “to modify the base and lancet mechanism of Olson by further incorporating the second threads of Mohammad to allow removal and replacement of the lancet mechanism should it become contaminated or damaged.” *Id.*

Appellant argues that Olson emphasizes how its lancet mechanism 212 moves with respect to its housing, which includes portions 204, 206, 208—the structures the Examiner relies on with respect to the claimed base. Appeal Br. 6–7. Appellant also argues that “Olson is directed to a lancing device wherein a lancet is ‘driven,’ ‘fired,’ or ‘launched’ to puncture a bulge of dermal tissue created by engagement of a cap of Olson’s lancing device against the dermal tissue.” Appeal Br. 7 (citing Olson ¶¶ 4, 9, 10, 67). According to Appellant, attaching lancet mechanism 212 to Olson’s housing via threads, as the Examiner proposes in the rejection, results in an

inoperative lancing device “because lancet mechanism 212 would not be able to be driven, fired, or launched.” *Id.*; *see also* Reply Br. 5. Appellant further argues that the proposed modification of Olson would change its principle of operation “from a lance that’s driven, fired, or launched to one where the lance is stationary during a fluid sample collection procedure.” Appeal Br. 8.

In response, the Examiner finds that “Olson’s disclosure of [the] lancet being movable with respect to the housing is not an explicit counter-teaching to the incorporation of threads for attaching a lancet to a housing as taught by Mohammad.” Ans. 11. The Examiner also finds that the “state of the pertinent art at the time the invention was made well and reasonably contemplates the usage of threaded portions to connect a mobile component to a stationary component; the incorporation of attachment threads does not explicitly restrict the movement of, for example, a lancet within a housing.” *Id.* The Examiner further finds that the “combination of the firing operation of Olson and the threaded attachment of Mohammad can be accomplished in such a way, using ordinary skill in the pertinent art, that the movement of the lancet 212 relative to the housing of Olson is still possible.” *Id.*

In its Reply, Appellant argues that “attaching Olson’s lancet mechanism 212 to its ‘base’ (i.e., either rear housing portion 208 or threaded portion 206) via threads would likely render Olson’s lancing device at least ineffective, if not inoperative, because lancet mechanism 212 would not be able to be driven, fired, or launched.” Reply Br. 5. Appellant argues that the Examiner misunderstands how Olson’s device works, and how threading lancet mechanism 212 in place would render it ineffective and inoperable. *Id.* at 5–6.

We agree with Appellant. The Examiner’s finding that one of ordinary skill in the art could add a threaded connection between lancet mechanism 212 and Olson’s “base,” and maintain the relative movement of lancet mechanism 212 necessary to preserve Olson’s function, lacks an adequate foundation. The Examiner finds that it “is still possible” to allow for relative movement between Olson’s lancet mechanism 212 and its base, even after adding a threaded connection, but does not explain how one of ordinary skill in the art would make this modification, or provide any further explanation. Ans. 11. Olson’s pertinent disclosure describes a “spring loaded” lancet, driven along an axis on release of the spring to puncture a patient’s skin. Olson ¶ 4. In order to work, the lancet must be allowed to move relative to the surrounding housing and threaded portions. *See id.* at ¶¶ 76–77, Figs. 12A, 12B. Adding a fixed, threaded connection between lancet mechanism 212 and any of Olson’s surrounding structures such as housing portion 208 would appear to fix lancet mechanism 212 in place with respect to those structures, rendering the device inoperable for its intended purpose as Appellant alleges. To the extent it remains “possible” to somehow retain Olson’s required movements even after adding the threaded connection, as the Examiner finds, the Examiner does not provide adequate evidence and explanation to support such a finding.

Under these circumstances, where the stated basis for the proposed combination lacks an adequate foundation, we do not sustain the rejection of claim 1. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001) (quoting *In re Spinnoble*, 405 F.2d 578, 587 (CCPA 1969)) (“If references taken in combination would produce a ‘seemingly inoperative

device,’ we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.”).

Remaining Claims

The pertinent limitations in independent claim 32 are nearly identical to those in claim 1. *See* Appeal Br. 15 (Claims App.). For claim 32, the Examiner relies on the same findings, and Appellant relies on the same arguments, as those made with respect to claim 1. *See* Final Act. 3–5, 7–8; Appeal Br. 10. Accordingly, we do not sustain the rejection of claim 32 for the same reasons as claim 1.

For the remaining dependent claims, Appellant relies on the same arguments made with respect to claims 1 and 32. *See* Appeal Br. 10–11. The Examiner’s findings made with respect to the dependent claims do not address the deficiencies in the rejection of claim 1 we addressed above. *See* Final Act. 5–9. Accordingly, we do not sustain the rejections of dependent claims 2–4, 6–8, 21–31, and 33.

DECISION

We reverse the decision of the Examiner to reject claims 1–4, 6–8, and 21–33.

DECISION SUMMARY

Claims Rejected	Basis	Affirmed	Reversed
1-4, 6, 7, 25-32	§ 103(a) Olson, Mohammad		1-4, 6, 7, 25-32
8, 21-24, 33	§ 103(a) Olson, Mohammad, Brown, and Allen		8, 21-24, 33
Overall Outcome			1-4, 6-8, and 21-33

REVERSED