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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/342,620	01/31/2006	Lynn A. Ziman	0100/0190	2493

135866 7590 02/21/2018
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EXAMINER

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ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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02/21/2018

PAPER

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

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LYNN A. ZIMAN and STEVEN HUU NGUYEN

Appeal 2016-000570
Application 11/342,620
Technology Center 3700

Before KEN B. BARRETT, BRANDON J. WARNER, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Lynn A. Ziman and Steven Huu Nguyen (Appellants) seek our review under 35 U.S.C. § 134(a) of the Examiner's rejection of claims 24–41. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

THE INVENTION

Appellants' claimed invention pertains to "a needle assembly that is designed to mate with an adapter for correct connection to a particular medication store or line." Spec. ¶ 1. Of the rejected claims, claims 24, 31, and 37 are independent claims. Claim 24, reproduced below, is illustrative of the subject matter on appeal.

24. In combination,

a fluid store or a fluid line having a conventional receptacle end with a conventional configuration adapted to mate with a needle hub having a conventional complementary receptacle end;

a one piece needle assembly having a needle hub formed by an elongate body having a circumferential wall of a given diameter that extends between a receptacle end and a second end, the receptacle end having an opening defined by the circumferential wall, the needle hub including a tapered closed end that extends integrally away from the second end of the elongate body, a needle not part of the needle hub extending from the closed end of the needle hub, the receptacle end of the needle hub having a given configuration that prevents it from mating with the conventional receptacle end of the fluid store or fluid line, the given configuration including two protrusions extending at opposite sides from an outer surface of the circumferential wall a particular distance along the elongate body from the opening and the circumferential wall having a thickness dimensioned to provide the opening and an internal passage along the elongate body to the opening with a defined cross section that does not accept a conventional male receptacle; and

an adapter having a first end with a conventional complementary receptacle end matable with a conventional receptacle end of conventional fluid stores or fluid lines and a second end with a configuration complementary to the given configuration of the receptacle end of the needle hub so that the second end of the adapter is matable with the receptacle end of the needle hub, a particular male receptacle at the second end of

the adapter configured to be accepted into the opening with the defined cross section at the needle assembly;

wherein when the fluid store or fluid line is connected to the first end of the adapter and the needle assembly is connected to the second end of the adapter, a through passage in the adapter establishes a fluid path between the fluid store or fluid line and the needle.

App. Br. 26 (Claims Appendix).

THE REJECTIONS

The following Examiner's rejections are before us for review:

1. Claims 24–41 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement;
2. Claims 24–41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention;
3. Claims 24–29, 31–35, and 37–41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Segal (US 2004/0201216 A1, filed Aug. 26, 2003, published Oct. 14, 2004), Sheppard (US 6,500,153 B1, issued Dec. 31, 2002), and Delvigo (US 5,925,028, issued July 20, 1999); and
4. Claims 30 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Segal, Sheppard, Delvigo, and Sinko (US 4,453,927, issued June 12, 1984).

ANALYSIS

A. The Enablement Rejection

Independent claim 24 recites a needle hub having an elongate body with a receptacle end and a second end where “a tapered *closed end* . . . extends integrally away from the second end of the elongate body” and with “a needle . . . extending from the *closed end* of the needle hub.” App. Br. 26 (Claims Appendix, emphasis added). Independent claims 31 and 37 contain similar recitations.

The Examiner maintains that “the end of Applicant’s hub is not actually closed” and “[b]ecause the distal end of the hub obviously has an opening for fluid to flow through (because it is attached to hollow needle which receives fluid from the hub), the recitation that this end is ‘closed’ fails to comply with the enablement requirement.” Non-Final Act. 3.

We agree with Appellants that one of ordinary skill, considering the claimed invention in light of the Specification, would not read the claim term “closed” as referring literally to a completely closed end. *See* App. Br. 11–12 (citing Spec. ¶ 18, Fig. 1). This understanding is consistent with the extrinsic evidence indicating that “closed end” has been used in the art to refer to the needle end of a syringe. App. Br., Evidence Appendix A (US 5,651,774, issued July 29, 1997), col. 5, ll. 55–57, Fig. 4; Evidence Appendix B (US 6,436,075 B1, issued Aug. 20, 2002), col. 2, ll. 13–18, Fig. 2.

We do not conclude that one would have to engage in undue experimentation in order to practice the claimed invention having a “closed end.” Accordingly, we do not sustain the enablement rejection.

B. The Indefiniteness Rejection

The independent claims recite certain components as having a “conventional” structure or configuration, and other components as being configured other than “conventional.” For example, claim 24, with emphasis added, recites “a *conventional* receptacle end with a *conventional* configuration adapted to mate with a needle hub having a *conventional* complementary receptacle end,” which is contrasted with “the receptacle end of the needle hub having a given configuration that prevents it from mating with the *conventional* receptacle end.” The Examiner rejected claims 24–41 as being indefinite, maintaining that the term “conventional” is a relative and subjective term that is not defined adequately in the Specification. Non-Final Act. 4–5; Ans. 4–5.

Appellants argue that an applicant may be his or her own lexicographer and that claims are properly construed in light of the Specification, and points to particular paragraphs in the Specification. App. Br. 13 (citing Spec. ¶¶ 18, 20, 23, Figs. 1, 4a–4f); *see also* Reply Br. 3 (Appellants asserting that “the terms ‘conventional’ and ‘nonconventional’ are described in the specification.”). However, the cited paragraphs merely use, without elaboration, the term “conventional” in modifying the words “needle,” “luer end,” and “luer connection,” respectively, and do not provide a lexicographical definition of the term “conventional” as used in the claims to modify “receptacle” and “fluid stores or fluid lines.”

Appellants also provide a proposed construction, arguing “conventional” and “non-conventional” “simply mean that they are not the same and that one is a ‘non’ of the other.” Reply Br. 4. We cannot accept as correct that proposed construction as it is an unjustified deviation from the

normal usage of the terms. It would, for example, encompass the use of two components that both are deemed to be “conventional” but yet are different from one another.

Although not dispositive, we also note that Sheppard’s specification defines with specificity the terms “typical syringe” and “typical needle.” Sheppard, col. 3, l. 60–col. 4, l. 10. This suggests that, in the pertinent art, there is a need to attach more clarity to the term “typical,” a term similar in connotation to that of “conventional.”

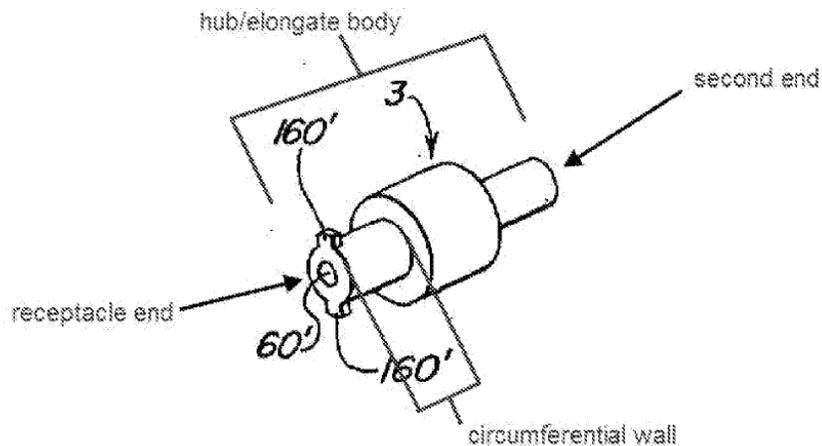
The meaning of the term “conventional” is sufficiently unclear to render indefinite the rejected claims. *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014). Accordingly, we affirm the Examiner’s indefiniteness rejection under § 112, second paragraph.

C. The Obviousness Rejection—Segal, Sheppard, and Delvigo

Independent claim 24 recites a needle hub formed by “an elongate body having a circumferential wall of a given diameter that extends between a receptacle end and a second end.” Independent claims 31 and 37 recite the same or similar language.

Appellants argue that the Examiner’s finding that Segal discloses this feature is erroneous. *See* App. Br. 16–17. The Examiner finds that Segal’s entire body 3, as shown in Figure 8D, is the elongate body of the needle hub. Non-Final Act. 5–6; Ans. 6–7. The Examiner provides an annotated figure, shown below, to explain the findings.

Fig A
(annotated Fig 8D of Segal)



Ans. 7. Figure A above is a portion of Segal’s Figure 8D depicting second female medical connector portion 3, with the Examiner’s annotations indicating the components deemed to correspond to recited features. The Examiner finds that the portion identified above as the “circumferential wall” satisfies the claim language “a given diameter that extends between a receptacle end and a second end.” *Id.* at 6–7. The Examiner reasons that the claim language does not require the “given diameter” to extend the full length of the elongate member, but “the claims only require the wall to extend *between* the two ends.” *Id.* According to the Examiner, “[t]he portion of the elongate body indicated as the ‘circumferential wall’ meets the limitations of the claim because it is of a given diameter and it lies between the receptacle end and the second end.” *Id.* at 6.

The Examiner applies an unreasonably broad construction to the pertinent claim phrase. While we will not read unrecited features from the Specification into the claim, we determine that one of ordinary skill reading the pertinent limitation in light of the Specification, and particularly the

figures, would understand that the subject phrase refers to a section having a constant diameter from the receptacle end to the second end (where the tapered section begins). Although the Specification provides little or no verbal description that sheds light on the meaning of the phrase, the figures consistently depict needle hub 4 as having a constant diameter from the receptacle end to the beginning of the taper. *See Spec.*, Figs. 1, 2, 3, 6; *see also id.* ¶ 19 (“Receptacle end of needle hub 4 comprises an elongate cylindrical portion . . .”). Thus, we determine that it is not enough, as the Examiner impliedly concludes, that a circumferential wall exist between two ends or extend from one towards the other, it must extend between the two ends for the full distance.

The Examiner identifies a wall extending from the receptacle end to a point well shy of that identified by the Examiner as the second end. This finding does not meet the recited limitation. As such, we cannot sustain the rejection of the independent claims, or of the dependent claims which necessarily contain the same limitation.

D. The Obviousness Rejection—Segal, Sheppard, Delvigo, and Sinko

In the rejection of claims 30 and 36, the Examiner relies on Sinko for the disclosure of a filter, but does not rely on Sinko in any manner that cures the defect of the underlying combination of Segal, Sheppard, and Delvigo. *See Non-Final Act.* 17–18. Accordingly, we cannot sustain the rejection of claims 30 and 36 as being obvious.

CONCLUSIONS

We conclude that the Appellants have shown that the Examiner erred in rejecting claims 24–41 under the enablement requirement and claims 24–

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41 as being obvious. We further conclude that the Examiner did not err in rejecting claims 24–41 as being indefinite.

DECISION

The decision of the Examiner to reject claims 24–41 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