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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* LYNN A. ZIMAN and STEVEN HUU NGUYEN

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Appeal 2018-002180  
Application 13/714,501  
Technology Center 3700

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

BARRETT, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>1</sup> appeals from the Examiner's decision to reject claims 1 and 3–20. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> 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 Smiths Medical ASD, Inc. Appeal Br. 3.

## I. THE INVENTION

Appellant's 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 claims on appeal, claims 1, 8, and 14 are independent. Claim 1, reproduced below with paragraphing added, is illustrative of the subject matter on appeal.

1. A one piece needle assembly comprising a needle hub having
  - an elongate cylindrical portion formed by a circumferential wall that extends from a hub receptacle end to an opposite end,
  - the opposite end of the elongate cylindrical portion tapers to a closed end from which a needle extends,
  - the circumferential wall of the cylindrical portion having a thickness that defines an opening at the receptacle end and a through passage along the elongate cylindrical portion of the needle hub to have a given cross section,
  - the hub receptacle end having a particular formation that prevents the hub receptacle end from mating with a luer of a medical device,
  - the particular formation including two protrusions formed at the outer surface of the circumferential wall at opposite sides of the elongate cylindrical portion a particular distance along the elongate cylindrical portion from the opening of the hub receptacle end so that the protrusions are passable through corresponding channels at a shroud and threadedly matable with an internal thread formed at an inner circumferential wall of the shroud having a complementary configuration to the particular formation,
  - the hub receptacle end with the protrusions not matable with a luer, the particular formation further

defined by the circumferential wall of the elongate cylindrical portion being dimensioned to have the thickness that effects the given cross section for the opening to prevent a male luer receptacle from being fittingly accepted into the opening.

Appeal Br. 29 (Claims Appendix) (with paragraphing added).

## II. THE REJECTIONS

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

1. Claims 1 and 3–20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement;
2. Claims 1, 3–5, 7–11, 13–18, and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Segal (US 2004/0201216 A1, published Oct. 14, 2004), Gettig (US 5,718,690, issued Feb. 17, 1998), and Delvigo (US 5,925,028, issued July 20, 1999); and
3. Claims 6, 12, and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Segal, Gettig, Delvigo, and Sheppard (US 6,500,153 B1, issued Dec. 31, 2002).

## III. ANALYSIS

### A. *The Enablement Rejection of Claims 1 and 3–20*

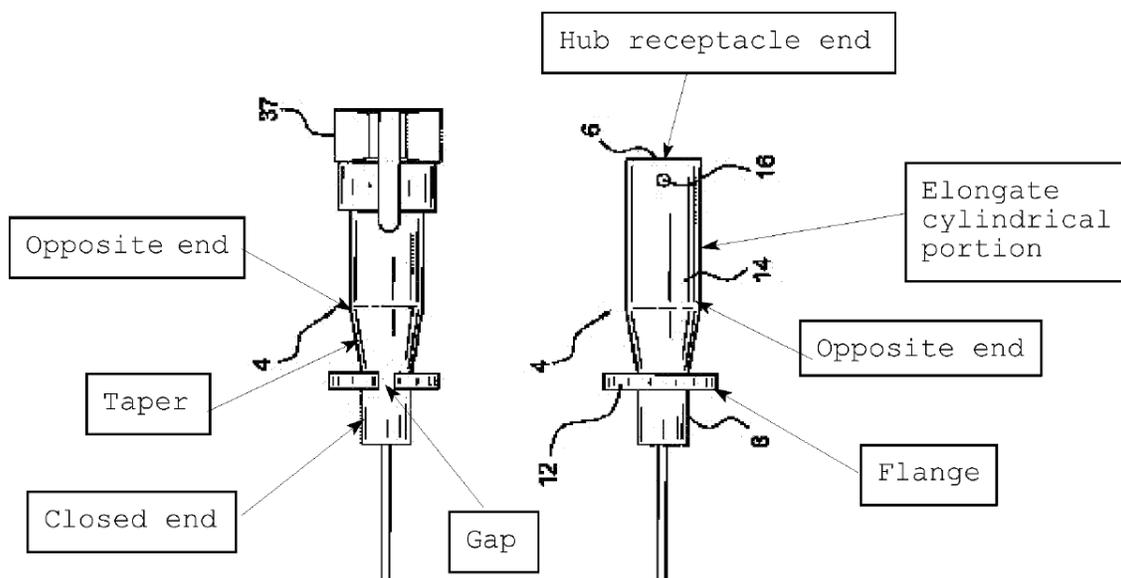
The Examiner rejected all of the claims on appeal as failing to satisfy the enablement requirement based on the recited taper. Non-Final Act. 3–4.

Claim 1, for example, recites a needle hub having “an elongate cylindrical portion formed by a circumferential wall that extends from a hub receptacle end to an opposite end” and where “the opposite end of the elongate cylindrical portion tapers to a closed end from which a needle extends.” Appeal Br. 29; *see id.* at 30 (independent claim 8 reciting the

same or similar language), 31 (independent claim 14 reciting an elongate cylindrical portion having “an opposite end that tapers to a closed end”).

The Examiner construes the language of the latter phrase as requiring that the opposite end be tapered and *also be* cylindrical. Non-Final Act. 3; *see also* Ans. 5 (“the language of the claims require[s] that the ‘opposite end’ itself tapers”). The Examiner maintains that the same component cannot be both cylindrical (i.e. with straight, parallel sides and constant diameter along its entire length) and tapered. Non-Final Act. 3–4 (citing the online Oxford Dictionary). Thus, according to the Examiner, the limitation is not enabled. *Id.* at 4.

Appellant argues that the Examiner has misconstrued the claim language; however, Appellant’s interpretation, at least in part, appears to be consistent with that of the Examiner. *See* Appeal Br. 9–10. In particular, Appellant asserts that “the ‘opposite end’ form[s] one end of the elongate cylindrical portion.” *Id.* at 9. Appellant’s position is explained, in part, via annotated Figures 3A and 3B, cropped views of which are shown below.



Shown above is a cropped version of Appellant's Figures 3A and 3B (side views of the needle assembly) annotated by Appellant to explain Appellant's identification of certain features. *Id.* at 10; Spec. 4 (describing the figures).

Based on Appellant's annotated figures, we understand Appellant to contend that the recited "opposite end" of the claims refers to a point or plane at one end of the "cylindrical portion." Appeal Br. 10; *cf.* Reply Br. 2 ("the other end of the circumferential wall [that forms the elongate cylindrical portion] ends at the opposite end"). Thus, we further understand the Examiner and Appellant to agree that the cylindrical portion is that portion that extends from a point labeled the "hub receptacle end" to a point labeled the "opposite end" and having straight, parallel sides and a constant diameter for its full length.

Appellant argues that "shown in Figs. 3A and 3B is that 'taper' that *extends from the opposite end* of the elongate cylindrical portion 14 to the closed end 8." Appeal Br. 9 (emphasis added). Appellant also argues that "it is clear that it is at the opposite end of the elongate cylindrical portion (d) that *the taper begins* towards the closed end." Reply Br. 3 (emphasis added). Appellant identifies, as the "taper," a portion of the hub between the cylindrical portion and a portion labeled the "closed end." *See* Appeal Br. 9–10. Appellant additionally argues that an artisan would be able to mold a needle hub as shown in Figures 3A and 3B and states that "appellants fail to see how there could be a non-enablement issue." *Id.* at 9.

Appellant's arguments are not consistent with the claim language, which, in claim 1 is "the opposite end of the elongate cylindrical portion tapers to a closed end." Appeal Br. 29. The claim does not, as Appellant

implies, recite a “taper” portion that extends from the opposite end or that begins at the opposite end. In the recited claim phrase, the term “tapers” is a verb,<sup>2</sup> not the noun “taper,” and refers to the “opposite end of the elongate cylindrical portion.” We agree with the Examiner that the claim calls for the cylindrical portion to taper. Appellant’s argument that the needle hub shown in the Figures is enabled is not on point as it is the claimed apparatus that must be enabled, not just that depicted in a figure. The Examiner’s rejection is that the invention defined by the appealed claims is not enabled.

Non-Final Act. 3–4; *see also* Ans. 3–5. By focusing on the alleged enablement of the disclosure, rather than of the claimed subject matter, and by applying an incorrect construction, Appellant has not identified an error in the rejection. *Cf. Ex parte Frye*, Appeal No. 2009–006013, at 9–10 (BPAI Feb. 26, 2010) (precedential) (The Board, as a general matter, reviews the appealed rejections for error based upon the issues identified by Appellant and in light of the arguments and evidence produced thereon.) (cited with approval in *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) (“[I]t has long been the Board’s practice to require an applicant to identify the alleged error in the examiner’s rejections.”)). Accordingly, we affirm the Examiner’s rejection of claims 1 and 3–20 for lack of enablement.

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<sup>2</sup> Appellant, in the Reply Brief, appears to concede that “tapers” is a verb. *See* Reply Br. 3 (quoting a dictionary definition for the verb form of “taper”).

*B. The Enablement Rejection of Claims 7, 13, and 20*

The Examiner additionally rejected dependent claims 7, 13, and 20 as failing to comply with the enablement requirement due to the flange feature. Non-Final Act. 5–6.

Claim 7, which depends directly from claim 1, is exemplary and recites “a flange between the opposite end of the elongate cylindrical portion and the closed end separating the needle from the rest of the needle hub.” Appeal Br. 30.

The Examiner concludes that the opposite end and the closed end are both part of the needle hub, and maintains that a flange located between these ends would not separate the needle from the rest of the needle hub “because the flange does not separate the closed end from the needle.” Non-Final Act. 5. The Examiner also asserts that the claim has not defined what constitutes the “rest” of the needle hub.<sup>3</sup> Ans. 6.

Appellant notes that claim 1, from which claim 7 depends, recites that the closed end is part of the needle hub and that it is “a closed end from which a needle extends.” Appeal Br. 12. Appellant refers to the Specification’s description that, “[a]s shown [in Figure 1], the closed end 8 is separated from the rest of needle hub 4 by a flange 12.” *Id.* (quoting Spec. ¶ 18). Appellant argues that, because the needle extends from the closed end, which is part of the needle hub, one would understand that Figure 1

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<sup>3</sup> To the extent that the Examiner implies that a lack of definition of “the rest of the needle hub” renders the claim unclear, we do not reach such an issue because an indefiniteness rejection is not before us.

depicts the needle also as separated from the rest of the needle hub by the flange, and therefore contends that there is no non-enablement issue. *Id.*

We do not read the “rest of the needle hub” as meaning that the needle is part of the needle hub, as the Examiner asserts and upon which the rejection is based. Ans. 6. Also, we do not agree with the implied assertion that the claim requires that the flange separate the needle from the entirety of the needle hub, as that would read the phrase “the rest of” out of the claim. Ans. 5–6. We are not persuaded by the Examiner’s articulation of the rejection that one of ordinary skill in the art would have to engage in undue experimentation in order to make and use the flange feature of the claimed invention. Accordingly, we do not sustain the Examiner’s enablement rejection of claims 7, 13, and 20.

*C. The Rejection of Claims 1, 3–5, 7–11, 13–18, and 20 as Obvious Over Segal, Gettig, and Delvigo*

A dispositive issue raised by Appellant’s arguments is whether the Examiner has provided an adequate reason why a person of ordinary skill in the art would have modified Segal’s device to have a one piece needle assembly with a hub component that tapers. *See* Appeal Br. 18, 22.

Claim 1, for example, recites:

A one piece needle assembly comprising a needle hub having an elongate cylindrical portion formed by a circumferential wall that extends from a hub receptacle end to an opposite end, the opposite end of the elongate cylindrical portion tapers to a closed end from which a needle extends.

*Id.* at 29. Appellant and the Examiner both appear to construe the recited “needle assembly” as comprising a needle hub and a needle, and appear to agree that the recitation of a “one piece” assembly limits the claimed

apparatus to one having the needle and hub as a single component. *See* Appeal Br. 12; Non-Final Act. 8.

The Examiner finds that Segal discloses an assembly that can connect to a needle but “does not disclose how the distal end of assembly 3 exactly connects to the needle.” Non-Final Act. 8 (citing Segal ¶ 30). Thus, according to the Examiner, Segal does not disclose a one piece assembly having a closed end from which a needle extends. *Id.* The Examiner also finds that Segal lacks a portion that tapers. *Id.* For those features, the Examiner relies on Gettig. *Id.* (citing Gettig, Fig. 19). The Examiner’s proposed modification includes the “replacement of Segal et al.’s needle with Gettig’s needle.” *Id.* at 9.

The Examiner also finds, in pertinent part, that Gettig teaches that “a needle 334 extends (as seen in Fig 19) for the purpose of injection of medicinal drugs into a patient.” *Id.* (citing Gettig, 1:14–16, 8:53–55). The Examiner relies on this latter finding as an explicit teaching to modify Segal. *Id.* at 8–9. Specifically, the Examiner reasons that:

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Segal et al. to replace the components of needle hub 3 that lie distal to the elongate cylindrical portion of Segal et al. as well as Segal et al.’s needle with a tapered portion and a closed end directly attached to a needle, as taught by Gettig, *for the purpose of injection of medicinal drugs into a patient.*

*Id.* (emphasis added) (citing Gettig, 1:14–16, 8:53–55). The Examiner additionally reasons that it would have obvious to replace Segal’s two piece needle and hub with the combined hub and needle of Gettig “since it has been held that forming in one piece an article which has formerly been

formed in two pieces and put together involves only routine skill in the art.”  
*Id.* (citing *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)).

Appellant argues that the Examiner has failed to set forth an adequate reason why one of ordinary skill in the art would have combined the identified features of Segal and Gettig. Appeal Br. 18. Appellant asserts that the Examiner is selectively picking and choosing parts of the references in order to reach the claimed combination and, in so doing, the Examiner has engaged in improper hindsight. *See* Appeal Br. 13, 17–18; Reply Br. 7. Appellant also argues that the *Detroit Stove Works* case does not support the Examiner’s position. Appeal Br. 18.

We agree with Appellant that the Examiner has not set forth adequate reasoning as to why one of ordinary skill in the art would have modified Segal’s connector to have the hub-needle assembly and taper of Gettig. As mentioned, the Examiner maintains that Gettig provides an explicit teaching to modify Segal in stating that the configuration, including the needle-hub assembly, is “for the purpose of injection of medicinal drugs into a patient.” Non-Final Act. 9 (citing Gettig, 1:14–16, 8:53–55); *cf.* Ans. 13 (The Examiner confirming that the rejection’s reasoning to combine references is an explicit teaching from a reference: “[A]s can be seen in the last Office Action, each modification has been provided with a motivation taken from the references and a citation for each of the motivations has been provided.”). The Examiner, however, acknowledges that Segal’s apparatus also has a needle, even if not shown in the figures. *See, e.g.*, Non-Final Act. 9 (proposing to replace Segal’s needle with Gettig’s needle). Also as the Examiner acknowledges, Segal’s needle is a “fluid conduit[] used to

transfer fluid from the proximal end of the device to a patient.” Ans. 10 (citing Segal ¶¶ 30, 48). Thus, Segal’s apparatus—in an unmodified form—already serves the purpose of injecting medications into a patient. Accordingly, we fail to see, and the Examiner has not adequately explained, why the relied-upon teaching of Gettig would have provided a reason to modify Segal’s device. Additionally, even if we were to find that Gettig’s teaching prompted a modification regarding the needle, we still would fail to see adequate reasoning by the Examiner as to why Segal would be modified to have the recited portion that tapers.

As to *Detroit Stove Works*, the Examiner does not elaborate on the application of that case to the facts before us. *See* Non-Final Act. 9.<sup>4</sup> We find the Examiner’s conclusory reliance on the *Detroit Stove Works* decision to be inadequate to sustain a rejection. *See In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (It is incorrect to rely on the use of *per se* rules.). And, again, even if any holding of *Detroit Stove Works* supported a determination that it would have been obvious to form Segal’s hub and needle as a single-piece structure, we still are left without an adequate reason to modify Segal to have a portion that tapers.

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<sup>4</sup> *Detroit Stove Works* involved a grate for a fire box of a heating stove. *Howard v. Detroit Stove Works*, 150 U.S. at 165, 169. We understand the Examiner to rely on the Court’s statement: “As to the third patent, it is void because the claims in it were clearly anticipated, and because it involves no invention to cast in one piece an article which has formerly been cast in two pieces, and put together,” *id.* at 169.

In the Answer, the Examiner asserts that Segal discloses the hub as “being connectable to a ‘fluid receiving device’ . . . [,] which can be a needle.” Ans. 10. The Examiner then reasons that:

[B]oth the “fluid receiving device” of Segal et al. and the needle 334 of Gettig are fluid conduits used to transfer fluid from the proximal end of the device to a patient; because both are fluid conduits used for similar purposes, one of ordinary skill in the art would recognize that it would be obvious to replace the fluid conduit of Segal et al. with that of Gettig and that it would also be obvious to modify the shape of the distal end of the hub (connector 3) of Segal et al. so as to have the shape of the distal end of the hub 330 of Gettig since the distal ends of both of these hubs are simply acting to hold the fluid conduits.

*Id.* at 11. The first part of this reasoning appears to be that it would be obvious to replace a needle with a needle, which, even if true, fails to explain adequately why one would replace Segal’s “connectable” needle with a needle and hub combination formed as a one-piece assembly. We further determine that the second part of this reasoning, presumably addressing the claimed portion that tapers, is an inadequate explanation as to why one of ordinary skill would modify a hub shape based on the asserted fact that both references teach a structure to hold a fluid conduit.

The three independent claims on appeal, claims 1, 8, and 14, all contain the same or similar recitation of a one-piece needle assembly and an opposite end of a hub that tapers to a closed end from which a needle extends. Because the Examiner has not adequately explained why the references would have been combined in a manner to arrive at claimed subject matter having these features, we do not sustain the Examiner’s obviousness rejection of claims 1, 3–5, 7–11, 13–18, and 20.

*D. The Rejection of Claims 6, 12, and 19 as Obvious Over Segal, Gettig, Delvigo, and Sheppard*

Claims 6, 12, and 19 each depend directly from an independent claim, and each further limits the needle to a specific type, such an epidural or spinal needle. Appeal Br. 29–31. The Examiner finds that Sheppard discloses a spinal/epidural needle, but does not rely on Sheppard in any manner that cures the deficiency of the underlying rejection of the independent claims based on Segal, Gettig, and Delvigo. Non-Final Act. 24. As such, we also reverse the rejection of claims 6, 12, and 19.

IV. CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1 and 3–20	§ 112, first paragraph (enablement)	1 and 3–20	
7, 13, and 20	§ 112, first paragraph (enablement)		7, 13, and 20
1, 3–5, 7–11, 13–18, and 20	§ 103(a) Segal, Gettig, and Delvigo		1, 3–5, 7–11, 13–18, and 20
6, 12, and 19	§ 103(a) Segal, Gettig, Delvigo, and Sheppard		6, 12, and 19
<b>Overall Outcome</b>		1 and 3–20	

V. DECISION

The decision of the Examiner to reject claims 1 and 3–20 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