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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte N. SANDOR RACZ

Appeal 2014-006943
Application 11/853,785¹
Technology Center 3700

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to a surgical needle. The '785 Application discloses that the needle can be used for spinal anesthesia and nerve blockade. '785 Application 1:8–17; 3:2–31. The Examiner finally rejected the claims as obvious under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 134. The Examiner's decision is affirmed.

¹ “The '785 Application.”

STATEMENT OF CASE

Appellant appeals from the Examiner's final rejection of claims 1, 3–9, 11, 12, 22, 23, and 25. The claims stand rejected by the Examiner as follows:

1. Claims 1, 3, 4, 11, 12, and 22 as obvious under 35 U.S.C. § 103(a) (pre-AIA) in view of Wang (U.S. Patent No. 5,320,110, patented June 14, 1994) and Racz (U.S. Patent No. 5,817,074, patented Oct. 6, 1998). Final Rej. 2.

2. Claims 5–9 as obvious under 35 U.S.C. § 103(a) (pre-AIA) in view of Wang, Racz, and VanTassel (U.S. Publ. Application No. 2003/0130626 A1, pub. July 10, 2003). Final Rej. 6.

3. Claims 23 and 25 obvious under 35 U.S.C. § 103(a) (pre-AIA) in view of Wang, Racz, and Yamamoto (U.S. Publ. Application No. 2004/0260241 A1, pub. Dec. 23, 2004). Final Rej. 8.

Claim 1 is illustrative of the claimed subject matter:

1. A surgical instrument, in a unitary arrangement, comprising:
an elongated, at least partially hollow nerve blocking needle shaft comprising a tip end and a connector end;
 wherein the tip end is closed; and
 wherein the tip end comprises at least two facets;
 wherein the tip end comprises a shoulder and at least one beveled edge extending from the shoulder to a point of the tip end;
 wherein the tip end is capable of insertion into a tissue of a patient, but the tip end is not as sharp as a needle point;
at least one side port located along the elongated, at least partially hollow shaft away from the closed tip end and separated from the shoulder by a distance of about 1 mm to 4 mm;

wherein the at least one side port has at least one of an inwardly beveled edge or an outwardly beveled edge; and wherein the tip end is able to enter at least one tissue without the assist of an introducer.

OBVIOUSNESS IN VIEW OF WANG AND RACZ

The Examiner found that Wang describes a surgical needle with the features of the claimed instrument, but not where the needle's side port is "located . . . away from the closed tip end and separated from the shoulder by a distance of about 1 mm to 4 mm" and not where the "side port has at least one of an inwardly beveled edge or an outwardly beveled edge." Final Rej. 2–3 (claim 1). However, the Examiner found that Racz describes a surgical needle with both features. *Id.* at 3. The Examiner found it obvious to modify Wang with these feature for the purpose of dispersing the agent in a desired location. *Id.*

Side port location

Wang teaches that side port ("aperture") "located about 4 mm and 7 mm, respectively, axially rearwardly from tip 171 of trocar 166." Wang, col. 8, ll. 3–6. Appellant contends that the claim "requires that the side port be separated from the shoulder by a distance of about 1 mm to 4 mm," while "Figs. 2 and 4 [of Wang] depict that the side port distance is measured to the *edge* of the side port closest to the tip." Reply Br. 27. For this reason, Appellant contends that Wang results in the side port being located in a different position than claimed. *Id.* at 27–28. Appellant further argues that the skilled worker would not have combined Wang and Racz because the instruments have different purposes. Appeal Br. 26–27; Reply Br. 28.

Fig. 2 of the '785 Application shows the distance between port 30 and shoulder 26. The shoulder 26 is shown as the distal leading edge from point 33 of the needle. Wang teaches that the port is a distance away from the point 171 of the needle (shown in Fig. 13 of Wang). Wang, however, teaches:

Outer trocar **166** is tubular with a hollow interior, and has a distally positioned notch **168** and an aperture **170** positioned to extend through the trocar side wall opposite notch **168**. The exact positioning of this aperture **170** is not critical but is preferably in the proximal half of the wall opposite notch **168**. In this embodiment, notch **168** begins and the *aperture is located about 5 mm and 7 mm*, respectively, axially rearwardly from the tip **171** of trocar **166**.

Wang, col. 7, l. 66 to col. 8, l. 6 (emphasis in italic added).

Since Wang is measured from the *tip* of the needle (proximal end), while the claimed distance is from the *shoulder* of the tip – a more distal location with respect the needle tip – a location of 4 mm from the *shoulder* would be located even further away from the needle tip. Thus, 4 mm from the shoulder as recited in claim 1 would be *more than 4 mm* away when measured from the tip of the needle as taught by Wang. In other words, the value of about 4 mm from the needle shoulder as recited in the claim is equivalent to 4 mm plus the distance from the shoulder to the needle tip. While there is no information on the distance between the shoulder and needle tip, it is evident that the claimed value of “about” 4 mm is more than about 4 mm, which brings it closer to the “about 5 mm” described by Wang. Wang, col. 8, ll. 3–6.

The claim requires a distance of “about 1 mm to 4 mm” from the shoulder. The term “about” is a word of approximation, indicating that the location is not *exactly* 4 mm from the shoulder. Appellant did not provide a

definition of “about” that would exclude it from corresponding to the “about 5 mm” value disclosed by Wang (at col. 8, ll. 3–6).

We conclude that the term “about,” coupled with the fact that Wang’s port location is measured from the needle tip, and not the needle shoulder, makes it reasonable to find that Wang’s port (“about 5 mm”) encompasses distances at the same or at overlapping locations as required by the claim. It is well established that, when there is a range disclosed in the prior art, and the claimed invention overlaps or falls within that range, there is a presumption of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004). Even if the location values do not precisely overlap, they “are so close that *prima facie* one skilled in the art would have expected them to have the same properties,” shifting the burden to the applicant to show they are different. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985).

In addition to these facts, Wang expressly teaches that “[t]he exact positioning of this aperture 170 is not critical but is preferably in the proximal half of the wall opposite notch 168.” Wang, col. 8, ll. 1–3. Thus, while the aperture in Wang is preferably about 5 mm and 7 mm from the needle tip, Wang explicitly teaches its placement is not critical. Consequently, we conclude that the claimed distance of about 4 mm is reasonably suggested by Wang.

Appellant also argues that the “fluid mechanics of a side port 1 to 4 mm away from open tip end would be different than the fluid mechanics of a side port 1 to 4 mm from closed tip end.” Appeal Br. 28. However, Appellant has not provided evidence of this. An argument made by counsel

in a brief does not substitute for evidence lacking in the record. *Estee Lauder Inc. v. L'Oréal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997).

Because Wang alone is adequate to meet the limitation of the location of the port, we find it unnecessary to reach the teachings in Racz with respect to this feature. *Cf. In re Boyer*, 363 F.2d 455, 458 n.2 (CCPA 1966).

Needle point

Claim 1 recites that “the tip end is capable of insertion into a tissue of a patient, but the tip end is not as sharp as a needle point.” The tip is required by the claim to have “at least one beveled edge extending from the shoulder to a point of the tip end.” As found by the Examiner, Wang describes a tip “sharpened” with beveled edges. Wang, col. 8, ll. 6–7. The Examiner also found that “needle points come in various degrees of sharpness.” Answer 14.

Appellant contends that Wang teaches that its needle is sharp (Appeal Br. 28), but doesn't explain how the claimed needle with at least beveled edge wouldn't be as “sharp” as Wang's needle with the same features. Furthermore, Wang doesn't require the tip to be sharpened, but discloses that it is “preferably sharpened.” *Id.* Consequently, a preponderance of the evidence supports the Examiner's finding that Wang discloses or reasonably suggests the claimed limitation of a “tip end is not as sharp as a needle point.”

Bevel and facet

Claim 1 requires that the “tip end comprises at least two facets” and “the tip end comprises a shoulder and at least one beveled edge.” Claim 4,

which depends from claim 1, further recites “tip end comprises at least two beveled edges.”

The Examiner found that Wang teaches “the tip end comprises at least two facets (‘beveled surfaces’; Col 8, Line 7); wherein the tip end comprises a shoulder and at least one beveled edge extending from the shoulder to a point of the tip end (as seen in Fig 13 and 14 . . .).” Final Rej. 2.

Appellant contends that the Examiner has used the terms bevel and facet interchangeably. Relying on a dictionary definition, Appellant argues that a “facet” is a level plane, while a “bevel” is angled. Appeal Br. 29.

This argument is not persuasive. During patent examination:

[T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

In this case, the ’785 Application discloses that the “angle of bevel is capable of being the same for all facets.” ’785 Application 9:2. Based on this description, the skilled worker reading the ’785 Application would have understood that a “facet” can be a “bevel.” Wang, as found by the Examiner, describes the tip of its instrument as having “beveled surfaces” (Wang, col. 8, ll. 6–7) and shows two beveled surfaces in Fig. 13. Consequently, Wang teaches a tip with at least two facets (“beveled surfaces”), where one of these facets is beveled, as required by claim 1.

The claim also requires “at least one side port has at least one of an inwardly beveled edge or an outwardly beveled edge.” The Examiner found that Racz describes a side port having “a beveled edge (as seen in Fig 2,3).”

Final Rej. 3. Appellant contends that this feature is not described by Racz. Reply Br. 26. Although the Examiner found that this feature was met by Racz in the Rejection dated Feb. 7, 2013, Appellant did not respond until the Reply Brief. The Board will not consider new arguments “not raised in the appeal brief, or is not responsive to an argument raised in the examiner's answer . . . unless good cause is shown.” 37 CFR 41.41(b)(2). Appellant did not explain why they waited until after the Appeal Brief to respond. Consequently, we shall not consider this new argument.

Claim 11

Claim 11 has substantially the same structural limitations as claim 1, but further recites:

the surgical instrument realizes at least one benefit selected from the group consisting of enhanced injection characteristics, increased operational efficiency, reduced cost per unit, reduced incidence of injury through intraneural/intravascular injection, and reduced incidence of injury through pricking/piercing.

As discussed above, the cited prior art reasonably suggests all the structural features of claim 1, including the position of the side port. Absent evidence to the contrary, utilizing a needle with such features would result in the recited benefits.

Appellant argues that the location of the side port would result in at least one of the claimed benefits. Appeal Br. 31. Appellant also makes the same unsubstantiated argument about how the position of the port affects the fluid mechanics. *Id.* However, since Wang discloses or reasonably suggests such a location, we conclude that such benefits would be an inherent property of placing the port in such location. Appellant did not provide

evidence that such benefit was unexpected nor *absent* from the needle of Wang. Consequently, we affirm the rejection of claim 11.

Claim 12

Claim 12, depends from claim 11, and further recites “wherein the connection is a plug and use connection.” The Examiner found this limitation met by Wang’s teaching of a proximal end “secured in a needle support.” Final Rej. 5.

Appellant contends that Wang does not describe a wire connector. Appeal Br. 32.

Appellant’s argument is not persuasive. Claim 12 does not require a wire plug and use connection. We do not read limitations into the claim. Nevertheless, the Examiner found that a plug and use connector explicitly comprising a wire as recited in claims 5 and 7–9 is described by VanTassel in combination with Wang and Racz. Final Rej. 7.

Claim 22

Appellant provides separate arguments for independent claim 22. However, these arguments are the same as those found unpersuasive regarding claims 1 and 11.

Summary

The obviousness rejection of claims 1, 3, 4, 11, 12, and 22 is affirmed. To the extent claims were not argued separately, they fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

OBVIOUSNESS IN VIEW OF WANG, RACZ, AND VANTASSEL

Claims 5–9 depend from claim 1 and further require a wire plug and use connector (claims 5 and 7–9) and an insulation around the shaft of the needle (claim 6). The Examiner found that these limitations are described in VanTassel. Final Rej. 7–8. The Examiner explained why it would have been obvious to one of ordinary skill in the art to have added such features to Wang. *Id.* Appellant makes the same unpersuasive arguments as for claim 1. Appeal Br. 34–36. Consequently, we affirm the rejection of claims 5–9 for the reasons set forth by the Examiner.

OBVIOUSNESS IN VIEW OF WANG, RACZ, AND YAMAMOTO

Claims 23 and 25 have substantially the same limitations as claim, but further require insulation along the needle shaft. The Examiner found that Yamamoto describes insulation that meets the claim limitation and explained why it would have been obvious to one of ordinary skill in the art to apply Yamamoto’s teaching to Wang and Racz. Final Rej. 10–11. Appellant makes the same unpersuasive arguments as they did for claims 1, 11, and 22. Consequently, we affirm the rejection of claims 23 and 25 for the reasons set forth by the Examiner.

TIME PERIOD

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

AFFIRMED