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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EMED Technologies Corporation,
Patent Owner

Appeal 2019-006499
Reexamination Control 90/013,585
Patent US 8,500,703 B2¹
Technology Center 3900

Before BRETT C. MARTIN, JEREMY M. PLENZLER, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

MARTIN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant,² EMED Technologies Corporation, appeals from the Examiner's decision to reject claims 1–12. We have jurisdiction under 35 U.S.C. § 6(b).

¹ Issued to Paul Lambert et al. on August 6, 2013. We direct the Examiner to *Repro-Med Sys., Inc. v. EMED Techs. Corp.*, IPR2015-01920, Paper 65 (PTAB Jan. 13, 2017), affirmed 725 F. App'x 1005 (Fed. Cir. April 3, 2018), cert. denied, 139 S. Ct. 418 (2018), for a Final Written Decision directed to claims for US 8,961,476 B2, a patent related to US 8,500,703 B2.

² 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 EMED Technologies Corporation. App. Br. 2.

We AFFIRM-IN-PART.

CLAIMED SUBJECT MATTER

The claims are directed to “devices and methods for protecting a user from a sharp tip of a medical needle.” Abstract. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A device for protecting a user from a sharp tip of a medical needle, the device comprising:

a central body portion in fluid connection with a delivery tube;

the medical needle having a first end and a second end in opposition to one another, the first end in fluid connection with the central body portion and the delivery tube, and the second end of the needle extending away from the central body portion to the sharp tip, and a line from the first end to the second end of the medical needle defining a longitudinal axis;

a pair of wings having an inner region and an outer region, the inner region of each one of the pair of wings in attachment to the central body portion, the outer region of each one of the pair of wings extending away from the central body portion, the pair of wings disposed in opposition to one another with the medical needle positioned therebetween, and the pair of wings being selectively positionable from a first position to a second position, the first position for placing the medical needle into a patient and delivering a medicinal fluid, and the second position for removing the medical needle from the patient;

a mechanical fastener disposed on at least one of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings

together with the medical needle positioned therebetween so as to protect the user from the sharp tip of the medical needle;

the mechanical fastener including a lip extending along at least a portion of the perimeter of at least one of the wings, and a mating portion along a perimeter of at least the other one of the wings; and

the mating portion and the lip configured to engage with one another to selectively attach the pair of wings together with the medical needle positioned therebetween so as to protect the user from the sharp tip of the medical needle.

The prior art relied upon by the Examiner is:

| | | |
|----------|-----------------|----------------|
| Norelli | US 4,820,277 | Apr. 11, 1989 |
| Ishikawa | US 5,147,319 | Sept. 15, 1992 |
| Harada | JP H9-66106 | Mar. 11, 1997 |
| Sasso | US 6,500,155 | Dec. 31, 2002 |
| Brimhall | US 2003/0065288 | Apr. 3, 2003 |

REJECTIONS

Claims 1, 5, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Harada. Final Act. 8.

Claims 1, 5–9, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ishikawa. Final Act. 10.

Claims 1, 5–8, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Norelli. Final Act. 12.

Claims 2, 10, and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ishikawa and Sasso. Final Act. 15.

Claims 3, 6, and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harada. Final Act. 16.

Claims 3, 4, and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Harada. *Id.*

OPINION

Anticipation by Ishikawa

Appellant argues claims 1, 4, 7–9 and 12 as a group. We select claim 1 as representative and the remainder of these claims stand or fall with claim 1. Appellant first argues that “in Ishikawa, the wings do not cover the needle but rather a sheath attached to the wing covers the needle.” App. Br. 13. As the Examiner correctly notes, however, the claims “recite that the mating portion and the lip selectively ‘attach the pair of wings together with the medical needle positioned therebetween so as to protect the user from the sharp tip of the medical needle.’” Ans. 22. The Examiner is correct that “the sheath portion 6 of Ishikawa is described as consisting of a ditched projection 7 ‘which is formed along one of the meeting edges of the wings 5a, 5b, and a lipped section 8 formed along the other meeting edge.’” *Id.* (citing Ishikawa col. 2, ll. 14–27). In this manner, Ishikawa satisfies the claim language at issue and Appellant’s arguments are not commensurate with the scope of claim 1.

Appellant next argues that Ishikawa’s “wings do not attach to a central body portion, but rather to arms 4a and 4b.” App. Br. 13. Appellant further argues that “[a]rms 4a and 4b are separate structures from the wings.” *Id.* We disagree. Appellant’s argument is inconsistent even with its own disclosed embodiments in that its wings 216, 218 attach to central body 202 via hinge-like members 220 as seen, for example, in Appellant’s Figure 2. These hinge-like members are both thinner and extend less than

the full length of the wing, similar to Ishikawa. Inasmuch as Ishikawa's arms 4a and 4b can be considered separate structures, then element 220 is also a separate member from the wings. Given that Appellant's disclosure considers elements 220 as part of the wings, we agree with the Examiner that arms 4a and 4b are likewise part of Ishikawa's wings. The examiner is also correct in addressing the Stoker Declaration. Ans. 24. Accordingly, they directly attach to the body in the same manner as Appellant's wings with an intervening structure that is still part of the wing, thus meeting both the broader language of claim 1 and the narrower language of claim 12.

Regarding claim 5, Appellant argues that the Examiner's finding that Ishikawa's flexible arms are semi-rigid "is flawed because it fails to consider the difference between materials that are 'elastic' versus 'semi-rigid.'" App. Br. 13. Appellant's Specification makes no distinction between semi-rigid and elastic and the Examiner is correct that the material in Ishikawa "cannot be so flaccid that the wings could not maintain the position shown in figure 1" and as such may be considered a semi-rigid material. Final Act. 11. The Examiner is also correct that Appellant's Specification fails to "provide any guidance as to the relative terms such as soft, rigid, and semi-rigid, and therefore is silent as to the properties required to classify a material into one of those categories." Ans. 26. As such, we agree that Ishikawa's flexible material that is capable of robust elastic deformation that snaps back to an original shape after mechanical deformation is sufficient to qualify as semi-rigid. Accordingly, we are not persuaded of error in the Examiner's anticipation rejection of these claims.

Obviousness over Ishikawa and Sasso

Appellant first argues that Ishikawa does not teach “a lip extending along a perimeter nor a female locking means along a perimeter of the other wing” because “coupling means 10b is not on the perimeter but exterior to the wing.” App. Br. 16. We do not find this argument persuasive because it is not commensurate with the scope of claim 1, from which claims 2, 10, and 11 depend. Appellant appears to argue that anything extending beyond the perimeter of the wing would not meet the claim language at issue, but the claim merely describes the lip as “extending along at least a portion of the perimeter of at least one of the wings.” The claims do not require that the lip stay within the perimeter and something that extends out from the perimeter still extends along the perimeter as claimed.

Lastly, Appellant argues that the Examiner erred in asserting that adding it would have been obvious to add Sasso’s handle to Ishikawa, as “Ishikawa does not teach a design wherein the handle of Sasso may be placed on the central body within the longitudinal axis of the medical needle.” App. Br. 17. Although the claims do not specifically use this language, we concede that the orientation of the needle in Ishikawa is in line with the central body, whereas both Sasso and Appellant’s Specification disclose a needle that extends in a direction perpendicular to the axis of the central body. Appellant is correct that “the handle of Sasso *cannot* be positioned in longitudinal alignment because it would interfere with delivery tube 11. Appellant’s explanation is sufficient for us to conclude that the meaning of the language of claim 11 encompasses the difference between an in-line needle as in Ishikawa and a perpendicularly positioned needle as in

Sasso as it relates to the positioning of the handle. As such we do not sustain the rejection of claim 11.

This language, however, does not appear in claims 2 and 10 and we see no reason why the Examiner is incorrect that a handle could still be placed on Ishikawa so as to meet the language of claims 2 and 10. Appellant's arguments apply only to claim 11 and Appellant presents no arguments to the more general language of claims 2 and 10. Accordingly, we sustain these rejections.

Obviousness over Ishikawa and Brimhall

Appellant repeats several arguments regarding claim 1, which we have already addressed above. As to the inclusion of a rigid material in claim 4, again, Appellant's arguments are not commensurate with the language at issue. The claims only require that the "wings include rigid material." Brimhall does disclose that its wings are made of soft, flexible material, but the Examiner's reliance on Brimhall is for the stiffening member, which Appellant admits "provides rigidity." App. Br. 20. Appellant appears to argue that the stiffening member is somehow not part of the wing, but it is fully encompassed within the flexible material and is clearly "included" as part of the wing. Appellant's claims do not require that the wing consist of a rigid material, which would be more commensurate with Appellant's arguments, and we are not persuaded that the Examiner's addition of a stiffening member to Ishikawa in order to meet the language of claim 4 is in error.

Regarding claims 3 and 6, Appellant argues that the Examiner erred because the circular openings of Brimhall "would not render the 'wings' of

Ishikawa to have a circular shape.” App. Br. 21. The Examiner is correct, however, that the claims do not require “that the wings *are circular in shape.*” Ans. 35. Although the Examiner has taken a relatively broad interpretation of the claim language at issue, we do not find it to be unreasonable. Inclusion of the holes of Brimhall would mean that the device *includes* circular shapes, which is a broad, but reasonable interpretation of the “hav[ing]” claim language. The Examiner has juxtaposed claim language that would be more in line with Appellant’s argument with the actual language, which allows for the Examiner’s broader interpretation. The Examiner does not argue that Brimhall discloses the argued circular-shaped wings, merely that the claim language does not require such a shape of the wing itself as argued. Accordingly, we sustain the Examiner’s rejection over Ishikawa and Brimhall.

We also sustain the Examiner’s rejection of claims 3 and 6 as obvious over Harada. As to claim 1, from which claims 3 and 6 depend, the above analysis with regard to Ishikawa generally applies to Appellant’s arguments regarding Harada. Further, the Examiner is correct that Harada meets all of the structural limitations and that Harada’s device performs the function of providing the needle with a cover, which is all the claim requires. Ans. 8–9. The Examiner is also correct that Harada teaches the claimed first and second positions and that, as explained in describing Fig. 1, “the needle cover (wings 3a, 3b) is opened and the injection needle is exposed at the time of use.” Ans. 10 (citing Harada ¶ 7). We agree with the Examiner that it is unclear how “the wings, when in this position, *do not allow* placing the needle into a patient.” Ans. 10. We also agree with the Examiner that it is

irrelevant that Harada discloses an injection needle because Harada meets the structural limitations of claim 1 in that it includes a central body via its needle base. Ans. 12. Nothing in the claims disqualifies their application to a device such as that disclosed in Harada. Similar to Ishikawa, we agree that Harada at least meets the broad language of claim 1 regarding the connection. *See* Ans. 12–18. Lastly, regarding the lip, the Examiner adequately addresses this limitation. *See* Ans. 19–20.

Turning specifically to claims 3 and 6, we agree with the Examiner’s finding that the claimed circular shape is a matter of mere design choice. Ans. 33. The Examiner is correct that the patent “does not attribute any criticality to the particular shape of the wings, and in fact, states that the wings may be configured in ‘various shapes’ and specifies circular and rectangular as exemplary shapes.” *Id.* We note that although the Examiner only made this rejection over Harada, the design choice rationale would apply equally to any of the base references the Examiner uses to reject the claims. Accordingly, we also affirm the Examiner’s rejection of at least claims 1,3 and 6 as obvious over Harada.

Remaining Rejections

As to the remaining rejections, we need not address them because the anticipation and obviousness rejections over Ishikawa encompass all of the claims subject to the remaining rejections. Claims 2, 10, and 11 are only rejected over Ishikawa and Sasso and so no other rejection reaches these claims.

Appeal 2019-006499
Reexamination Control 90/013,585
Patent US 8,500,703 B2

DECISION

The Examiner's rejections are AFFIRMED-IN-PART.

DECISION SUMMARY

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|------------------------|--------------------|---------------------------|-----------------|-----------------|
| 1, 5, 7-9, 12 | 102 | Ishikawa | 1, 5, 7-9, 12 | |
| 3, 4, 6 | 103 | Ishikawa and Brimhall | 3, 4, 6 | |
| 2, 10, 11 | 103 | Ishikawa and Sasso | 2, 10 | 11 |
| 1, 3, 6 | 103 | Harada | 1, 3 | |
| Overall Outcome | | | 1-10, 12 | 11 |

AFFIRMED-IN-PART

alw

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