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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL ANTHONY ZANI, JOHN CHRISTIAN GOHDE,
ALLAN JON CETRONE, and URIYAH DUCHUN ROBINSON

Appeal 2020-001051
Application 15/479,833
Technology Center 3700

Before MICHAEL C. ASTORINO, NINA L. MEDLOCK, and
TARA L. HUTCHINGS, *Administrative Patent Judges*.

ASTORINO, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), the Appellant¹ appeals from the Examiner's decision to reject claims 1, 2, 5, 7, 9–11, and 24–27.² 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. The Appellant identifies the real party in interest as C.R. Bard, Inc. Appeal Br. 4.

² Claims 12–23 are withdrawn. Appeal Br. 4. Claims 3, 4, 6, and 8 are cancelled. *Id.* at 29–30.

STATEMENT OF THE CASE

Claimed Subject Matter

Claims 1 and 11 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A patient care protocol package configured to improve performance and standardization of one or more catheter pre-insertion and/or post-insertion patient care protocols, the patient care protocol package comprising:

a container;

one or more wipes disposed in the container, the one or more wipes for use in performing the one or more catheter pre-insertion and/or post-insertion patient care protocols; and

at least one labeling provided on the container, the at least one labeling including:

a first labeling configured to improve performance and standardization of the one or more catheter pre-insertion and/or post-insertion patient care protocols, the first labeling including a first column and a second column, each of the first and second columns including at least one picture;

wherein the first column of the first labeling facilitates correct usage of the one or more wipes and facilitates correct performance of the one or more catheter pre-insertion and/or post-insertion patient care protocols with regards to female anatomy;

wherein the second column of the first labeling facilitates correct usage of the one or more wipes and facilitates correct performance of the one or more catheter pre-insertion and/or post-insertion patient care protocols with regards to male anatomy;

a second labeling spaced from the first labeling that includes substantially only words; and

at least one token disposed in or on the container, the at least one token configured to be removed from the container, wherein the at least one token at least one of performs, verifies, or assists with the one or more catheter pre-insertion and/or post-insertion patient care protocols.

Rejections

Claims 24 and 25 are rejected under 35 U.S.C. § 112(a) as failing to comply with the written description requirement.

Claims 1, 2, 5, 7, 9–11, and 24–27 are rejected under 35 U.S.C. § 103 as unpatentable over Morelli et al. (US 2010/0274205 A1, pub. Oct. 28, 2010) (“Morelli”) in view of Monroe (US 2009/0128330 A1, pub. May 21, 2009).

Claims 1, 2, 5, 7, 9–11, and 24–27 are rejected under 35 U.S.C. § 103 as unpatentable over Morelli in view of Mazel et al. (US 2001/0044427 A1, pub. Nov. 22, 2001) (“Mazel”).

ANALYSIS

Written Description

The Examiner finds that claim 24, which recites, “[t]he patient care protocol package of claim 1, wherein the container includes only the one or more wipes disposed therein,” fails to comply with the written description requirement. Final Act. 5. The Examiner explains that claim 24 requires the container to include “only wipes,” yet the Specification fails to limit the contents of the container to be only wipes. *See id.*; Ans. 8. Additionally, the Examiner finds that the container may include syringes and gloves. Final Act. 5.

The Appellant argues that the subject matter of claim 24 is adequately supported by the original Specification. Appeal Br. 12–13; Reply Br. 4–5. The Appellant points out that the Specification discloses wipes and gloves as alternative elements that can be included the container. *Id.* (citing Spec. ¶¶ 44, 52). And, as alternative elements, only wipes disposed in the

container may be claimed. *Id.* (Manual of Patent Examining Procedure (“MPEP”) § 2173.05(i), Negative Limitations (9th ed., rev. 10.2019, last rev. June 2020) (“[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.”). We agree with the Appellant’s argument.

Obviousness

Independent claim 1 recites “one or more wipes disposed in the container, the one or more wipes for use in performing the one or more catheter pre-insertion and/or post-insertion patient care protocols.” Appeal Br., Claims App. Similarly, independent claim 11 recites, “one or more wipes disposed in the container, the one or more wipes for use in performing the one or more catheter post-insertion patient care protocols.” *Id.*

For the rejections of claims 1 and 11, as unpatentable over Morelli in view of Monroe and Morelli in view of Mazel, the Examiner finds that Morelli’s protective barrier wipe 16 corresponds to the claimed “one or more wipes.” Final Act. 6, 7, 9; *see* Morelli ¶ 19. The Examiner finds that Morelli describes “wiping the healthy skin with the barrier wipe” and that protective barrier wipe 16 is “fully capable of performing some protocol related to catheter insertion such as but not limited to wiping skin either before or after catheter insertion.” Ans. 9; *see* Morelli ¶ 32.

The Appellant argues that the Examiner’s finding lacks adequate support because the Examiner fails to explain on the record how Morelli’s protective barrier wipe 16 is “capable of ‘performing the one or more catheter pre-insertion and/or post-insertion patient care protocols,’ as recited in independent claim 1.” Appeal Br. 14–15; *see* Reply Br. 6. The Appellant

points out that Morelli's protective barrier wipe 16 is a specific type of wipe, namely a wipe that creates a protective barrier. *See* Appeal Br. 14–15 (citing Morelli ¶ 32). The Appellant contends that “the Examiner did not demonstrate how the barrier formed by the barrier wipe affects a catheter, perineal region of an individual, the odds of developing a catheter-associated urinary tract infection, etc.” *Id.* at 15. The Appellant's argument is persuasive.

As discussed above, the Examiner finds that Morelli's protective barrier wipe 16 corresponds to “one or more wipes” as recited in claims 1 and 11. For this finding to be adequately supported, the Examiner needs to explain how Morelli's protective barrier wipe 16 is able to perform at least one catheter pre-insertion and/or post-insertion patient care protocol. The Examiner may do so by either: identifying a catheter pre-insertion and/or post-insertion patient care protocol and explaining how Morelli has the ability of performing it; or explaining how Morelli's wipe is the same type of wipe as described in the Appellant's Specification.

The Examiner does not identify a catheter pre-insertion and/or post-insertion patient care protocol that Morelli's protective barrier wipe 16 has the ability of performing. Some examples of the one or more catheter pre-insertion and/or post-insertion patient care protocols are identified in the Specification. For instance, “[i]n some embodiments, the post-insertion patient care protocol may require that five different portions of the patient's periurethral region, the patient's perineal region, and the drainage bag system 100 be washed using, for example, non-antiseptic wipes.” Spec. ¶ 52. The Specification also instructs that the wipes “may be used to clean the genitalia of the male (*e.g.*, wipe the foreskin and the meatus, foreskin,

the periphery thereabout) and/or female (wipe the meatus),” “may be use[d] to clean the inner thigh of the patient,” and may be “used to clean a portion of the catheter 114.” *Id.* ¶ 53, Figs. 1C, 1D. The Examiner does not adequately explain — using evidence or technical reasoning — how Morelli’s protective barrier wipe 16 has the ability of performing any of these protocols. Additionally, there is no support in the record for the assumption that wiping the healthy skin with a protective barrier wipe 16 corresponds to a catheter pre-insertion and/or post-insertion patient care protocol.

The Examiner also does not show that Morelli’s wipe is the same type of wipe as described in the Appellant’s Specification. In this regard, we note that the Specification provides “[a]n example of wipes that may be included in the package 124 include Provon® products available from GOJO.com.” *Id.* ¶ 53. Morelli describes that “protective barrier wipe 16 can be item number MSC 1505, Sureprep® No-Sting, manufactured by Medline Industries, Inc. (Mundelein, Ill.)” Morelli ¶ 19. Moreover, Morelli appears to distinguish protective barrier wipe 16 from “[o]ther wound and skin preparation materials,” for example, “wound cleansers, such as hydrogen peroxide and saline.” *Id.* Accordingly, the example product described in the Specification appears to be a different type of product than the example protective barrier wipe product described in Morelli.

In view of the foregoing, we determine that the Examiner’s finding Morelli’s protective barrier wipe 16 corresponds to “one or more wipes disposed in the container, the one or more wipes for use in performing the one or more catheter pre-insertion and/or post-insertion patient care protocols,” as recited in claim 1, as well as the similar recitation of claim 11,

lacks adequate support. Further, we note that the Examiner fails to rely on Monroe or Mazel in any manner that would remedy the deficiency in the Examiner's finding as discussed above. Thus, we do not sustain the Examiner's rejections of independent claims 1 and 11, and the claims that depend therefrom, as unpatentable Morelli in view of Monroe or Mazel.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	References/Basis	Affirmed	Reversed
24, 25	112(a)	Written Description		24, 25
1, 2, 5, 7, 9-11, 24-27	103	Morelli, Monroe		1, 2, 5, 7, 9-11, 24-27
1, 2, 5, 7, 9-11, 24-27	103	Morelli, Mazel		1, 2, 5, 7, 9-11, 24-27
Overall Outcome				1, 2, 5, 7, 9-11, 24-27

REVERSED