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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN G. WHITNEY,
ALLISON BEDELL, and SAAGAR PATEL

Appeal 2018-005206
Application 14/244,885
Technology Center 3700

Before EDWARD A. BROWN, JAMES P. CALVE, and
JILL D. HILL, *Administrative Patent Judges*.

CALVE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the decision of the Examiner to reject claims 3–6, 17, and 18. Br. 1. Claims 1 and 2 are cancelled. *Id.* at 10 (Claims App.). Claims 7–16 are withdrawn. *Id.* at 10–13. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ “Appellant” refers to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies Whitney Products, Inc. as the real party in interest. Appeal Br. 3.

CLAIMED SUBJECT MATTER

17. A sterile bag for containing non-sterile objects comprising:
a front surface including a front top edge;
a back surface including a back top edge;
a proximal sealed end; and
a distal end that provides for an open configuration and a subsequent sealed configuration adjacent the front and back top edges;
wherein, in the open configuration, the distal end includes:
a cuff forming an opening to an interior of the bag and including a visible demarcation identifying a sterile portion and a non-sterile portion of the bag;
a tear guide adjacent to the cuff;
first and second fold lines adjacent to the tear guide and distal to the cuff; and
a closure mechanism adjacent to the second fold line and distal to the tear guide; and
an indicator including a first portion along the back top edge and a second portion along the front top edge; and
wherein, in the sealed configuration and after a user removes the cuff via the tear guide and folds the distal end twice along the first and second fold lines, the distal end includes a folded edge closed by the closure mechanism such that the first and second portions of the indicator are aligned to identify that the bag is sealed.

REJECTIONS

Claims 3, 4, 17, and 18 are rejected under 35 U.S.C. § 103(a) as unpatentable over Oliverius (US 5,178,278, iss. Jan. 12, 1993), Stecklein (US 2006/0088450 A1, pub. Apr. 27, 2006), and Austreng (US 2008/0056622 A1, pub. Mar. 6, 2008).

Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as unpatentable over Oliverius, Stecklein, Austreng, and Walchle (US 3,698,791, iss. Oct 7, 1972).

ANALYSIS

Claims 3, 4, 17, and 18 Rejected over Oliverius, Stecklein, and Austreng

Appellant argues claims 3, 4, 17, and 18 as a group. Appeal Br. 5–8. We select claim 17 as representative. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Regarding independent claim 17, the Examiner relies on Oliverius to teach a sterile bag for containing non-sterile objects with a cuff forming an opening to an interior of the bag and a tear guide (perforation 57) adjacent to the cuff, but finds that Oliverius lacks a visible demarcation identifying a sterile portion and a non-sterile portion of the bag. Final Act. 2 (citing Figs. 2, 5, 6). The Examiner finds that Stecklein teaches a visible demarcation as sterilization indicator 20, which identifies sterile and non-sterile portions of the bag. *Id.* at 3. The Examiner finds that portion 20 is a line and may be printed on the pouch interior close to the top of the pouch so the printed ink is seen as soon as the product begins to be presented aseptically. Ans. 7. The Examiner finds that this visual demarcation “would communicate to the user, sterilization status of the portions of the bag” and “portion 20 is clearly shown as a visible demarcation between portions of a bag (Fig. 5).” *Id.*

The Examiner finds that Oliverius also lacks a first and a second fold line and indicator with first and second portions that align to identify that the bag is sealed. *Id.* The Examiner finds that Austreng teaches first and second fold lines 24, 26 adjacent to the distal end of the bag, a closure mechanism (adhesive tape 28) adjacent to second fold line 26, and an indicator (tamper evident tear tape 18) having a first portion along the back top edge and a second portion along the front top edge where both halves of tamper evident tape 18 align when the bag is closed. Final Act. 4; Ans. 7–8 (citing Fig. 6).

Appellant argues that the sterilization indicator of the container of Stecklein is merely an agent that is activated upon exposure to a non-sterile environment, and it does not indicate portions of the bag that are sterile and non-sterile. Br. 7. Appellant argues that the claimed indicator is attached to or integral to the bag whereas Austreng's tamper evident structure is applied to the package after the package is sealed. *Id.* Appellant also argues that the tamper evident structure of Austreng lacks the claimed first and second portions that align to identify that the bag is sealed. *Id.* at 7–8.

Visible Demarcation Identifying Sterile and Non-Sterile Portions of Bag

Regarding Stecklein's sterilization indicator, claim 17 recites "a cuff . . . including a visible demarcation identifying a sterile portion and a non-sterile portion of the bag." Br. 13 (Claims App.). The cuff and its visible demarcation are part of a sterile bag for containing non-sterile objects recited in the preamble. The Specification describes this feature as follows:

As taught herein, it may be advantageous to provide a sterile bag 100 that includes a visible demarcation 108 between the sterile and non-sterile portions of the bag 100. The visible demarcation 108 may enable users to quickly visually identify which portion of the bag 100 they may handle (*e.g.*, users with scrubbed hands may handle the bag 100 on the proximal side of the visible demarcation 108 and users with non-scrubbed hands may handle the bag 100 on the distal side of the visible demarcation 108). As used herein, the proximal side of the visible demarcation 108 is the sterile portion of the bag 100 and distal side of the visible demarcation 108 is the portion of the bag 100 that may contact non-sterile materials or be touched by the unscrubbed user.

Spec. ¶ 52. The non-sterile portion is the part of the sterile bag that may be touched by persons with non-scrubbed (*i.e.*, non-sterile) hands. The sterile portion of the sterile bag may be handled by users with scrubbed hands. *Id.*

Claim 17 does not, however, recite different properties for the “sterile portion” and “non-sterile portion” of the bag. The Specification makes clear that both portions have the same properties. They are different parts of the same *sterile* bag separated by a “visible demarcation.” *Id.* ¶¶ 52, 54. Visible demarcation 108 may be a solid line or a visible indication located around protective cuff 106 to visibly separate a *designated* non-sterile part of sterile bag 100 from a sterile part of bag 100. *Id.* ¶ 54. Thus, this visible indicia essentially instructs parties with unscrubbed (non-sterile) hands where they may touch the interior “non-sterile” portion of the bag. *Id.* Parties with scrubbed hands may only touch the exterior “sterile” portion of the bag. *Id.*

The “sterile” and “non-sterile” portions thus indicate how different portions of the bag are to be handled or *used*. The different suggested uses of the bag do not impart different structure/properties to the sterile or non-sterile portion of the sterile bag. Before the bag is used, the “sterile portion” and the “non-sterile portion” of the bag have the same properties. They are sterile. *See id.* ¶ 52. *In use*, visible demarcation 108 indicates the portion of sterile bag 100 that a user should touch depending on whether the user’s hands are scrubbed. *Id.* Only if users with non-sterile hands touch the “non-sterile portion” does the “non-sterile portion” then become non-sterile. *Id.* “It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Furthermore, a claim to an apparatus cannot define that apparatus in terms of method steps of using the apparatus. *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (holding a claim that recites a system and method steps of using the system is indefinite).

We agree with the Examiner that Stecklein's bag includes an integral sterilization indicator 20 that provides a visible demarcation along a cuff to divide the bag into an inner portion that receives an article 22 to be sterilized and an outer portion that can be handled by users with unsterilized hands 27. Stecklein ¶¶ 29–31, Figs. 4, 5. Similar to visible demarcation line 108 in Appellant's Specification, Stecklein's sterilization indicator 20 (Fig. 5) divides a sterilized bag into two portions. One portion contains sterilized article 22. The other portion can be handled by a person with unsterilized hands. *Id.* Stecklein thus discloses a sterile bag structure that satisfies the intended use in claim 17 even if given patentable weight. Ans. 7.

Indicator with Portions that Align to Indicate the Bag is Sealed

We also agree with the Examiner that Austreng teaches an indicator as tamper evident tape 18 that is attached to a bag with a first portion along a back top edge and a second portion along a front top edge as claimed. Final Act. 3. The two portions of tape 18 align when the bag is folded along first and second fold lines to indicate the bag is sealed as claimed. Ans. 7–8.

Appellant's argument that the claimed indicator is attached to the bag, but the tamper evident seal of Austreng's package is applied after a package is sealed (Br. 7), is not persuasive because Austreng's tamper evident tape 18 is attached permanently to the package. Austreng ¶¶ 34, 35, Figs. 5, 6. Furthermore, claim 17 does not recite that the indicator is attached to, or integral with, the bag. Nor does it recite any structure of the indicator that distinguishes it over Austreng's tamper evident tape 18. To the extent that Appellant may be urging us to do so, we are not permitted to read unclaimed features from the Specification into claim 17. *See* Spec. ¶ 63 (indicator 115 may be any suitable color, word, phrase, symbol, or sound among others).

Nor has Appellant apprised us of error in the Examiner’s finding that Austreng’s tamper evident tape 18 includes two portions that align when the bag is closed to indicate that the bag is sealed as claimed. Br. 7–8; *see* Ans. 7–8; *see also* 37 C.F.R. § 41.37(c)(1)(iv) (“The arguments [in the Appeal Brief] shall explain why the examiner erred as to each ground of rejection contested by appellant.”).

Thus, we sustain the rejection of claim 17 and claims 3, 4, and 18, which fall therewith.

Claims 5 and 6

Rejected over Oliverius, Stecklein, Austreng, and Walchle

Appellant does not present arguments for this rejection. *See* Br. 5–8. Thus, we summarily sustain this rejection.

CONCLUSION

Claims Rejected	35 U.S.C. §	Reference/Basis	Affirmed	Reversed
3, 4, 17, 18	103(a)	Oliverius, Stecklein, Austreng	3, 4, 17, 18	
5, 6	103(a)	Oliverius, Stecklein, Austreng, Walchle	5, 6	
Overall Outcome			3–6, 17, 18	

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