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McCarter & English, LLP/LifeCell 265 Franklin Street Boston, MA 02110			CLEVELAND, TIMOTHY C	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PATRICK LEAMY, QING-QING QIU, MICHAEL S. POHLE,
JASON MICHAEL POMERLEAU, and JEROME CONNOR

Appeal 2019-003716
Application 15/185,280
Technology Center 1700

Before BEVERLY A. FRANKLIN, JEFFREY B. ROBERTSON, and
BRIAN D. RANGE, *Administrative Patent Judges*.

RANGE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the
Examiner's decision to reject claims 1–10. We have jurisdiction under
35 U.S.C. § 6(b).

We AFFIRM.

¹ 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 LifeCell
Corporation. Appeal Br. 1.

CLAIMED SUBJECT MATTER²

Appellant describes the invention as relating to a packaging for a medical device where the device is packaged prior to treating the medical device in a supercritical carbon dioxide (SC-CO₂) chamber. Spec. ¶ 7.

Claim 1 is illustrative:

1. A packaging system for a medical device, comprising an outer package, the outer package comprising a first portion and a second portion, wherein the first portion is permeable to supercritical carbon dioxide (SC-CO₂) and a sterilant, and wherein when the second portion is sealed it is impermeable to moisture;

an inner structure configured to hold the second portion open during sterilization, wherein the inner structure is separate from the outer package; and

an inner package that is permeable to SC-CO₂ and a sterilant, wherein the inner package is positioned within the inner structure.

REFERENCES

The Examiner relies upon the prior art below in rejecting the claims on appeal:

<u>Name</u>	<u>Reference</u>	<u>Date</u>
Yan	US 2005/0268573 A1	Dec. 8, 2005
Christensen et al. ("Christensen")	US 7,108,832 B2	Sep. 19, 2006
Mermet et al. ("Mermet")	WO 2009/150488 A1	Dec. 17, 2009

² In this Decision, we refer to the Final Office Action dated February 26, 2018 ("Final Act."), the Appeal Brief filed August 27, 2018 ("Appeal Br.") (with corrected claims appendix filed January 8, 2019), the Examiner's Answer dated February 7, 2019 ("Ans."), and the Reply Brief filed April 8, 2019 ("Reply Br.").

REJECTIONS

The Examiner maintains the following rejections on appeal:

- A. Claims 1–9 under 35 U.S.C. § 103 as obvious over Yan in view of Mermet. Ans. 3.
- B. Claim 10 under 35 U.S.C. § 103 as obvious over Yan in view of Mermet and Christensen. *Id.* at 5.

OPINION

We review the appealed rejections for error based upon the issues identified by Appellant and in light of the arguments and evidence produced thereon. *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential), (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.”). After considering the evidence presented in this Appeal and each of Appellant’s arguments, we are not persuaded that Appellant identifies reversible error. Thus, we affirm the Examiner’s rejections for the reasons expressed in the Final Office Action and the Answer. We add the following primarily for emphasis.

The Appellant does not present any substantively distinct argument for claims other than claim 1. Appeal Br. 14–15. We therefore limit our discussion to claim 1. All other claims stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(iv) (2013).

The Examiner finds that claim 1 is obvious over Yan in view of Mermet. Ans. 3. The Examiner finds that Yan teaches a package containing a medical device during a sterilization process. *Id.* (citing Yan). The Examiner finds that Yan’s package has gas permeable and gas impermeable

portions corresponding to the portions claim 1 recites. *Id.* The Examiner finds that Yan is silent in regard to claim 1's recited inner structure. *Id.* The Examiner finds, however, that Mermet also teaches a sterile packaging for a medical device and that Mermet discloses a rigid part (6) that is capable of maintaining an opening during a sterilization process. *Id.* at 3–4 (citing Mermet). The Examiner determines it would have been obvious to combine the rigid, porous part of Mermet into the package of Yan because doing so, among other things, would “optimiz[e] the exposure of the medical device to the sterilant composition” and “provid[e] another barrier to further protect the device from microbial contamination.” *Id.* at 4.

Appellant argues that a person of skill in the art would not have combined the rigid part of Mermet into the Yan package because Yan requires flattening. Appeal Br. 8; Reply Br. 4. Appellant argues that if someone flattened Yan's package while Mermet's rigid part were in it, the rigid portion would break and leave plastic fragments in the package. Appeal Br. 8; Reply Br. 5. Appellant also argues that failure to flatten Yan prior to sealing it would force air into the container. Reply Br. 4.

The Examiner, however, finds that Yan's flattening is optional. Ans. 5–6. The preponderance of the evidence supports the Examiner's position. Yan indicates that the flattening that Appellant emphasizes is optional by using the word “may.” In particular, Yan states, “the container **may** be flattened.” Yan ¶ 36 (emphasis added). After removing sterilizing gas and optionally flattening the container, Yan's partition line 46 may be flattened and sealed using “heat sealing, adhesive bonding, ultrasonic welding, and the like.” *Id.* After sealing and severing the permeable portion 14 from the impermeable portion 12, the impermeable portion 12 “is then ready for

transportation and storage.” *Id.* While skipping flattening might make Yan’s package more bulky for shipping, Yan does not indicate that there would be a problem with, for example, heat sealing without first flattening the impermeable portion 12. Appellant does not identify evidence to the contrary. Reply Br. 4. “[A]rguments of counsel cannot take the place of evidence lacking in the record.” *Estee Lauder Inc. v. L’Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997) (internal quotes and citation omitted).

Appellant further argues that a person of skill in the art would have no reason to modify Yan because Yan is already an effective sterilization package. Appeal Br. 13. The Examiner, however, finds that inclusion of the rigid part of Mermet can help protect the packaged device from damage and also results in improved sterilization by allowing a homogenous exposure to sterilization fluid. Ans. 6–7. The Examiner’s findings are supported by the preponderance of the evidence. Mermet explains the benefit of its rigid part (container 6) as follows:

The rigidity of container 6 makes it possible to preserve the integrity of the objects 5 during the evacuation operation. . . . This rigidity also has the advantage of granting a fixed shape to the assembly formed by these objects, optimized for a homogenous exposure to the sterilization fluid. . . . The rigid of the container 6 also has the advantages of making it possible to increase the capacity of a packing relative to the maximum capacity which a known flexible packing can have.

Mermet 7:24–8:2. A person of skill in the art would have weighed the advantages of the rigid part that Mermet teaches against any disadvantages (e.g., not being able to fully flatten for compact shipping) and make a choice that best suits the needs of the person’s particular application. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“a

given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine”).

Appellant also argues that claim 1 provides unexpected results for sterilization because Appellant’s Specification shows that sterilization is more effective when the inner structure holds open a portion of the package during sterilization. Appeal Br. 14; Reply Br. 5. Superior results alone, however, are not sufficient to show that the results is unexpected. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007) (“[A]ny superior property must be *unexpected* to be considered as evidence of non-obviousness.” (emphasis in original)). Here, the Examiner correctly determines that Appellant lacks evidence that this result is unexpected. Ans. 7. Indeed, the preponderance of the evidence indicates superior sterilization is not unexpected because Mermet teaches that its rigid part provides the same benefit. Mermet 7:27–29.

Because Appellant’s arguments do not identify error, we sustain the Examiner’s rejections.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–9	103	Yan, Mermet	1–9	
10	103	Yan, Mermet, Christensen	10	
Overall Outcome			1–10	

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TIME PERIOD FOR RESPONSE

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