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GE Healthcare - Grogan, Tuccillo & Vanderleeden LL 1350 Main Street, 5th Floor Springfield, MA 01103			HOBBS, MICHAEL L	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* PARRISH M. GALLIHER, GEOFFREY L. HODGE,  
MICHAEL FISHER, PATRICK GUERTIN, and DAN MARDIROSIAN

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Appeal 2019-006788  
Application 14/743,960  
Technology Center 1700

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Before JEFFREY T. SMITH, GEORGE C. BEST, 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), Appellant<sup>1</sup> appeals from the Examiner's decision to reject claims 1, 2, 7, 10, 13, 17, 18, 20, 22, 23, 25, 26, 32–34, 39–41, 44–46, 49, and 58.<sup>2</sup> We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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<sup>1</sup> 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 GE Healthcare Bio-Sciences Corp. Appeal Br. 2.

<sup>2</sup> The Office Action Summary refers to claim 9 rather than claim 10, but the Examiner rejects claim 10. Final Act. 8. This error is harmless; Appellant is aware that the Examiner rejected claim 10. Appeal Br. 4.

CLAIMED SUBJECT MATTER<sup>3</sup>

Appellant describes the invention as relating to systems for containing and manipulating liquids relating to “cell culture, cell containment, bioreactor, and/or pharmaceutical manufacturing systems.” Spec. 1:10–14. Claim 1 is illustrative:

1. A system, comprising:
  - a first apparatus, comprising:
    - a first collapsible bag adapted for containing a liquid, the first collapsible bag including at least one inlet, at least one outlet, and a base plate that is attached to the collapsible bag and configured to support an impeller;
    - a first reusable support structure adapted for surrounding and supporting the first collapsible bag; and
    - a second apparatus in fluid communication with the first apparatus comprising:
      - a second collapsible bag, at least one inlet and at least one outlet, and operative to separate solids from the liquid;
  - wherein an outlet of the first collapsible bag is in fluid communication with an inlet of the second apparatus, and
  - an outlet of the second apparatus is in fluid communication with an inlet of the first collapsible bag to facilitate recycling of the solids separated from the liquid back to the first collapsible bag.

Appeal Br. 17 (Claims App.).

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<sup>3</sup> In this Decision, we refer to the Final Office Action dated October 29, 2018 (“Final Act.”), the Appeal Brief filed April 11, 2019 (“Appeal Br.”), the Examiner’s Answer dated July 18, 2019 (“Ans.”), and the Reply Brief filed September 18, 2019 (“Reply Br.”).

## REFERENCES

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

<b>Name</b>	<b>Reference</b>	<b>Date</b>
Chang et al. ("Chang")	US 6,596,521 B1	July 22, 2003
Hodge et al. ("the '167 Patent")	US 7,629,167 B2	Dec. 8, 2009
Hodge et al. ("Hodge")	US 2005/0272146 A1	Dec. 8, 2005
Selker et al. ("Selker")	US 2008/0032389 A1	Feb. 7, 2008

## REJECTIONS

The Examiner maintains (Ans. 3) the following rejections on appeal:

- A. Claim 1 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of the '167 Patent in view of Chang and Selker. Final Act. 5.
- B. Claims 1, 2, 7, 10, 13, 17, 18, 20, 22, 23, 25, 26, 32–34, 39–41, 46, 49, and 58 under 35 U.S.C. § 103 as obvious over Hodge in view of Chang and Selker. *Id.* at 8.
- C. Claims 44 and 45 under 35 U.S.C. § 103 as obvious over Hodge in view of Chang. *Id.* at 16.

## 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.

Rejection 1, nonstatutory obviousness-type double patenting.

Appellant responds to this rejection by referring to the arguments Appellant raises with respect to Rejection 2. Appeal Br. 8. Because those arguments are unpersuasive for the reasons we explain below, we sustain this rejection.

Rejection 2, obviousness over Hodge, Chang, and Selker.

The Examiner rejects claims 1, 2, 7, 10, 13, 17, 18, 20, 22, 23, 25, 26, 32–34, 39–41, 46, 49, and 58 under 35 U.S.C. § 103 as obvious over Hodge in view of Chang and Selker. Final Act. 8. Appellant argues all claims as a group. *See* Appeal Br. 9–15. Therefore, consistent with the provisions of 37 C.F.R. § 41.37(c)(1)(iv) (2017), we limit our discussion to claim 1, and all other claims on appeal stand or fall together with claim 1.

The Examiner finds that Hodge teaches a disposable bioreactor system teaching most recitations of claim 1. Final Act. 8–10 (citing Hodge). The Examiner finds that Hodge differs with regards to explicit disclosure of a second apparatus. *Id.* at 9. The Examiner finds that Chang discloses a system for continuous fermentation that uses a fermenter in fluid communication with a cell separator. *Id.* at 10 (citing Chang). The Examiner finds that Chang teaches the second apparatus and recycling aspects of claim

1. *Id.* at 10–11. The Examiner determines that it would have been obvious to modify Hodge to employ Chang’s separator “to separate the culture cells/microorganisms from the culture medium” and states that the suggestion for doing so would be “to separate and recycle the microorganisms and separate out the ferment containing the product.” *Id.* at 11 (citing Chang). The Examiner further determines that modified Hodge does not teach hollow fibers within a bag, and the Examiner relies on Selker as teaching such fibers. *Id.* at 11 (citing Selker). The Examiner provides a rationale why a person of skill in the art would have combined Selker’s teachings with the teachings of Hodge and Chang. *Id.*

Appellant states that it “incorporates herein, its arguments made in the prior responses.” Appeal Br. 10. The applicable rules do not permit such incorporation. 37 C.F.R. § 41.37(c)(1)(iv) (“the brief shall contain . . . [t]he arguments of appellant with respect to each ground of rejection, and the basis therefor”). Below, we address arguments Appellant presents in the Appeal Brief and Reply Brief.

Appellant argues that a person of skill in the art would not have combined the teachings of Hodge and Chang because Hodge “require[s] a high level of sterility that Chang is simply not capable of meeting.” Appeal Br. 11. Appellant relies on the July 23, 2018, Declaration of Dr. Chor Sing Tan (“Tan Decl.”) as providing evidence to support this argument. *Id.* This argument is unpersuasive for two reasons. First, the Tan Declaration is conclusory; it does not explain why a person of skill in the art would not have been able to combine the teachings of Hodge and Chang while maintaining sterility. Tan Decl. ¶ 5. Second and most importantly, the Examiner finds that Hodge does not require sterility for every application.

Ans. 7. The Examiner's finding is supported by a preponderance of the evidence. *See, e.g.*, Hodge ¶¶ 3 (“Such devices may also be used for sterile mixing as well as non-sterile mixing applications.”), 9 (“embodiments of the invention . . . also include advantages in non-sterile applications”).

Appellant argues that the Examiner does not state a specific non-sterile use of Hodge. Reply Br. 7–8. Such a statement is unnecessary; as explained above, Hodge teaches that its apparatus is useful for non-sterile applications. A person of skill in the art would, therefore, understand that sterility is not absolutely necessary to use Hodge's apparatus. Appellant also argues that non-sterile uses go against the Examiner's stated rationale for combining Hodge and Chang. *Id.* We disagree. The Examiner determines that a person of skill in the art would have combined the teachings of Hodge and Chang to separate and recycle microorganisms and ferment containing the product. Final Act. 11. Appellant presents no evidence or persuasive argument to show that sterility is required for all such processes. Meanwhile, Hodge suggests just the opposite. Hodge ¶¶ 3, 9.

Appellant next argues that Chang teaches filtering microorganisms “within the same vessel/fermenter in which the microorganisms are cultivated” and thus teaches away from combining two apparatuses. Appeal Br. 12. The Examiner, however, finds that Chang teaches a separate filter and fermenter. The preponderance of the evidence supports the Examiner's position. *See* Chang Fig. 1 (indicating separate fermenters and cell separators), 5:38–43 (“more than two stages of fermenters can be connected with a cell-recycle multiple-stage continuous ferment[e]r in a serial manner, *each of which is equipped with cell separator to filtrate the ferment.*” (emphasis added)). Although Chang states that “microorganisms are

separated and recycled in the fermenter” (*id.* at 5:17–21), a person of skill in the art would have understood this statement, in the context of Chang as a whole, as using “the fermenter” to refer to a broader apparatus that includes distinct fermenting and separation portions. Moreover, as the Examiner finds, even if Chang taught that its separator and fermenter are combined, Chang also teaches a second vessel for filtering. Ans. 7–8; Chang Fig. 1.

Appellant’s argument is also unpersuasive because Appellant does not establish a teaching away. Appellant does not identify how either reference criticizes, discredits, or otherwise discourages the solution of claim 1. *See, e.g., In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

Appellant next argues that a person of skill in the art would not have combined the teachings of Hodge and Chang because doing so would add complexity and cost while gaining no benefit. *Id.* at 12–13; *see also* Tan Decl. ¶ 6. This argument does not persuasively refute the Examiner’s stated reason why a person of skill in the art would have combined the references’ teachings—“to separate and recycle the microorganisms and separate out the ferment containing the product.” Final Act. 11. To the extent modified Hodge would be more complex or costly, a person of skill in the art would weigh this disadvantage against benefits for a given 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 is patentable due to unexpected commercial success. Appeal Br. 13–14; Reply Br. 8; Tan Decl. ¶¶ 8–9, Ex. 1. Commercial success of a product embodying an invention tends to show nonobviousness when “the commercial success . . . results from the



claimed invention” and is “due to the merits of the claimed invention beyond what was readily available in the prior art.” *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Commercial success can be demonstrated by significant sales of the claimed product in a relevant market. *Id.* However, information solely on numbers of units sold is insufficient to establish commercial success. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 391 (Fed. Cir. 1991). Moreover, evidence of commercial success is only significant if there is a nexus between the claimed invention and the commercial success. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–12 (Fed. Cir. 2006); *see also In re Mageli*, 470 F.2d 1380, 1384 (CCPA 1973) (holding that conclusory statements or opinions that increased sales were due to merits of invention are entitled to little weight).

Here, the evidence presented by Dr. Tan is of limited persuasive value because Dr. Tan provides no information regarding the relevant market. Tan Decl. ¶¶ 8–9. Without accurate and persuasive evidence as to the relevant market, evidence of unit sales carries little probative value. *In re Baxter Travenol Labs.*, 952 F.2d at 391 (“information solely on numbers of units sold is insufficient to establish commercial success”). Although Dr. Tan purports to present sales figures for bags before and after implementation of claim 1, the difference in sales could have been, for example, due to increased demand over time or change in marketing. The evidence presented is not sufficient to establish that the XDR bags have commercial success beyond sales of bags that are not within the scope of claim 1.

Dr. Tan’s declaration is also unpersuasive because it is conclusory. Dr. Tan does not explain how the bags sold are unique to a system

implementing the recitations of claim 1 or why the features of claim 1 contributed to increased sales. Ans. 9–10. Dr. Tan’s declaration does not provide information about the relevant market. *See In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (holding that sales figures without information about the size of market “provides a very weak showing of commercial success, if any”) (emphasis original). Thus, Appellant’s argument regarding evidence of commercial success does not, based on the totality of the evidence before us, outweigh the evidence indicating obviousness or otherwise identify error in the Examiner’s obviousness conclusion. *See Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1070 (Fed. Cir. 2016) (holding that, based on totality of evidence, the evidence of secondary considerations did not “tip the scales of patentability”) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966)).

Appellant also argues that evidence of copying demonstrates non-obviousness of claim 1. Appeal Br. 14–15; *see also* Tan Decl. ¶¶ 10–16 Exs. 2–6. Appellant’s evidence does not establish copying. Rather, the evidence, at most, shows advertising of products with some similarity to claim 1. Appellant does not attempt to establish that the products meet each recitation of claim 1, and Appellant lacks evidence that the products were copied from Appellant. Ans. 10–11.

Because Appellant’s arguments do not persuade us of Examiner error, we sustain the Examiner’s rejection.

### Rejection 3, obviousness over Hodge and Chang.

The Examiner rejects claims 44 and 45 under 35 U.S.C. § 103 as obvious over Hodge in view of Chang. Final Act. 16. Appellant refers to the

arguments we address above. Appeal Br. 15. Because those arguments are unpersuasive, we sustain this rejection.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1		Nonstatutory Double Patenting	1	
1, 2, 7, 10, 13, 17, 18, 20, 22, 23, 25, 26, 32–34, 39–41, 46, 49, 58	103	Hodge, Chang, Selker	1, 2, 7, 10, 13, 17, 18, 20, 22, 23, 25, 26, 32–34, 39–41, 46, 49, 58	
44, 45	103	Hodge, Chang	44, 45	
<b>Overall Outcome</b>			1, 2, 7, 10, 13, 17, 18, 20, 22, 23, 25, 26, 32–34, 39–41, 44–46, 49, 58	

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