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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL GOODEN and RANDALL LECROY

Appeal 2019-005550
Application 14/174,252
Technology Center 1700

Before CATHERINE Q. TIMM, MONTÉ T. SQUIRE, and JEFFREY R. SNAY, *Administrative Patent Judges*.

SQUIRE, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

Appellant[2] appeals under 35 U.S.C. § 134(a) from the Examiner's decision to finally reject claims 1–3, which are all of the claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] This Decision refers to the Specification filed Feb. 6, 2014 ("Spec."); Final Office Action dated May 16, 2018 ("Final Act."); Appeal Brief filed Apr. 16, 2019 ("Appeal Br."); Examiner's Answer dated May 16, 2019 ("Ans."); and Reply Brief filed July 15, 2019 ("Reply Br.").

[2] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Capitol Vial Inc. and Thermo Fisher Scientific Inc. as the real parties in interest. Appeal Br. 5.

CLAIMED SUBJECT MATTER

The invention relates to containers and, more particularly, to an apparatus and method for forming a container having a receptacle and an integral cap. Spec. ¶ 2, Abstract. Claim 1 illustrates the subject matter on appeal and is reproduced below from the Claims Appendix to the Appeal Brief:

> 1. A ***sterile-by-process container having a closed sterile internal cavity defined during manufacture of the container***, the sterile-by-process container comprising:
>
> a receptacle having a body portion defining the sterile internal cavity and a neck portion defining an opening to the internal cavity, the body portion having a first cross-section dimension and the neck portion having a second cross-section dimension that is less than the first cross-section dimension along the entire longitudinal length of the body portion, the neck portion further including an outer surface having at least one thread positioned thereon configured to provide a screw-on connection with a separate device; and
>
> a cap integrally formed with the receptacle and configured to seal the opening to the sterile internal cavity so as to define the closed sterile internal cavity when the cap is initially closed to seal the opening during manufacture of the container.

Appeal Br. 17 (key disputed claim language italicized and bolded).

REFERENCES

The Examiner relies on the following prior art references as evidence in rejecting the claims on appeal:

Name	Reference	Date
Abrams	US 4,783,056	Nov. 8, 1988
Brotz	US 4,974,757	Dec. 4, 1990
Mueller	US 5,008,066	Apr. 16, 1991

Delman et al. ("Delman")	US 2006/0076309 Al	Apr. 13, 2006
Ostrowski ("the '797 Patent")	US 7,472,797 B2	Jan. 6, 2009

REJECTIONS

On appeal, the Examiner maintains (Ans. 3) the following rejections:

1. Claim 1 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Delman in view of Mueller and Abrams ("Rejection 1"). Ans. 7.

2. Claims 2 and 3 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Delman in view of Mueller and Abrams as applied to claim 1 above, and further in view of Brotz ("Rejection 2"). Ans. 8.

3. Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of the '797 Patent in view of Mueller and Abrams ("Rejection 3"). Ans. 4.

4. Claims 2 and 3 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of the '797 Patent in view of Mueller, Abrams, and Brotz ("Rejection 4"). Ans. 5.

OPINION

Having considered the respective positions the Examiner and Appellant advance in light of this appeal record, we affirm the Examiner's rejections based essentially on the fact-finding and reasoning the Examiner provides in the Answer and Final Office Action, which we adopt as our own. We add the following primarily for emphasis.

Rejection 1

The Examiner determines that the combination of Delman, Mueller, and Abrams suggests a container satisfying the limitations of claim 1 and concludes the combination would have rendered the claim obvious. Ans. 7–8 (relying on Delman, Figs. 1–5, ¶¶ 2–5, 15–18; Mueller, Fig. 1; Abrams, Fig. 5, 1:12–22, 1:36–46).

Appellant argues the Examiner's rejection of claim 1 should be reversed because Mueller teaches away from a "sterile-by-process container having a closed sterile internal cavity defined during manufacture of the container," as recited in the claim. Appeal Br. 13; Reply Br. 5 (arguing "Mueller is not a proper reference . . . because it teaches away from the invention"). Appellant contends that, in contrast to the claimed invention, Mueller teaches forming a preform by injection molding and then transferring the preform to a conventional blow molding apparatus with the closure cover (closure cover 20) kept in the open position. Appeal Br. 13 (citing Mueller, Figs. 1, 5, 7, 8, 5:17–67); *see also id.* at 14 ("Mueller not only does not contemplate producing a sterile-by-process container, it expressly teaches away from it.").

Appellant further argues Mueller is completely silent with respect to a "sterile-by-process container having a closed sterile internal cavity defined during manufacture of the container," as recited in the preamble of claim 1, and that Mueller does not describe how the container is sterilized before it reaches the filling mechanism to be filled. *Id.* at 13.

Appellant also argues the Examiner's rejection should be reversed because a person of ordinary skill in the art would not have been motivated to combine Delman with Mueller and Abrams to arrive at the claimed

invention as recited in claim 1. *Id.* at 15. In particular, Appellant contends "the Examiner fails to provide a sound rationale for modifying Delman with the disclosure of Mueller." *Id.* at 14; *see also* Reply Br. 7 (arguing "the Examiner has not provided a sufficient rationale to combine the references"). Rather, Appellant argues the Examiner's proposed combination of Delman with Mueller and Abrams is improper because

> such a combination would fail to achieve Appellants claimed sterile-by-process container having a closed sterile internal cavity that is defined when the cap is initially closed to seal the opening to the internal cavity during manufacture of the container, in combination with the particular shape as claimed.

Appeal Br. 15.

We do not find Appellant's arguments persuasive of reversible error in the Examiner's rejection in view of the fact-finding and reasons the Examiner provides at pages 7–13 of the Answer and pages 5–7 of the Final Office Action, which a preponderance of the evidence supports. As the Examiner finds (Ans. 7), Delman discloses a breast milk container having upper opening 13, shoulder/lip 15, circumferential threaded outer arrangement 17, body portion 7, and integral cap 9, which snaps onto the upper opening when closed. Delman, Figs. 1–3, ¶¶ 15, 17. As the Examiner further finds (Ans. 7), Delman teaches that the container can be any suitable structure sufficient to receive and retain breastmilk and there is a need to seal the container for easy closure and to keep sterile the interior of the container upon closing the container with the cap. Delman ¶ 3 (disclosing "[c]ontamination of breastmilk can present health hazards to an infant" and "to prevent contamination, breastmilk should be stored only in clean containers . . . and immediately sealed and stored if the breastmilk is to be

fed to an infant"), ¶ 4 (cautioning that "[g]iven the health implications for an infant, the cleanliness and sterilization are of significant concern"), ¶ 5 (disclosing "there is a need for a closure assembly that can be formed with . . . the container mouth in a non-screw-on fashion for easy closure").

As the Examiner further finds (Ans. 8), Mueller discloses a container (container 10) having an integral cap (cover 20) and a main hollow section (receptacle 12) that is larger in cross-section than the container's neck portion (neck 14) along the entire longitudinal length of the main hollow section. Mueller, Fig. 1, 3:30–35 (disclosing "container **10** includes a main hollow portion or receptacle **12** having reduced cross-sectional dimensions at neck **12**").

As the Examiner also finds (Ans. 8), regarding the "sterile-by-process-container" recitation of claim 1, Abrams discloses a container (vial 12) having an integral cap (cap 14) and describes a process for making wherein the cap and vial are sealed closed within the mold to maintain the sterility of the interior of the vial prior to use. Abrams, Fig. 5, 1:7–11 (describing "a process for making the vial in the mold . . . wherein the vial is sealed closed within the mold"), 1:17–21 (disclosing "[i]t is important to maintain the sterility of the interior of the vial prior to use" and "in order to maintain the sterility . . . the cap must be closed onto the vial while the vial is in an aseptic environment"), 1:36–41 (disclosing "the heat of the molding process could be utilized to maintain sterility during closing"), 3:67–4:8. In describing the process, Abrams explains that

> [b]ecause the interior of the vial **12** is preferably maintained in a sterile condition, the mold **10** is adapted to seat the cap **14** onto the vial **12** in a sealing manner while the vial **12** is still in the mold **10**.

Id. at 4:5–8.

The Examiner also provides a reasonable basis to evince why one of ordinary skill in the art would have had reason to combine the teachings of the cited art to arrive at the claimed invention. *See* Ans. 5 (explaining it would have been obvious to one of ordinary skill in the art to modify Delman's container to have a main hollow section (body portion) with a cross-section larger than the container's neck portion, as taught by Mueller, for the purpose of increasing the volume capacity of the container); *see also id.* at 5 (explaining it would have also been obvious to one of ordinary skill in the art to modify Delman's container by sealing the container within the mold, as taught by Abrams, to maintain the sterility of the inside of the container and avoid a separate sterilizing step); *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007) (explaining that any need or problem known in the art can provide a reason for combining the elements in the manner claimed).

Appellant's arguments do not reveal reversible error in the Examiner's factual findings, analysis, and conclusions in this regard. Appellant's contention that Mueller teaches away from the "sterile-by-process container" limitation of the claim (Appeal Br. 13–14) is not persuasive of reversible error in the Examiner's rejection because Appellant does not identify evidence sufficient to support it, and we will not read into the references a teaching away where no such language exists. *Cf. DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1364 (Fed. Cir. 2006). Appellant's contention that "Mueller is completely silent with respect to a sterile-by-process container" (Appeal Br. 13) is equally unpersuasive because "silence does not imply teaching away." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 964 (Fed. Cir. 2014).

Rather, as the Examiner finds and explains at pages 10–12 of the Answer, the fact that Mueller describes, as an embodiment, a process where an injection molded preform is transferred from a first injection mold to a second blow mold (Mueller, Fig. 8, 5:17–25, 5:29–31), without more, does not teach away from, discredit, criticize, or discourage a "sterile-by-process container having a closed sterile internal cavity," as recited in claim 1, which is a product claim. *In re Fulton*, 391 F.3d 1195, 1201 (finding that there is no teaching away where the prior art's disclosure "does not criticize, discredit, or otherwise discourage the solution claimed").

Mueller's disclosure in this regard also does not negate or take away from Mueller's broad disclosure regarding a container having a main hollow receptacle with reduced cross-sectional dimensions at the neck portion (Mueller, Fig. 1, 3:30–35), which the Examiner relies upon in the rejection. *See In re Susi*, 440 F.2d 442, 445–46 (CCPA 1971) (explaining that disclosure of particular preferred embodiments does not teach away from a prior art reference's broader disclosure); *see also In re Applied Materials, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012) ("A reference must be considered for everything that it teaches, not simply the described invention or a preferred embodiment.").

Appellant's arguments in this regard are also misplaced because, as the Examiner explains (Ans. 11–12), the "sterile-by-process" recitation of claim 1 is a product-by-process type limitation, and Appellant has not established, either by persuasive technical reasoning or evidence, that the claimed product is patentably distinct from the product of the prior art. "The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a

product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citations omitted); *see also In re Pilkington*, 411 F.2d 1345, 1348 (CCPA 1969) ("[The] patentability of a claim to a product does not rest merely on a difference in the method by which that product is made. Rather, it is the product itself which must be new and unobvious."). Indeed, as the Examiner finds (Ans. 11), Appellant does not provide or direct us to any persuasive evidence in the record that the container of claim 1 has any unexpected properties or is otherwise not the same as or obvious from the container of the prior art. *Thorpe*, 777 F.2d at 697.

Appellant's contentions that the Examiner "fails to provide a sound rationale for modifying Delman with the disclosure of Mueller" (Appeal Br. 14) and "has not provided a sufficient rationale to combine the references" (Reply Br. 7) are not persuasive because, as we previously discuss above, the Examiner does provide articulated reasoning with rational underpinning sufficient to explain why one of ordinary skill in the art would have had reason to combine the teachings of Delman, Mueller, and Abrams to arrive at the claimed invention. *See* Ans. 5, 12–13. Appellant's disagreement as to the Examiner's factual findings and reasons for combining the references, without more, is insufficient to establish reversible error. *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) ("[M]ere statements of disagreement . . . as to the existence of factual disputes do not amount to a developed argument.").

Accordingly, we affirm the Examiner's rejection of claim 1 under pre-AIA 35 U.S.C. § 103(a) as obvious over Delman, Mueller, and Abrams.

Rejection 2

The Examiner rejects claims 2 and 3 under § 103 as obvious over the combination of Delman, Mueller, Abrams, and Brotz. Ans. 8–9. In response to the Examiner's rejection, Appellant does not present any additional substantive arguments. Rather, Appellant relies on the same arguments Appellant presents above in response to the Examiner's rejection of claim 1. *See* Appeal Br. 10.

Thus, based on the fact-finding and reasoning the Examiner provides in the record, and for principally the same reasons we discuss above for affirming the Examiner's rejection of claim 1 (Rejection 1), we affirm the Examiner's rejection of claims 2 and 3 under pre-AIA 35 U.S.C. § 103(a) as obvious over Delman, Mueller, Abrams, and Brotz (Rejection 2).

Rejections 3 and 4

The Examiner rejects claim 1 (Rejection 3) and claims 2 and 3 (Rejection 4) on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of the '797 Patent in view of Mueller and Abrams. Ans. 4–6.

In response, Appellant argues the Examiner's rejections should be reversed because the '797 Patent is "silent with respect to a sterile-by-process container having the particular shape as recited in Claim 1" (Appeal Br. 15) and "Mueller teaches away from the claimed invention" (*id.* at 16). We do not find these arguments persuasive of reversible error in the Examiner's rejections because they are conclusory and unsupported by persuasive evidence in the record. Attorney argument is not evidence. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984); *see also In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (explaining that mere lawyer's arguments

or conclusory statements, which are unsupported by concrete factual evidence, are entitled to little probative value).

Also, because Appellant's arguments in this regard are analogous to and/or rely on essentially the same arguments Appellant presents above in response to the Examiner's obviousness rejection of claim 1 (Rejection 1), we do not find them persuasive of reversible error in the Examiner's nonstatutory double patenting rejections (Rejections 3 and 4) in view of the fact-finding and reasoning the Examiner provides in the record, and for essentially the same reasons we discuss above for affirming the Examiner's Rejection 1.

Accordingly, we affirm the Examiner's rejections of claim 1 (Rejection 3) and claims 2 and 3 (Rejection 4) on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of the '797 Patent in view of Mueller and Abrams.

CONCLUSION

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1	103(a)	Delman, Mueller, Abrams	1	
2, 3	103(a)	Delman, Mueller, Abrams, Brotz	2, 3	
1		Nonstatutory double patenting	1	
2, 3		Nonstatutory double patenting	2, 3	
Overall Outcome			**1–3**	

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