UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/498,617	03/28/2012	Helen Mary Trill	PB63742US	1248

23347 7590 11/15/2018

GLAXOSMITHKLINE
Global Patents UP4110
1250 South Collegeville Road
Collegeville, PA 19426

EXAMINER
LOUIS, LATOYA M

ART UNIT	PAPER NUMBER
3785	

NOTIFICATION DATE	DELIVERY MODE
11/15/2018	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

laura.m.mccullen@gsk.com
US_cipkop@gsk.com
eofficeaction@appcoll.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HELEN MARY TRILL and WILLIAM FREDRICK

Appeal 2018-001633
Application 13/498,617
Technology Center 3700

Before PHILIP J. HOFFMANN, KENNETH G. SCHOPFER, and BRADLEY B. BAYAT, *Administrative Patent Judges*.

HOFFMANN, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellants[1] appeal from the Examiner's rejection of claims 25–28, 34–39, 41–47, 50, 53, and 56–61. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

According to Appellants, the invention "relates to a pressuri[z]ed metered dose inhaler (pMDI) and, in particular, componentry therefor."

---

[1] According to Appellants, the real party in interest is "Glaxo Group Limited d/b/a GlaxoSmithKline." Appeal Br. 4.

Spec. 1. Claims 25–27 are the independent claims on appeal. Below, we reproduce claim 25 as illustrative of the appealed claims.

> 25. A pressurized metered dose inhaler (pMDI) metering valve comprising at least one component which comprises a desiccant-entrained material which is a mixture comprising a base polymer, a desiccant and a channeling agent that facilitates transmission of water into the material, wherein the channeling agent comprises polyethylene glycol with an average molecular weight which is at least 16000 daltons.

REJECTIONS AND PRIOR ART

The Examiner rejects the claims as follows:

I. claims 25–28, 34–37, 39, 41, 43, 45, 46, 50, 53, 56–59, and 61 under 35 U.S.C. § 103(a) as unpatentable over Cripps et al. (US 2003/0180228 A1, pub. Sept. 25, 2003) ("Cripps), Hekal (US 6,214,255 B1, iss. Apr. 10, 2001), and Rowe et al. (US 6,939,557 B2, iss. Sept. 6, 2005) ("Rowe");

II. claims 38 and 42 under 35 U.S.C. § 103(a) as unpatentable over Cripps, Hekal, Rowe, and Kay (US 8,353,706 B2, iss. Jan. 15, 2013); and

III. claims 44, 47, and 60 under 35 U.S.C. § 103(a) as unpatentable over Cripps, Hekal, Rowe, and Millar (US 7,566,445 B1, iss. July 28, 2009).

ANALYSIS

Rejection I

Based on our review of the record, including the Examiner's Final Office Action and Answer, and Appellants' Appeal Brief and Reply Brief,

Appellants do not persuade us that the Examiner errs in rejecting claims 25–28, 34–37, 39, 41, 43, 45, 46, 50, 53, 56–59, and 61 as obvious based on Cripps, Hekal, and Rowe. Thus, we sustain the rejection.

> Appellants argue that the rejection is in error because
>
> there is no clear articulated reason to support an obviousness rejection. All that the Office has done in citing Cripps is to allegedly draw attention to a pMDI system that may utilize a component made from a desiccant entrained material which is a mixture of a desiccant and a channeling agent of PEG. No reason or rationale has been set forth as to why one would even want to modify Cripps. . . . Closely examining Hekal clearly indicates that it is directed to desiccant entrained polymers including means by which desiccant located within interior portions of the polymer structure are exposed to moisture that is exterior to the polymer body. . . . Nothing would suggest using [Hekal's] materials in [Cripps's] pMDI as claimed.

Appeal Br. 8.

In the obviousness rejection (Final Action 3), the Examiner cites Cripps's paragraph 69, which discloses "[t]he moisture absorbing means will generally comprise a desiccant material" (Cripps ¶ 69). In addition, the Examiner cites (Final Action 6) paragraph 87 of Cripps, which discloses "[i]n conjunction with the desiccant[,] an additional compound may be added to act as a conduit/channeling agent to increase/optimi[z]e the efficiency of the moisture absorption. Such materials may include compounds such as polyethylene glycols" (Cripps ¶ 87). Although the Examiner finds that Hekal, rather than Cripps, discloses the claimed desiccant-entrained material (Final Action 3), the Examiner determines that "[i]t would have been obvious . . . to manufacture the desiccant entrained material of Cripps to include the desiccant, channeling agent, and base

polymer as a mixture as taught by Hekal to provide enhanced moisture absorption and moisture reduced environments" (*id.*; *see* Answer 3, 9).

We are not persuaded of error because the Examiner's reason for replacing Hekal's material with Cripps's material is supported adequately by Hekal. For example, Hekal discloses that the material provides advantages "such as rigidity and durability," and "normally acts as a moisture barrier in a solidified state . . . so that the channeling agent forms passages in the mixture through which moisture is communicable to [a] desiccating agent that is entrained within the mixture." Hekal, Abstract. Hekal further discloses that "[t]he desiccant[-]entrained polymer of the present invention is particularly useful in the manufacture of containers and packaging for items requiring moisture reduced environments." Hekal col. 1, ll. 19–22. By way of additional example, Hekal discloses that "it is a well[-]known practice to include a desiccating unit together with . . . medication in the container." *See* Hekal col. 1, ll. 39–46; *see also* Hekal col. 5, ll. 25–31 ("The present invention[] has been developed in response to a recognized need for structures constructed from polymers that normally act as moisture barriers in their solid, rigid state, but when produced according to the present invention have a desiccant entrained therein which is capable of absorbing moisture exterior to the polymer."). Thus, based on the foregoing, we

disagree with Appellants that "[n]othing would suggest using [Hekal's] materials in [Cripps's] pMDI as claimed."[2] Appeal Br. 8.

Appellants argue that the Examiner errs because "Rowe teaches away from the" Examiner's proposed combination of Rowe with Hekal and Cripps. Appeal Br. 11; *see also id.* at 9–11. More specifically, according to Appellants,

> the [Examiner] has not taken into account all of Rowe's teachings when combining it with the other references. Rowe is directed to biodegradable compositions for sustained-release drug delivery[,] and methods for administering a biologically active substance ("BAS") via these compositions . . . . Such BASs are acknowledged by Rowe to be difficult to formulate in biodegradable polymers to allow a desired release into the patient's system. In furtherance of this end, Rowe teaches a biocompatible therapeutic article for delivery of a BAS, in which the article comprises a macromer, a molecule[,] or [a] mixture of molecules which preferentially excludes proteins and the BAS. The macromer[] comprises a region forming a central core, and least two decradable regions attached to the core and at least two polymerizable end groups . . . . The region forming a central core is taught to be a water soluble region that may include poly(ethylene glycol) . . . . Accordingly, one skilled in the art would understand that the PEG is to dissolve over time. However, this is the complete antithesis of the requirements of the claimed invention, where leaching of PEG into the inhalable drug formulation is to be strictly avoided, due to the impact it would have on dose consistency, termed "FPM" in [Appellants'] [S]pecification.

---

[2] We note that the Summary of the Invention section of Appellants' Specification indicates that their desiccant-entrained material may be the "material . . . disclosed in" U.S. Patent no. 5,911,937 ("the '937 patent"), issued June 15, 1999, to Hekal et al., which is "incorporated [t]herein by reference." Spec. 6. Each of the '937 patent and Hekal is a continuation-in-part of U.S. Application no. 08/424,996, filed April 19, 1995.

Appeal Br. 9–10 (citations omitted). We disagree with Appellants, however.

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006) (citations and internal quotation marks omitted). *See also In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (noting that merely disclosing more than one alternative does not teach away from any of these alternatives if the disclosure does not criticize, discredit, or otherwise discourage the alternatives). In this case, Appellants' argument does not persuade us that one of ordinary skill, when reading the references, would be discouraged from combining the references as the Examiner proposes. For example, Appellants do not present any evidence tending to establish that "leaching of PEG into the inhalable drug formulation" would occur to the extent that "it would [impact] dose consistency," as Appellants argue. Appeal Br. 10.

Appellants argue that the Examiner errs because it is only based on impermissible hindsight that the Examiner combines Rowe with Hekal and Cripps. *See id.* at 10–11. We disagree with Appellants. Instead, despite differences among the references, we agree with the Examiner that "[o]ne of ordinary skill . . . upon seeing the PEG of Cripps would recognize that the molecular weight of greater than 16,000 Daltons as taught by Rowe would provide the advantage of adequate channeling effect. Thus[,] Rowe is relevant." Answer 10. Appellants' remarks are insufficient to persuade us otherwise.

Therefore, based on the foregoing, we sustain the Examiner's obviousness rejection of claims 25–28, 34–37, 39, 41, 43, 45, 46, 50, 53, 56–59, and 61.

Rejections II and III

Appellants do not argue against the Examiner's obviousness rejections of dependent claims 38, 42, 44, 47, and 60. Thus, inasmuch as we sustain the rejection of the independent claims from which claims 38, 42, 44, 47, and 60 depend, we also sustain the dependent claims' rejections.

DECISION

We AFFIRM the Examiner's obviousness rejections of claims 25–28, 34–39, 41–47, 50, 53, and 56–61.

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