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Paper 58
Entered: May 29. 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and MYLAN PHARMACEUTICALS INC.,
Petitioners,

v.

ALMIRALL, LLC,
Patent Owner.

IPR2019-00207[1]
Patent 9,517,219 B2

Before SUSAN L. C. MITCHELL, CHRISTOPHER G. PAULRAJ, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

[1] Mylan Pharmaceuticals Inc., the petitioner in IPR2019-01095, has been joined in this proceeding. When referring herein to "this case" or "this proceeding" or "this *Inter Partes* Review," or variants of these, we refer to both IPR2019-00207 and IPR2019-01095.

I. INTRODUCTION

Almirall, LLC ("Patent Owner") is the owner of U.S. Patent 9,517,219 B2 (Ex. 1001, "the '219 patent"). Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal" or "Petitioner") filed a Petition requesting *inter partes* review of claims 1–8 of the '219 patent. Paper 3 ("Pet."). We instituted trial in this matter on May 10, 2019. Paper 13 ("Institution Decision"). On November 27, 2019, IPR2019-01095 was instituted between Mylan Pharmaceuticals Inc. ("Mylan") and Almirall, LLC over the '219 patent and Mylan joined this proceeding. Paper 35 ("me-too" joinder). Unless otherwise stated, we include Mylan when referring to Petitioner herein.

Following institution and joinder, Patent Owner filed a Response. Paper 20 ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response and Patent Owner filed a Sur-Reply to Petitioner's Reply. Paper 28 ("Pet. Reply"); Paper 37 ("PO Sur-Reply"). A hearing was conducted on February 7, 2020, where the parties presented oral argument. Paper 55 ("Hr'g Tr.").

We have jurisdiction under 35 U.S.C. § 6. After considering the parties' arguments and supporting evidence, we conclude that Petitioner has proven by a preponderance of the evidence that claims 1–8 of the '219 patent are unpatentable. 35 U.S.C. § 316(e) (2012).

Petitioner and Patent Owner each separately filed Motions to Exclude regarding certain evidence of record. Paper 41 ("Pet. Mot. Exclude"); Paper 43 ("PO Mot. Exclude"). We deny Patent Owner's motion and deny-in-part and dismiss-in-part Petitioner's motion.

II. BACKGROUND

A. REAL PARTIES-IN-INTEREST

Amneal identifies the real parties-in-interest to be "Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals of New York, LLC." Pet. 64. Patent Owner identifies the real party-in-interest to be "Almirall, LLC ('Almirall')" and states that "Almirall is a wholly-owned subsidiary of Almirall, S.A." Paper 5. Mylan identifies the real parties-in-interest to be "Mylan Pharmaceuticals Inc., DPT Laboratories, Ltd., Mylan Inc., and Mylan N.V.," which "are subsidiaries of Mylan N.V." *Mylan Pharma. Inc. v. Almirall, LLC*, IPR2019-01095, Paper 1, 68 (PTAB June 7, 2019).

B. RELATED MATTERS

Petitioner has disclosed:

> The following matters would affect, or be affected by, a decision in this proceeding: (1) IPR2018-00608, challenging claims of the related [U.S. Patent 9,161,926 ("the '926 patent")], which are directed to the same topical dapsone compositions as the '219 patent; and (2) *Almirall, LLC v. Taro Pharmaceutical Industries Ltd.*, C.A[.] 1-17-cv-00663 (consolidated) (D.Del.) . . . . Petitioners are not a party [to the district court case].

Pet. 64–65. In IPR2018-00608, the Board determined that the challenged claims of the '926 patent were not shown to be unpatentable. IPR2018-00608, Paper 50. Patent Owner identifies the same related matters. *See* Paper 5. In its petition, Mylan identifies these same related matters and added IPR2019-00207, the current proceeding, which it sought to join. *Mylan Pharma. Inc. v Almirall, LLC*, IPR2019-01095, Paper 1 at 68 (PTAB June 7, 2019).

C. THE '219 PATENT

The '219 patent issued December 13, 2016, from US Application 14/855,805, which was filed October 16, 2015. Ex. 1001, codes (45), (21), (22). This application is identified as a divisional of US Application 14/082,955, filed November 18, 2013 (now US 9,161,926 B2). *Id.* at code (62). The '219 patent further asserts priority to provisional 61/728,403 filed November 20, 2012, and provisional 61/770,768 filed February 28, 2013. *Id.* at code (60). The parties each rely upon and do not dispute that the earliest priority date, November 20, 2012, is the applicable date for analyzing the patentability issues in this proceeding. *See, e.g.*, Pet. 6, 7; PO Resp. 2, 3.

The '219 patent has eight claims, all of which are challenged and of which claims 1 and 6 are independent claims. Independent claim 1 is illustrative and is reproduced below:

> 1. A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer; and
>
> water;
>
> wherein the topical pharmaceutical composition does not comprise adapalene.

Id. at 15:40–16:13. Claim 6 is very similar to claim 1. The only difference between claims 1 and 6 is that claim 6 more specifically claims "about 30% w/w diethylene glycol monoethyl ether" ("DGME")[2] and "about 4% w/w of the viscosity building acrylamide/sodium acryloyldimethyl taurate copolymer" (also identified by the commercial product name Sepineo and referred to in this proceeding as "A/SA"—*see* Hr'g Tr. 37:1–5). *Id.* at 16:23–36. Claims 2–5 each depends directly from claim 1, and claims 7 and 8 each depends directly from claim 6. Ex. 1001, 16:14–22, 16:37–40.[3]

> The '219 patent's abstract states:
>
> Dapsone and dapsone/adapalene compositions can be useful for treating a variety of dermatological conditions. The compositions of this disclosure include dapsone and/or adapalene in a polymeric viscosity builder. Subject compositions can be adjusted to optimize the dermal delivery profile of dapsone to effectively treat dermatological conditions and improve the efficiency of pharmaceutical products applied to the skin. Use of the polymeric viscosity builder provides compositions with increased concentrations of diethylene glycol monoethyl ether relative to compositions without the polymeric viscosity builder.

Id. at Abstract. The Specification of the '219 patent further states:

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[2] DGME is also called ethoxydiglycol and is known by the commercial product name Transcutol. *See* Pet. 1; Ex. 1040, 17:23–21:20 (Dr. Osborne's (Patent Owner's expert) deposition testimony discussing his published patent application (Ex. 1007) and confirming that in 2006, a formulation of 7.5% dapsone and 30% Transcutol/DGME was created).

[3] The claims that were considered in IPR2018-00608 recited a similar composition to that included as part of the method of treatment claims of the '219 patent, except that claim 1 of the '926 patent recited about 2% w/w to about 6% w/w of a polymeric viscosity builder "consisting of" (instead of "comprising") acrylamide/sodium acryloyldimethyl taurate copolymer. *See* IPR2018-00608, Paper 50, 4–5.

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