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Paper No. 13
Filed: May 10, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC
Petitioners,

v.

ALMIRALL, LLC,
Patent Owner.

Case IPR2019-00207
Patent 9,517,219 B2

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

FLAX, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

Almirall, LLC ("Patent Owner") is the owner of U.S. Patent No. 9,517,219 B2 (Ex. 1001, "the '219 patent"). Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals of New York, LLC (collectively, "Petitioners") filed a Petition requesting *inter partes* review of claims 1–8 of the '219 patent. Paper 3 ("Pet."). Patent Owner, in turn, filed a Preliminary Response. Paper 8 ("Prelim. Resp."). Further, pursuant to our authorization, Petitioners and Patent Owner filed a Reply and a Sur-reply, respectively. Papers 10, 11.

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under Section 311, and any response filed under Section 313, shows that there is a reasonable likelihood that the Petitioners would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314. After reviewing the parties' submissions, we conclude that Petitioners have demonstrated a reasonable likelihood that they would prevail in showing at least one claim of the '219 patent is unpatentable. Therefore, we institute *inter partes* review of all aforementioned claims on all grounds raised in the petition, pursuant to 35 U.S.C. § 314; *see also* Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/trials/guidance-impact-sas-aia-trial).

I. BACKGROUND

A. *RELATED MATTERS*

Petitioners have 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], 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.), to which[, the district court case,] Petitioners are not a party.

Pet. 64–65. Patent Owner identifies the same related matters. *See* Patent Owner's Mandatory Notices (filed Jan. 10, 2019) (Paper 5).

B. *THE CLAIMED INVENTION*

The invention claimed in the '219 patent relates to a method for treating at least one of acne vulgaris or rosacea by administering a compound including dapsone, diethylene glycol (also called ethoxydiglycol, diethylene glycol monoethyl ether, and DGME), acrylamide/sodium acryloyldimethyl taurate copolymer (also identified by the commercial product name Sepineo P 600), and water, but not including adapalene. Ex. 1001, 15:40–16:13. 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:

> Dapsone, (4,4′-diaminodiphenyl sulfone) is a medicament possessing several beneficial medicinal activities. Dapsone is typically administered as one of the medicinal agents used in the treatment of leprosy. Dapsone and its derivatives are also effective for treatment of bacterial infections, protozoal infections such as malaria, *pneumocystis carinii*, and plasmonic infections such as toxoplasmosis.
>
> Dapsone is also useful as an anti-inflammatory agent. It has been used to treat skin diseases characterized by the abnormal infiltration of neutrophils, such as Dermatitis herpetic-formis, linear IgA dermatosis, pustular psoriasis, pyoderma gangrenosum, acne vulgaris, and Sweet's Syndrome.

Id. at 2:12–24.

Regarding the additional claimed components used in the claimed acne/rosacea-treating method, the '219 patent states, "[d]iethylene glycol monoethyl ether is a solubilizer for dapsone, thereby allowing compositions to be prepared with increased solubilized concentrations of dapsone." *Id.* at 2:48–50. The '219 patent further states:

> use of a polymeric viscosity builder minimizes the intensity of yellowing of the composition caused by the increased solubility of dapsone in diethylene glycol monoethyl ether. In addition, the polymeric viscosity builder influences dapsone crystallization. This, in turn, results in compositions with improved aesthetics (i.e., reduction in particle size which minimizes "gritty" feeling upon application).

Id. at 2:54–61. Regarding this polymeric viscosity builder, the '219 patent further states, "[i]n some embodiments, the polymeric viscosity builder is an acrylamide/sodium acryloyldimethyltaurate copolymer, and further includes isohexadecane, sorbitan oleate, water, and Polysorbate 80." *Id.* at 5:47–50. The '219 patent describes 62 different "embodiments" where various amounts of these, and other, components are provided for an acne/rosacea-

treating composition. *Id.* at 6:58–12:40. The '219 patent also describes eight different "examples" of formulations including these, and other, components. *Id.* at 12:42–15:33.

The '219 patent has eight claims, of which claims 1 and 6 are independent claims. Independent claims 1 and 6 are illustrative and 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.
>
> **6.** 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 diethylene glycol monoethyl ether;
>
> about 4% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer; and
>
> water;

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