### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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### BEFORE THE PATENT TRIAL AND APPEAL BOARD

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# MYLAN PHARMACEUTICALS INC., Petitioner,

v.

# ALMIRALL, LLC., Patent Owner.

U.S. Patent No. 9,517,219 to Warner *et al*.

Issue Date: December 13, 2016

Title: Topical dapsone and dapsone/adapalene compositions and methods for use thereof

Inter Partes Review No.: IPR2019-01095

PETITIONER'S MOTION FOR JOINDER

UNDER 37 C.F.R. §§ 42.22 AND 42.122(b)

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### I. STATEMENT OF RELIEF REQUESTED

Petitioner Mylan Pharmaceuticals Inc. (hereinafter "Mylan" or "Petitioner") respectfully requests joinder of the concurrently filed petition for *inter partes* review of U.S. Patent No. 9,517,219 ("the '219 patent") (IPR2019-01095) with *Amneal Pharmaceuticals LLC et al v. Almirall, LLC et al.*, IPR2019-00207, filed November 6, 2018 and instituted May 10, 2019 (hereinafter, "the Amneal IPR"). *See* IPR2019-00207, Paper 13. The instant Petition is the same as the Amneal IPR: it involves the same patent, same claims, same grounds of unpatentability, and the same evidence (including the same prior art combinations) as the Amneal IPR. If joined, as discussed further below, Mylan will assume a "silent understudy" role and will not take an active role in the *inter partes* review proceeding unless the Amneal Petitioner ceases to participate in the instituted IPR.

While the instant Petition includes the declarations of Dr. Serota and Dr. Stinchcomb ("Mylan Declarants"), these declarations present identical expert testimony to that put forth by Dr. Gilmore and Dr. Michniak-Kohn ("Amneal Declarants") in the Amneal IPR. If Amneal allows Mylan to use the Amneal Declarants, then Mylan will withdraw the Mylan Declarants, and rely only the Amneal Declarants. The PTAB has acknowledged that such concessions are sufficient to minimize the impact on the original proceeding. *SAP America Inc. v. Clouding IP, LLC*, IPR2014-00306, Paper 13 at 4 (May 19, 2014). Thus, the



proposed joinder will neither unduly complicate the Amneal IPR nor delay its schedule. As such, the joinder will promote judicial efficiency in determining the patentability of the Amneal IPR without prejudice to Patent Owner.

Although Mylan is not otherwise time barred pursuant to 37 C.F.R. § 42.101(b), this Motion for Joinder, and accompanying Petition, are timely because it is filed less than one month after a decision instituting trial in the Amneal IPR. 37 C.F.R. § 42.122(b) ("no later than one month after the institution date of any *inter partes* review for which joinder is requested."). Accordingly, Mylan respectfully requests that the Board grant this Motion for Joinder.

### II. STATEMENT OF REASONS FOR RELIEF REQUESTED

### A. Legal Standards

The Leahy-Smith America Invents Act (AIA) permits joinder of *inter partes* review (IPR) proceedings. Joinder is governed by 35 U.S.C. § 315(c), which states:

(c) JOINDER. – If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.



A motion for joinder should "(1) set forth the reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified." *Dell Inc. v. Network-1 Sec. Solutions, Inc.*, IPR2013-00385, Paper 17 (PTAB July 29, 2013); *Hyundai Motor Co. v. Am. Vehicular Sciences LLC*, IPR2014-01543, Paper No. 11 at 3 (Oct. 24, 2014); *Macronix Int'l Co. v. Spansion*, IPR2014-00898, Paper 15 at 4 (Aug. 13, 2014) (quoting *Kyocera Corporation v. Softview LLC*, IPR2013-00004, Paper 15 at 4 (April 24, 2013)).

## **B.** Mylan's Motion is Timely

A Motion for Joinder is timely if the moving party files within one month of institution of the *inter partes* review for which joinder is requested. 37 C.F.R. § 42.122(b). Because Mylan files this motion less than one month after a decision on the institution of the Amneal IPR, this motion is timely.

## **C.** Joinder is Appropriate

Joinder is appropriate because Mylan's Petition does not raise any new grounds of unpatentability and does "not present issues that might complicate or delay" the Amneal IPR. *See Enzymotec Ltd. v. Neptune Techs & Bioresources, Inc.*, IPR2014-00556, Paper 19 (PTAB July 9, 2014). Mylan's Petition is identical to the petition in the Amneal IPR, challenging the same claims of the '219 patent



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