Trials@uspto.gov
571-272-7822

Paper No. 50
Entered: August 27, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2018-00608
Patent 9,161,926 B2

Before GRACE KARAFFA OBERMANN, SHERIDAN K. SNEDDEN, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
Claims 1–6 Not Shown to Be Unpatentable
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

ORDERS

Dismissing Petitioner's Motion to Exclude (Paper 34)
37 C.F.R. § 42.64(c)

Dismissing Patent Owner's Motion to Exclude (Paper 36)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has failed to establish by a preponderance of the evidence that claims 1–6 of U.S. Patent No. 9,161,926 B2 (Ex. 1001, "the '926 patent") are unpatentable.

A. Procedural History

Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–6 of the '926 patent. Paper 2 ("Pet."). Biogen, Inc. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp."). Based on the information set forth in the Petition, we instituted trial on the following grounds of unpatentability asserted by Petitioner:

Ground	Claims	Basis	References
1	1–6	§ 103(a)	Garrett[1] and Nadau-Fourcade[2]
2	1–6	§ 103(a)	Garrett and Bonacucina[3]

Decision to Institute (Paper 10, "DI").

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 23, "PO Resp."), Petitioner filed a Reply (Paper 29; "Reply"), and Patent Owner filed a Sur-Reply (Paper 33; "Sur-Reply").

Petitioner relies on the Declarations of Bozena B. Michniak-Kohn, Ph.D. (Exs. 1002, 1050) and Dr. Elaine Gilmore, M.D., Ph.D. (Exs. 1018, 1034) in support of the proposed grounds of unpatentability.

Patent Owner relies on the Declarations of Alexander M. Klibanov, Ph.D. (Ex. 2003) and Julie Harper, M.D. (Ex. 2022).

Oral argument was conducted on June 5, 2019. A transcript is entered as Paper 48 ("Tr.").

B. The '926 patent

The '926 patent describes compositions containing the drug dapsone, which are useful for treating a variety of dermatological conditions.

---

[1] Ex. 1004, International Patent Application Publication No. WO 2009/061298 ("Garrett").

[2] Ex. 1015, Bonacucina, G., et al., *Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer*, 10 AAPS PHARMASCITECH 368–75 (2009) ("Bonacucina").

[3] Ex. 1005, International Application Publication No. WO 2010/072958 A2, English Translation at pages 38–72 ("Nadau-Fourcade").

Ex. 1001, Abst. The '926 patent discloses that "[u]se 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 Abst.

The '926 patent describes the invention as follows:

> it has been found that 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 2:46–53.

According to one embodiment, the compositions include about 5% w/w to about 10% w/w dapsone, a first solubilizing agent (i.e., diethylene glycol monoethyl ether), optionally at least one second solubilizing agent, a polymeric viscosity builder, and water. *Id.* at 2:54–59.

Example 1 of the '926 patent "show[s] the impact of acrylamide/sodium acryloyldimethyltaurate copolymer based thickener on dapsone particle size." *Id.* at 12:23–26. The results disclosed in that example show that larger crystals were observed in the sample with carbomer homopolymer type C, as compared to an acrylamide/sodium acryloyldimethyltaurate copolymer based thickener. *Id.* at 12:23–35.

C. Illustrative Claims

Independent claims 1 and 5, reproduced below, are illustrative:

1. 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 consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the composition does not comprise adapalene.

5. 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 consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the composition does not comprise adapalene.

Ex. 1001, 15:21–16:14–21.

II. DISCUSSION

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person having ordinary skill in the art ("POSA") "would have the knowledge of both a formulator of topical pharmaceutical compositions and [a] clinician with experience treating dermatological diseases." Pet. 7. Petitioner asserts that a "formulator POSA"

> would possess a Ph.D. or equivalent degree in pharmaceutics, chemistry or a related discipline such as pharmacology, who also has practical experience (at least two years) of formulating topical drug delivery products, or the POSA could possess a

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.