

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

U.S. Patent No. 9,517,219

Second Declaration of Elaine S. Gilmore, M.D., Ph.D.

*Inter Partes Review of U.S. Patent No. 9,517,219
Second Declaration of Elaine S. Gilmore, M.D., Ph.D.
(Exhibit 1044)*

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I, Elaine S. Gilmore, hereby declare as follows.

I. Overview

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Petitioners Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$500/hr. I understand that the petition for IPR involves U.S. Patent No. 9,517,219 (“the ’219 patent”), AMN1001, which resulted from U.S. Application No. 14/885,805 (“the ’805 application”), filed on October 16, 2015, naming Kevin S. Warner, Ajay P. Parashar, Vijaya Swaminathan, and Varsha Bhatt as inventors. The ’219 patent issued on December 13, 2016, from the ’805 application.

3. To the extent that I have not responded to all of Dr. Kircik’s opinions, I understand that another expert may be responding to those opinions.

II. Scope of testimony and documents considered

4. Previously, I submitted a declaration in support of Amneal’s Petition. *See* AMN1018. I understand from Counsel for Amneal that Almirall submitted in support of its Patent Owner’s Response (“POR”) the declaration of Leon Kircik,

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MD. EX2055 (“Kircik Decl.”). I have been asked to respond to the portions of Dr.

Kircik’s declaration relied upon by Patent Owner Almirall.

5. In formulating my opinions, I considered the following documents:

Exhibit or Paper No.	Description
1001	Warner <i>et al.</i> , “Topical Dapsone and Dapsone/Adaplene Compositions and Methods for Use Thereof, U.S. Patent No. 9,517,219 (filed October 16, 2013; issued December 13, 2016)
1004	Garrett <i>et al.</i> , “Topical Treatment With Dapsone in G6PD-Deficient Patients” WO 2009/061298 (filed November 7, 2007; published May 14, 2009)
1007	Lathrop, “Emulsive Composition Containing Dapsone” U.S. Pat. Appl. Publ. No. 2006/0204526 (filed February 13, 2006; published September 14, 2006)
1008	U.S. Patent Publication No. 2010/0029781 (“Morris”)
1010	<i>Physician’s Desk Reference</i> , 65 th ed., pp. 599-602 (2011) (ACZONE Gel 5% Label)
1018	Declaration of Elaine S. Gilmore, M.D., Ph.D.
1023	Thiboutot, D., <i>et al.</i> , “Pharmacokinetics of Dapsone Gel, 5% for the Treatment of Acne Vulgaris” <i>Clin. Pharmacokinet.</i> 46: 697-712 (2007)
1024	Nguyen, R. and Su, J., “Treatment of Acne Vulgaris” <i>Pediatrics and Child Health</i> 21: 119-125 (2010)
1025	Williams, H., <i>et al.</i> , “Acne vulgaris” <i>Lancet</i> 379: 361–72 (2012) (“Williams”)
1035	Poster Abstracts for the Journal of the American Academy of Dermatology 2017 Annual Meeting
1047	Kircik, L.H., “Use of Dapsone 5% Gel as Maintenance Treatment of Acne Vulgaris Following Completion of Oral Doxycycline and Dapsone 5% Gel Combination Treatment,” <i>Journal of Drugs in Dermatology</i> 15(2):191-195 (2016)
1048	Tanghetti, E., <i>et al.</i> , “The Efficacy and Tolerability of Dapsone 5% Gel in Female vs. Male Patients With Facial Acne Vulgaris: Gender as a Clinically Relevant Outcome Variable,” <i>Journal of Drugs in Dermatology</i> 11:1417-1421 (2012)
2001	International Patent Application Publication No. WO

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	2009/108147 (“Garrett II”)
2008	International Patent Application Publication No. WO 2011/014627 (“Ahluwalia”)
2009	Dina Anderson, <i>Finding a Place for Topical Anti-inflammatory Acne Therapy</i> , Practical Dermatology 17 (July 2009) (“Anderson”)
2012	Barry Coutinho, <i>Dapsone (Aczone) 5% Gel for the Treatment of Acne</i> , Am. Family Physician (2010) (“Coutinho”)
2017	Michael Ghods et al., <i>The Role of Dapsone Gel in the Acne Armamentarium</i> , The Dermatologist (June 10, 2010) (“Ghods”)
2019	Kirk A. James et al., <i>Emerging Drugs for Acne</i> , 14 Expert Opinions on Emerging Drugs 649 (2009) (“James 2009”)
2020	Leon H. Kircik, <i>Harnessing the Anti-inflammatory Effects of Topical Dapsone for Management of Acne</i> , 9 J. Drugs Dermatol. 667 (2010) (“Kircik 2010”)
2024	H.C. Korting & C. Schöllmann, <i>Current topical and systemic approaches to treatment of rosacea</i> , 23 J. Eur. Acad. of Dermatology and Venereology 876, 876 (2009) (“Korting”)
2025	John Kraft & Anatoli Freiman, <i>Management of acne</i> , 183 Canadian Med. Assoc. J. E430 (2011) (“Kraft”)
2031	MaryAnn Steiner, <i>Dapsone Topical Gel for Acne</i> , 12 J Pharm Soc. Wisc. 67 (2009) (“Steiner”)
2034	Emil Tanghetti et al., <i>Clinical Evidence for the Role of a Topical Anti-Inflammatory Agent in Comedonal Acne: Findings From a Randomized Study of Dapsone Gel 5% in Combination With Tazarotene Cream 0.1% in Patients With Acne Vulgaris</i> , 10 J. Drugs Dermatol. 783 (2011) (“Tanghetti”)
2036	Diane Thiboutot et al., <i>New insights into the management of acne: An update from the Global Alliance to Improve Outcomes in Acne Group</i> , 60 J. Am. Acad. Dermatol. S1 (2009) (“Thiboutot 2009”)
2038	Stephen Titus & Joshua Hodge, <i>Diagnosis and Treatment of Acne</i> , 86 Am. Family Physician 734 (2012) (“Titus”)
2045	2005 Aczone 5% approval letter
2055	Declaration of Leon H. Kircik, M.D.

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