

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: IPR2018-00608

U.S. Patent No. 9,161,926

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

*Inter Partes Review of U.S. Patent No. 9,161,926
Second Declaration of Elaine S. Gilmore, M.D., Ph.D.
(Exhibit 1034)*

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***Inter Partes Review of U.S. Patent No. 9,161,926
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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. 9,161,926 (“the ’926 patent”), AMN1001, which resulted from U.S. Application No. 14/082,955 (“the ’955 application”), filed on November 18, 2013, naming Kevin S. Warner, Ajay P. Parashar, Vijaya Swaminathan, and Varsha Bhatt as inventors. The ’926 patent issued on October 20, 2015, from the ’955 application.

II. Scope of testimony and documents considered

3. 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 Julie Harper, MD. EX2022 (“Harper Decl.”). I have been asked to respond to the portions of Dr. Harper’s declaration relied upon by Patent Owner Almirall.

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

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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. 9,161,926 (filed November 18, 2013; issued October 20, 2015)
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	ACZONE™ Gel 5% Package Insert
1012	Epiduo Product Label, approved December 8, 2008 (“Epiduo Label”)
1018	Declaration of Elaine S. Gilmore, M.D., Ph.D.
1022	Wozel, D., “Innovative Use of Dapsone” <i>Dermatol. Clin.</i> 28: 599–610 (2010)
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)
1027	Barclay, L., “Use of Topical Corticosteroids for Dermatologic Conditions Reviewed” <i>Medscape</i> - Jan 21, 2009, accessed from https://www.medscape.com/viewarticle/587159_print
1035	Tanghetti, E., <i>et al.</i> , “The Efficacy and Tolerability of Dapsone So/o 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)
1036	Fleisher, Jr., A., <i>et al.</i> , “Dapsone Gel So/o in Combination With Adapalene Gel 0.1 o/o, Benzoyl Peroxide Gel 4 o/o or Moisturizer for the Treatment of Acne Vulgaris: A 12-Week, Randomized, Double-Blind Study,” <i>Journal of Drugs In Dermatology</i> 9: 33-40 (2010)
1037	Physicians’ Desk Reference, 60 th ed., Solagé®, pp. 740-742 (2006)
1038	Physicians’ Desk Reference, 61 st ed., Tri-Luma®, pp. 1213-

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	1215 (2007)
1039	Physicians' Desk Reference, 63 rd ed., Ziana [®] , pp. 1942-1945 (2009)
1040	Physicians' Desk Reference, 65 th ed., Veltin [®] , pp. 3145-3148 (2011)
2005	International Patent Application Publication No. WO 2011/014627
2006	International Patent Application Publication No. WO 2009/108147
2013	MaryAnn Steiner, <i>Dapsone Topical Gel for Acne</i> , J. Pharm. Soc. Wisc. 12(6): 67-71 (2009)
2016	Kirk A. James, <i>Emerging drugs for acne</i> , Expert. Opin. Emerging Drugs 14(4): 649-659 (2009)
2017	Barry Coutinho, <i>Dapsone (Aczone) 5% Gel for the Treatment of Acne</i> , American Family Physician (Dec. 2010)
2022	Declaration of Julie Harper, M.D.
2024	John Kraft & Anatoli Freiman, <i>Management of acne</i> , 183 Canadian Med. Assoc. J. E430-E435 (2011)
2026	Stephen Titus & Joshua Hodge, <i>Diagnosis and Treatment of Acne</i> , 86 Am. Family Physician 734-740 (2012)
2040	Dina Anderson, <i>Finding a Place for Topical Anti-inflammatory Acne Therapy</i> , Practical Dermatology 17-18 (July 2009) ("Anderson")
2041	Michael Ghods et al., <i>The Role of Dapsone Gel in the Acne Armamentarium</i> , The Dermatologist (June 10, 2010)

III. The existence of other alternative acne treatments would not have led a POSA away from dapsone.

5. I understand that Almirall and Dr. Harper argue that a POSA would not have selected dapsone for two reasons: (1) that Almirall contends that benzoyl peroxide and retinoids were more common first-line acne treatments, and (2) that dapsone was ineffective against rosacea. I disagree for at least the reasons below.

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