

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
and MYLAN PHARMACEUTICALS INC.,
Petitioners

v.

ALMIRALL, LLC,
Patent Owner

Case IPR2019-00207¹
Patent 9,517,219

PATENT OWNER'S EXHIBIT LIST

¹ Cases IPR2019-00207 and IPR2019-01095 have been joined in this

IPR2019-00207
 Patent Owner's Exhibit List

Exhibit No.	Description
2001	International Patent Application Publication No. WO 2009/108147 ("Garrett II")
2002	International Patent Application Publication No. WO 2010/105052 ("Hani")
2003	Redline Comparison of Petitions in IPR2018-00608 and IPR2019-00207
2004	Redline Comparison of Michniak-Kohn Declarations in IPR2018-00608 and IPR2019-00207
2005	Redline Comparison of Gilmore Declarations in IPR2018-00608 and IPR2019-00207
2006	Petitioner's Notice of Paragraph IV Certification to Patent Owner (February 22, 2019) (truncated)
2007	Declaration of Elizabeth B. Hagan in Support of Patent Owner Almirall, LLC's Motion for Admission <i>Pro Hac Vice</i>
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")
2010	Christin N. Collier et al., <i>The prevalence of acne in adults 20 years and older</i> , 58 J. Am. Acad. Dermatol. 56 (2008) ("Collier")
2011	Loren Cordain et al., <i>Acne Vulgaris: A Disease of Western Civilization</i> , 138 Arch Dermatol. 2584 (2002) ("Cordain")
2012	Barry Coutinho, <i>Dapsone (Aczone) 5% Gel for the Treatment of Acne</i> , Am. Family Physician (2010) ("Coutinho")
2013	James Q. Del Rosso, <i>Newer Topical Therapies for the Treatment of Acne Vulgaris</i> , 80 Cutis 400 (2007) ("Del Rosso 2007")

Exhibit No.	Description
2014	Gabriella Fabbrocini et al., <i>Resveratrol-Containing Gel for the Treatment of Acne Vulgaris: A Single-Blind, Vehicle-Controlled, Pilot Study</i> , 12 Am. J. Clin. Dermatol. 133 (2011) (“Fabbrocini”)
2015	Zoe D. Draelos et al., <i>Two randomized studies demonstrate the efficacy and safety of dapsone gel, 5% for the treatment of acne vulgaris</i> , 46 J. Am. Acad. Dermatol. 439.e1 (2007) (“Draelos”)
2016	A. B. Fleischer et al., <i>Dapsone Gel 5% in Combination with Adapalene Gel 0.1%, Benzoyl Peroxide Gel 4% or Moisturizer for the Treatment of Acne Vulgaris: A 12-Week, Randomized, Double-Blind Study</i> , 9 J. Drugs Dermatol. 33 (2010) (“Fleischer”)
2017	Michael Ghods et al., <i>The Role of Dapsone Gel in the Acne Armamentarium</i> , The Dermatologist (June 10, 2010) (“Ghods”)
2018	William D. James, <i>Acne</i> , 352 New Eng. J. Medicine 463 (2005) (“James 2005”)
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”)
2021	Leon Kircik and Adam Friedman, <i>Optimizing Acne Therapy With Unique Vehicles</i> , 9 J. Drugs Dermatol. S53 (2010) (“Kircik 2010a”)
2022	Leon H. Kircik, <i>Synergy and Its Clinical Relevance in Topical Acne Therapy</i> , 4 J. Clin. Aesthet. Dermatol. 30 (2011) (“Kircik 2011”)
2023	Leon H. Kircik, <i>Microsphere Technology: Hype or Help?</i> , 4 J. Clin. Aesthet. Dermatol. 27 (2011) (“Kircik 2011a”)

Exhibit No.	Description
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”)
2026	Evgenia Makrantonaki et al., <i>An update on the role of the sebaceous gland in the pathogenesis of acne</i> , 3 Dermato-Endocrinology 41 (2011) (“Makrantonaki”)
2027	Otto H. Mills et al., <i>Comparing 2.5%, 5%, and 10% Benzoyl Peroxide on Inflammatory Acne Vulgaris</i> , 25 Int’l J. Dermatology 664 (1986) (“Mills”)
2028	Warren W. Piette et al., <i>Hematologic Safety of Dapsone Gel, 5%, for Topical Treatment of Acne Vulgaris</i> , 144 Arch. Dermatol. 1564 (2008) (“Piette”)
2029	Frank C. Powell, <i>Rosacea</i> , 352 New Eng. J. Med. 793 (2005) (“Powell”)
2030	Thierry Simonart, <i>Newer Approaches to the Treatment of Acne Vulgaris</i> , 13 Am. J. Clin. Dermatol. 357 (2012) (“Simonart”).
2031	MaryAnn Steiner, <i>Dapsone Topical Gel for Acne</i> , 12 J Pharm Soc. Wisc. 67 (2009) (“Steiner”)
2032	John S. Strauss, <i>Biology of the Sebaceous Gland and the Pathophysiology of Acne Vulgaris</i> , Chapter 13 in Pathophysiology of Dermatologic Diseases, Second Edition, N. A. Soter and H. Baden eds., McGraw-Hill, New York (1991) (“Strauss 1991”)
2033	John S. Strauss et al., <i>Guidelines of care for acne vulgaris management</i> , 56 J. Am. Acad. Dermatol. 651 (2007) (“Strauss 2007”)

Exhibit No.	Description
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”)
2035	Diane Thiboutot et al., <i>An aqueous gel fixed combination of clindamycin phosphate 1.2% and benzoyl peroxide 2.5% for the once-daily treatment of moderate to severe acne vulgaris: Assessment of efficacy and safety in 2813 patients</i> , 59 J. Am. Acad. Dermatol. 792 (2008) (“Thiboutot 2008”)
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”)
2037	Anja Thielitz and Harald Gollnick, <i>Topical Retinoids in Acne Vulgaris – Update on Efficacy and Safety</i> , 9 Am. J. Clin. Dermatol. 369 (2008) (“Thielitz”)
2038	Stephen Titus & Joshua Hodge, <i>Diagnosis and Treatment of Acne</i> , 86 Am. Family Physician 734 (2012) (“Titus”).
2039	<i>Physicians’ Desk Reference</i> (2011) (excerpt)
2040	<i>Physicians’ Desk Reference</i> (2012) (excerpt)
2041	Epiduo Press Release (Dec. 15, 2011), available at https://www.galderma.com/us/news/1-branded-topical-acne-product-epiduo-gel-recvies-fda-approval-new-convenient-pump-dispenser
2042	Aczone 5% Medical Review(s) (excerpt)
2043	Aczone 5% Clinical Pharmacology and Biopharmaceutics Review(s)
2044	2008 Aczone 5% label

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