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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALMIRALL, LLC
Patent Owner

Case IPR2019-00207¹
Patent 9,517,219 B2

PETITIONERS' EXHIBIT LIST

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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

<i>Amneal Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 9,517,219
1002	Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S.
1003	<i>Curriculum Vitae</i> for Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S.
1004	International Patent Application Publication No. WO 2009/061298 (“Garrett”)
1005	International Application Publication No. WO 2010/072958 (“Nadau-Fourcade”)
1006	Certification for Translation of WO 2010/072958
1007	U.S. Patent Publication No. 2006/0204526 (“Lathrop”)
1008	U.S. Patent Publication No. 2010/0029781 (“Morris”)
1009	Osborne, D.W., “Diethylene glycol monoethyl ether: an emerging solvent in topical dermatology products,” <i>J. Cosmetic Derm.</i> 10:324-329 (2011) (“Osborne I”)
1010	<i>Physician’s Desk Reference</i> , 65 th ed., pp. 599-602 (2011) (ACZONE Gel 5% Label)
1011	U.S. Patent No. 7,820,186 (“Orsoni”)
1012	Epiduo Product Label, approved December 8, 2008 (“Epiduo Label”)
1013	U.S. Patent Publication No. 2007/0190019 (“Guo”)
1014	Rowe, R.C. et al. (Eds.), <i>Handbook of Pharmaceutical Excipients</i> , 6th Ed., Pharmaceutical Press: London, UK (2009)
1015	Bonacucina, G., <i>et al.</i> , “Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer,” <i>AAPS PharmaSciTech</i> 10:368-375 (2009) (“Bonacucina”)
1016	U.S. Patent No. 5,863,560 (“Osborne II”)
1017	File History of U.S. Patent No. 9,517,219
1018	Declaration of Elaine S. Gilmore, M.D., Ph.D.

<i>Amneal Exhibit #</i>	<i>Description</i>
1019	<i>Curriculum Vitae</i> for Elaine S. Gilmore, M.D., Ph.D.
1020	Affidavit of Christopher Butler
1021	<i>Intentionally left blank</i>
1022	Wozel, D., “Innovative Use of Dapsone” <i>Dermatol. Clin.</i> 28: 599–610 (2010) (“Wozel”)
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) (“Thiboutot”)
1024	Nguyen, R. and Su, J., “Treatment of Acne Vulgaris” <i>Pediatrics and Child Health</i> 21: 119-125 (2010) (“Nguyen”)
1025	Williams, H., <i>et al.</i> , “Acne vulgaris” <i>Lancet</i> 379: 361–72 (2012) (“Williams”)
1026	Sepineo™ P 600 Brochure
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 (“Barclay”)
1028	Remington: The Science and Practice of Pharmacy, 21st Ed., Lippincott Williams & Wilkins: Baltimore, MD (2005) (“Remington”)
1029	Kim, J-Y., <i>et al.</i> , “Rheological properties and microstructures of Carbopol gel network system,” <i>Colloid. Polym. Sci.</i> 281:614–623(2003) (“Kim”)
1030	<i>Intentionally left blank</i>
1031	Spain's Almirall bets on dermatology with \$650 million U.S. deal, Retrieved from https://www.reuters.com/article/us-allergan-m-a-almirall/spains-almirall-bets-on-dermatology-with-650-million-us-deal-idUSKBN1KO10N , last accessed October 26, 2018
1032	Piskin, S. <i>et al.</i> “A review of the use of adapalene for the treatment of acne vulgaris,” <i>Therapeutics and Clinical Risk Management</i> 3(4): 621–624 (2007) (“Piskin”)
1033	<i>Intentionally left blank</i>

<i>Amneal Exhibit #</i>	<i>Description</i>
1034	Andersson, D., "Evonik-Degussa expands its cooperation with Alsiano," <i>Pharma & Healthcare News</i> : 1-10 (2007)
1035	Poster Abstracts for the Journal of the American Academy of Dermatology 2017 Annual Meeting
1036	Email dated October 8, 2019 from Liz Hagan to Tyler Liu, Dennies Varughese, Adam LaRock and James Trainor regarding conference call
1037	Email dated October 8, 2019 from Tyler Liu to trials@uspto.gov requesting authorization to file a motion for additional discovery
1038	<i>Almirall, LLC v. Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc.</i> , Case 1:17-cv-00663 [Proposed] Joint Pretrial Order, Document 142, February 5, 2019
1039	Deposition Transcript for Leon H. Kircik, M.D., Case IPR2019-00207 (October 4, 2019)
1040	Deposition Transcript for David W. Osborne, Ph.D., Case IPR2019-00207 (October 18, 2019)
1041²	Allergan Announces Agreement to Acquire Aczone® Gel 5%, Retrieved from https://www.businesswire.com/news/home/20080609005407/en/Allergan-Announces-Agreement-Acquire-Aczone-Gel-5 , last accessed on October 7, 2019
1042	U.S. Patent No. 7,326,408
1043	Second Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S.
1044	Second Declaration of Elaine S. Gilmore, M.D., Ph.D.

² Exhibits 1041 and 1042 were served on counsel for Almirall on October 18, 2019.

<i>Amneal Exhibit #</i>	<i>Description</i>
1045	Inactive Ingredient Search for Approved Drug Products: Frequently Asked Questions, Retrieved from https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredient-search-approved-drug-products-frequently-asked-questions#inactive%20as%20active? , last accessed on October 25, 2019
1046	Lubrizol Technical Data Sheet, Dispersion Techniques for Carbopol® Polymers
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)
1049	<i>Intentionally left blank</i>
1050	Neutralizing Carbopol® and Pemulen® Polymers in Aqueous and Hydroalcoholic Systems, published January 2002 (“Noveon Technical Data Sheet”)
1051	2010 Inactive Ingredient Database, available at: http://wayback.archive-it.org/7993/20170112022245/http://www.fda.gov/Drugs/InformationOnDrugs/ucm113978.htm .
1052	FDA Drug Master File Database, available at: https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/drugmasterfilesdmfs/default.htm .
1053	Sullivan, D., <i>et al.</i> , “A review of the nonclinical safety of Transcutol®, a highly purified form of diethylene glycol monoethyl ether (DEGEE) used as a pharmaceutical excipient,” <i>Food and Chemical Toxicology</i> 72: 4-50 (2014)
1054	FDA Inactive Ingredient Database Field Descriptions
1055	Andersson, D., “Evonik-Degussa expands its cooperation with Alsiano,” <i>Pharma & Healthcare News</i> 7:1-10 (2007)
1056	File History of U.S. Patent No. 9,161,926
1057	Deposition Transcript for Julie C. Harper, M.D., Case IPR2018-00608 (March 11, 2019)

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