

IN THE 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. Pat. No. 9,161,926

PETITIONERS' EXHIBIT LIST

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<i>Amneal Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 9,161,926
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	Aczone® Gel 5% Product Label, approved July 7, 2005 (“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.), Handbook of Pharmaceutical Excipients, 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	U.S. Patent No. 9,161,926 File History
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	Viscosity of Carbopol® Polymers in Aqueous Systems, published August 13, 2010 (“Lubrizon Technical Data Sheet”)
1021	“Formulating Semisolid Products,” published October 29, 2008 (“Lubrizon Pharmaceutical Bulletin 21”)
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	Neutralizing Carbopol® and Pemulen® Polymers in Aqueous and Hydroalcoholic Systems, published January 2002 (“Noveon Technical Data Sheet”)
1031	U.S. Patent No. 9,517,219 File History
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: 621–624 (2007) (“Piskin”)
1033	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Patent and Exclusivity for: N207154

<i>Amneal Exhibit #</i>	<i>Description</i>
SUPPL. AMN1034	Supplemental Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S. ¹ (served not filed)
SUPPL. AMN1035	Andersson, D., “Evonik-Degussa expands its cooperation with Alsiano,” <i>Pharma & Healthcare News</i> 7:1-10 (2007) (served not filed)
1034	Second Declaration of Elaine S. Gilmore, Ph.D.
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. 1213-1215 (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)
1041	Dollars for Docs, available at https://projects.probulica.org/d4d-archive/payments/9854537
1042	Dollars for Docs, available at https://projects.propublica.org/d4d-archive/11947951
1043	Julie C. Harper -2013-Top Companies Making General Payments, available at https://openpaymentsdata.cms.gov/physician/264589/general-payments

¹ The Supplemental Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S. was inadvertently marked as AMN1035 when served on opposing counsel. This declaration should be marked as AMN1034.

<i>Amneal Exhibit #</i>	<i>Description</i>
1044	Julie C. Harper -2014-Top Companies Making General Payments, available at https://openpaymentsdata.cms.gov/physician/264589/general-payments
1045	Julie C. Harper -2015-Top Companies Making General Payments, available at https://openpaymentsdata.cms.gov/physician/264589/general-payments
1046	Julie C. Harper -2016-Top Companies Making General Payments, available at https://openpaymentsdata.cms.gov/physician/264589/general-payments
1047	Julie C. Harper -2017-Top Companies Making General Payments, available at https://openpaymentsdata.cms.gov/physician/264589/general-payments
1048	Aczone – Dollars for Docs, available at https://projects.propublica.org/docdollars/products/drug-aczone
1049	Transcript from the Deposition of Dr. Julie Harper, M.D., Case IPR2018-00608 (March 11, 2019)
1050	Second Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S.
1051	List of Dr. Klibanov’s clerical errors
1052	<i>intentionally left blank</i>
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	FDA Inactive Ingredient Database FAQs
1056	FDA Drug Master File Database, available at: https://www.fda.gov/drugs/developmentapprovalprocess/formssubmissionrequirements/drugmasterfilesdmfs/default.htm .

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