IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS X LLC, Petitioner,

v.

ANACOR PHARMACEUTICALS, INC., Patent Owner.

Case No. IPR2015-01776 Patent No. 7,582,621

PATENT OWNER PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107

DC: 5863873-19



LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
Ex. 2001	FDA Approved Label for KERYDIN® (Rev. 3/2015)
Ex. 2002	Fairchild et al., In Vitro Determination of Uptake, Retention,
	Distribution, Biological Efficacy, and Toxicity of Boronated
	Compounds for Neutron Capture Therapy: A Comparison of
	Porphyrins with Sulfhydryl Boron Hydrides, Cancer Res., vol. 50, pp. 4860-65 (1990)
Ex. 2003	Charif et al., A Historical Perspective on Onychomycosis, Dermatol.
	Ther. vol. 3, pp. 43-45 (1997)
Ex. 2004	Heath et al., Fatty Acid Biosynthesis as a Target for Novel
	Antibacterials, Curr. Opin. Invest. Drugs, vol. 5, pp. 146-53 (2004)
Ex. 2005	Baldock et al., A Mechanism of Drug Action Revealed by Structural
	Studies of Enoyl Reductase, Science, vol. 274, pp. 2107-10 (1996)
Ex. 2006	Biobor, R.E.D. Facts, EPA-738-R-93-004 (June 1993),
	http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=200009P5.PDF
Ex. 2007	Lefkovits et al., Direct Thrombin Inhibitors in Cardiovascular
	<i>Medicine</i> , Circulation, vol. 90, pp. 1522-36 (1994)
Ex. 2008	Grassberger et al., Preparation and Antibacterial Activities of New
	1,2,3-Diazaborine Derivatives and Analogs, J. Med. Chem., vol. 27,
	no. 8, pp. 947-53 (1984)
Ex. 2009	Baldock et al., Mechanism of Action of Diazaborines, Biochem.
	<i>Pharm.</i> , vol. 55, pp. 1541-49 (1998)
Ex. 2010	Heindel et al., The Developmental Toxicity of Boric Acid in Mice,
	Rats, and Rabbits, Environ. Health Perspect., vol. 102, suppl. 7, pp.
	107-12 (1994)
Ex. 2011	Richardson, Clinical Update: Proteasome Inhibitors in
	Hematologic Malignancies, Cancer Treatment Rev., vol. 29, suppl.
	1, pp. 33-39 (2003)
Ex. 2012	Bross et al., Approval Summary for Bortezomib for injection in the
	Treatment of Multiple Myeloma, Clin. Cancer Res., vol. 10, pp.
E 2012	3954-64 (2004)
Ex. 2013	Adams, Proteasome Inhibitors as Therapeutic Agents, Expert Opin.
E 2014	Ther. Patents, vol. 13, no. 1, pp. 45-57 (2003)
Ex. 2014	Dorland's Illustrated Medical Dictionary, p. 211 (29th ed. 2000)



EXHIBIT	DESCRIPTION
E 2015	Stadman's Madical Distingues at 2014 (27th ad 2000)
Ex. 2015	Stedman's Medical Dictionary, p. 204 (27th ed. 2000)
Ex. 2016	Random House Webster's Unabridged Dictionary, p. 209 (2nd ed. 2001)
Ex. 2017	Jordon et al., Boric Acid Poisoning: A Report of a Fatal Adult Case from Cutaneous Use. A Critical Evaluation of the Use of This Drug in Dermatologic Practice, JAMA Derm, vol. 75, pp. 720-28 (1957).
Ex. 2018	Zhdankin et al., Synthesis and Structure of Benzoxaboroles: Novel Organoboron Heterocycles, Tetrahedron Lett., vol. 40, pp. 6705-08 (1999)
Ex. 2019	Triggle, <i>Pharmacological Receptors: A Century of Discovery—and More</i> , Pharm. Acta Helvetiae, vol. 74, pp. 79-84 (2000)
Ex. 2020	Larsen et al., The Prevalence of Onychomycosis in Patients with Psoriasis and Other Skin Diseases, Acta Derm. Venereol., vol 83, pp. 206-09 (2003)
Ex. 2021	Tatsumi et al., Therapeutic Efficacy of Topically Applied KP-103 Against Experimental Tinea Unguium in Guinea Pigs in Comparison with Amorolfine and Terbinafine, Antimicrobial Agents and Chemotherapy, vol. 46, no. 12, pp. 3797-3801 (2002)
Ex. 2022	Osborne et al., Antifungal Drug Response in an In Vitro Model of Dermatophyte Nail Infection, Med. Mycol., vol. 42, pp. 159-63 (2004)
Ex. 2023	Favre et al., Comparison of In Vitro Activities of 17 Antifungal Drugs Against a Panel of 20 Dermatophytes by Using a Microdilution Assay, J. Clin. Microbiol., vol. 41, no. 10, pp. 4817- 19 (2003)
Ex. 2024	Sangster, Octanol-Water Partition Coefficients of Simple Organic Compounds, J. Phys. Chem. Ref. Data, vol. 18, pp. 1111-1227 (1989)
Ex. 2025	Powers et al., Structure-Based Approach for Binding Site Identification on AmpC β-Lactamase, J. Med. Chem., vol. 45, pp. 3222-34 (2002)
Ex. 2026	Boric Acid, R.E.D. Facts, EPA-738-F-93-006 (Sept. 1993), http://archive.epa.gov/pesticides/reregistration/web/pdf/0024fact.pdf
Ex. 2027	Vander Straten et al., Cutaneous Infections: Dermatophytosis, Onychomycosis, and Tinea Versicolor, Infect. Dis. Clinics N. Am., vol. 17, pp. 87-112 (2003)



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