UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01131[1]
Patent 8,648,048

PATENT OWNER ALLERGAN'S MOTION FOR OBSERVATIONS ON THE CROSS-EXAMINATION TESTIMONY OF IVAN T. HOFMANN

[1] Cases IPR2017-00585 and IPR2017-00600 have been joined with this proceeding.

EXHIBIT LIST

Exhibit No.	Description
EX. 2001	NDA 21-023 Cyclosporine Ophthalmic Emulsion 0.05%, Original NDA Filing, Vol. 1 (Feb. 24, 1999)
EX. 2002	U.S. Pat. No. 4,839,342
EX. 2003	Said et al., Investigative Ophthalmology & Visual Science, vol. 48, No. 11 (Nov. 2007):5000-5006
EX. 2004	Alba et al., Folia Ophthalmol. Jpn. 40:902-908 (1989)
EX. 2005	Stedman's Medical Dictionary, definition of therapeutic
EX. 2006	Dorland's Illustrated Medical Dictionary, definition of therapeutic
EX. 2007	Stedman's Medical Dictionary, definition of palliative
EX. 2008	RESTASIS® label
EX. 2009	Murphy, R., "The Once and Future Treatment of Dry Eye," Review of Optometry, pp. 73-75 (Feb. 15, 2000)
EX. 2010	RESERVED
EX. 2011	Agarwal, Priyanka and Ilva D. Rupenthal, "Modern Approaches to the Ocular Delivery of Cyclosporine A," Drug Discovery Today, vol. 21, no. 6 (June 2016)
EX. 2012	Damato et al., "Senile Atrophy of the Human Lacrimal Gland: The Contribution of Chronic Inflammatory Disease," British Journal of Ophthalmology (1984)
EX. 2013	Higuchi, "Physical Chemical Analysis of Percutaneous Absorption Process From Creams and Ointments," Seminar, New York City (1959)
EX. 2014	Lallemand et al., "Cyclosporine a Delivery to the Eye: A Pharmaceutical Challenge," European Journal of Pharmaceutics and Biopharmaceutics (2003)
EX. 2015	das Neves et al., " Mucosal Delivery of Biopharmaceuticals:

	Biology, Challenges and Strategies," Springer Science (2014)
EX. 2016	Power et al., "Effect of Topical Cyclosporin A on Conjunctival T Cells in Patients with Secondary Sjögren's Syndrome," Cornea 12(6): 507-511 (1993)
EX. 2017	Schaefer et al., "Skin Permeability," Springer-Verlag (1982)
EX. 2018	Stern et al., "The Pathology of Dry Eye: The Interaction Between the Ocular Surface and Lacrimal Glands," Cornea 17(6): 584-589 (1998)
EX. 2019	Wepierre, Jacques and Jean-Paul Marty, "Percutaneous Absorption of Drugs," Elsvier/North-Holland Biomedical Press (1970)
EX. 2020	Williamson et al., "Histology f the Lacrimal Gland in Keratoconjunctivitis Sicca," Brit. F. Ophthal /91973)
EX. 2021	"Approved Drug Products with Therapeutic Equivalence Evaluations," U.S. Department of Health and Huma Services, 37th Edition (2017)
EX. 2022	Lemp, Michael A., " Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eyes," CLAO Journal, vol. 21, no. 4 (October 1995)
EX. 2023	Deposition transcript of Mansoor Amiji, Ph.D
EX. 2024	Declaration of John D. Sheppard, M.D., M.M.Sc.
EX. 2025	Declaration of Dr. Thorsteinn Loftsson, Ph.D.
EX. 2026	Declaration of Eric Rubinson
EX. 2027	Allergan PK-98-074 Report
EX. 2028	Declaration of Robert S. Maness, Ph.D.
EX. 2029	DiMasi, "Risks in New Drug Development: Approval Success Rates for Investigational Drugs," Clinical Pharmacology and Therapeutics, May 2001
EX. 2030	FDA Review, "The Drug Development and Approval Process"
EX. 2031	Allergan – NYSE: AGN – Company Profile

EX. 2032	Drugs@FDA: FDA Approved Drug Products, http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021023
EX. 2033	Drugs@FDA: FDA Approved Drug Products, Restasis Approved, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-023_Restasis_Approv.PDF
EX. 2034	Drugs@FDA: FDA Approved Drug Products, http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=050790
EX. 2035	Facts About Dry Eye, https://nei.nih.gov/health/dryeye/dryeye
EX. 2036	Christopher Glenn, "New Thinking Spurs New Products," Review of Ophthalmology, February 15, 2003
EX. 2037	Mark B. Abelson, MD and Jason Casavant, "Give Dry Eye a One-two Punch," Review of Ophthalmology, March 15, 2003
EX. 2038	Deposition of David LeCause, February 17, 2017
EX. 2039	Joan-Marie Stiglich ELS, "Restasis: the road to approval," Ocular Surgery News, March 1, 2003
EX. 2040	Lynda Charters, "Increased Tear Production," Ophthalmology Times, February 1, 2003
EX. 2041	RESERVED
EX. 2042	Jonathan R. Pirnazar, MD, "Taking a Custom Approach to Dry Eye Treatment," Ophthalmology Management, February 1, 2004
EX. 2043	RESERVED
EX. 2044	FDA label for Xiidra®
EX. 2045	RESERVED
EX. 2046	Restasis Strategic Plan Forecast 2009-2013
EX. 2047	Allergan Inc., Credit Suisse First Boston Equity Research Report, Jan 30, 2003
EX. 2048	Allergan Inc., Buckingham Research Group Equity Research

	Report, Feb 5, 2003
EX. 2049	Allergan Inc., SalomonSmithBarney Equity Research Report, Feb 12, 2003
EX. 2050	Allergan Inc., Morgan Stanley Equity Research Report, Jan 30, 2003
EX. 2051	Restasis P&L (US Only excl. Canada and Puerto Rico)
EX. 2052	Allergan Inc., Morgan Stanley Equity Research Report, Apr 30, 2004
EX. 2053	Allergan Inc., JP Morgan Equity Research Report, Nov 1, 2005
EX. 2054	RESERVED
EX. 2055	"commercial Restasis Formulary June 2006.xls"
EX. 2056	"NOVEMBER 2006 input MHC Report Restasis Playbook data.ppt"
EX. 2057	Restasis® 2013 Managed Markets Tactics & Preliminary Budget, August 8, 2012
EX. 2058	RESERVED
EX. 2059	RESERVED
EX. 2060	"Allergan Inc. (AGN) - Q4 2002 Financial Release Conference Call Wednesday, January 29, 2003 11:00 am" Fair Disclosure Financial Network
EX. 2061	Restasis Launch Marketing Plan, dated February 12-13, 2003
EX. 2062	Allergan Dry Eye, "Dry Eye Franchise 2014 Business Plan," 2014 U.S. Eye Care Sales & Marketing Plan, September 9, 2013
EX. 2063	Allergan Eye Care, "US Dry Eye Strat Plan Narrative: Summary Version," April 16, 2011
EX. 2064	Kline, Kate, "Restasis Professional Critical Issues," Allergan Dry Eye, 2010
EX. 2065	Allergan Dry Eye, "Restasis Business Update," August 16, 2010

EX. 2066	"Sales-Units_2011-2016_AllData_NSP_Feb-19-2017_RESTASIS.xlsx"
EX. 2067	RESERVED
EX. 2068	Iazuka and Jin, "The Effect of Prescription Drug Advertising on Doctor Visits," Journal of Economics and Management Strategy, 2007
EX. 2069	Bradford, Kleit, Nietert, et al, "How Direct-to-Consumer Television Advertising for Osteoarthritis Drugs Affect Physicians' Prescribing Behavior," Health Affairs, 2006
EX. 2070	Calfee, Winston, and Stempski, "Direct-to-Consumer Advertising and the Demand for Cholesterol Reducing Drugs," Journal of Law and Economics, 2002
EX. 2071	Bradford, Kleit, Nietert, et al, "Effects of Direct-to-Consumer Advertising of Hydroxymethylglutaryl Coenzyme A Reductase Inhibitors or Attainment of LDL-C Goals," Clinical Therapeutics, 2006
EX. 2072	Restasis NPA Monthly
EX. 2073	Restasis Projects, Global R&D Cost
EX. 2074	Refresh Endura Lubricant Eye Drops (Allergan), Theodora
EX. 2075	Declaration of Jonathan Singer in support of Petitioner's Motion for *Pro Hac Vice* Admission
EX. 2076	Memorandum Opinion and Order, *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., et al.*, Case No. 2:15-cv-1455-WCB
EX. 2077	Nussenblatt, R. et al. *Local Cyclosporine Therapy for Experimental Autoimmune Uveitis in Rats*. Arch Ophthalmology, Volume 103, October 1985.
EX. 2078	Medical Officer's Review of NDA 21-023
EX. 2079	Correction to Sall article (Ex. 1007), Opthalmology, Vol. 107, No. 7, July 2000.
EX. 2080	GraphPad Calculation of Bloch Table 2 – 3 mo. B vs A.

EX. 2081	GraphPad Calculation of Bloch Table 2 – 3 mo. C vs A.
EX. 2082	Deposition transcript of Andrew F. Calman, M.D., Ph.D.
EX. 2083	Deposition transcript of Daniel A. Bloch, Ph.D.
EX. 2084	Deposition transcript of Ivan T. Hofmann

Patent Owner Allergan hereby submits observations on the deposition testimony of Petitioner's Declarant Mr. Ivan T. Hofmann given on July 14, 2017 (Ex. 2084).

Mr. Hofmann Does Not Dispute That Restasis® is a Commercial Success

In Ex. 2084 at p. 8, lines 22 to 25, Mr. Hofmann admitted that Restasis® has experienced significant sales and profits, indicating that it is a commercial success. Mr. Hofmann's testimony is relevant to his statement in ¶ 29 of his declaration (Ex. 1041) where he states that he "ha[s] not seen evidence demonstrating that the claimed commercial success of Restasis® is attributable to novel features of the alleged inventions of the Patents-at-Issue." Mr. Hofmann's deposition testimony is relevant because it demonstrates that his dispute with Allergan's claim of commercial success is premised solely on establishing the nexus between the claimed invention and Restasis®, not on whether Restasis® itself was commercially successful.

Mr. Hofmann Fails to Define a Relevant Market After Incorrectly Criticizing Dr. Maness for the Same

In Ex. 2084 at p. 17 lines 5 to 19, Mr. Hofmann acknowledges that Dr. Maness provided a definition for a relevant market in his declaration. Mr. Hofmann also acknowledges that he did not define the relevant market in his testimony. *See* Ex. 2084 at p. 18 lines 2-17 ("I haven't done a definitive definition of which products would comprise the relevant market."). Mr. Hofmann's

testimony is relevant to his statement in ¶ 28 of his declaration (Ex. 1041) that "sales must be considered in light of the relevant market" and in ¶ 42 that "[t]he Maness Declaration is incomplete and flawed because it fails to provide the appropriate context to the performance of Restasis® in the relevant market". The deposition testimony is relevant because it demonstrates that, by his own standard, Mr. Hofmann's analysis is flawed, as he did not analyze the relevant market in which the sales took place.

Mr. Hofmann Does Not Dispute That Mere Presence of Product Marketing Does Not Indicate Lack of Nexus

In Ex. 2084 at p. 47, line 25 to p. 48 line 6, Mr. Hofmann agrees that the mere fact that a product is marketed does not mean there is a lack of nexus between the commercial performance of a product and the patented invention. Further, in Ex. 2084 at p. 48 lines 7-12, Mr. Hofmann admits that he did not quantify how much marketing spend he considers excessive. Mr. Hofmann's testimony is relevant to his statement in ¶ 70 of his declaration (Ex. 1041) that "the fact that Allergan has had to invest so heavily in sales and marketing efforts for Restasis® undermines the Maness Declaration's contention that a nexus exists between the commercial performance of Restasis® and the claims of the Patents-at-Issue." The deposition testimony is relevant because it demonstrates that marketing itself is not conclusive proof of lack of nexus, and that Mr. Hofmann did not quantify about how much marketing is excessive.

Mr. Hofmann Fails to Credit Marketing as a Percentage of Sales

In Ex. 2084 at p. 36 line 11 to p. 37 line 7, Mr. Hofmann testified that he does not consider marketing as a percentage of sales to be relevant to the role that marketing plays in driving the commercial success of Restasis®. He does not argue that Dr. Maness's calculations are erroneous (*see* Ex. 2084 at p. 44 lines 9 to 15, where he agrees "the math checks out"), but argues that the metric "diminishes the marketing intensity," or in other words, downplays Allergan's marketing efforts. Mr. Hofmann's deposition testimony is relevant to his statements at ¶¶ 63-64 of his declaration (Ex. 1041) where he discusses the purported effect of advertising and promotion on the commercial success of Restasis®. Mr. Hofmann's testimony is relevant because it demonstrates that he has not taken into account the marketing expenses in the broader context of Restasis® sales in assessing the commercial success of Restasis®.

Mr. Hofmann Fails to Compare Expenditures to Other Products in the Industry

In Ex. 2084 at p. 41 line 5 to p. 42 line 2, Mr. Hofmann admits that he does not compare the sales and marketing expenses of Restasis® compared to other pharmaceutical products with sales levels similar to Restasis®. *See also* Ex. 2084 p. 38 line 1 to p. 39 line 5. Mr. Hofmann's testimony is relevant to ¶¶ 69-70 of his declaration (Ex. 1041) where he sets forth the total sales and marketing expenses of Restasis® from launch through 2016, and comments that "if the features of the

claims of the Patents-at-Issue were as novel and important as the Maness Declaration implies, Allergan would not have needed to engage in the degree of such extensive, prolonged, and continued marketing efforts as described below." Mr. Hofmann's testimony is relevant because, without a comparison of Allergan's marketing efforts for Restasis® to the "continued marketing efforts" of other pharmaceutical products with similar net sales, his assertion that such extensive marketing would not have been required lacks context and support.

Mr. Hofmann Fails to Conduct an Apportionment Analysis After Criticizing Dr. Maness for the Same

In Ex. 2084 at p. 84 line 17 to p. 85 line 7, Mr. Hofmann criticizes Dr. Maness for not apportioning the Restasis® sales and revenues across the prior art patents and across the individual patents-in-suit. Mr. Hofmann acknowledges that Dr. Maness considered apportionment (*see* Ex. 1034 at 250:10-251:9, 251:24-252:21) and determined that it was inappropriate. Ex. 2084 at p. 85 lines 8-23. Mr. Hofmann further admits that he never performed a quantitative apportionment analysis, either across the alleged prior art patents (Ex. 2084 at p. 87 line 15 to p. 88 line 21) or across the individual patents-in-suit (Ex. 2084 at p. 85 line 24 to p. 86 line 17). *See also* Ex. 2084 at p. 89 lines 3 to 10. Mr. Hofmann's testimony is relevant to his statement in ¶ 105 of his declaration (Ex. 1041) that "[t]he failure to apportion the sales and identify nexus to the Patents-at-Issue individually, as well as other drivers of the performance of Restasis®, such as the '979 Patent and '342

Patent, is incomplete, flawed and unreliable." The deposition testimony is relevant because it demonstrates that again, by his own standard, Mr. Hofmann's analysis is flawed.

Mr. Hofmann Is Not Qualified to Interpret Scope of Patent Claims

In Ex. 2084 at p. 14, lines 5 to 8, Mr. Hofmann admitted that he is not an expert in interpreting patent claims related to clinical features of pharmaceutical formulations. Additionally, he testified at p. 99 lines 19 to 23, that "to determine whether a patent is a blocking patent, you have to determine the scope of the claims." Ex. 2084; *see also id.* at p. 80 line 20 to p. 81 line 6. Mr. Hofmann's deposition testimony is relevant to his statements in ¶ 31 of his declaration (Ex. 1041) where he interprets the scope of the Ding '979 patent to encompass Restasis®, and is further relevant to his opinions at ¶¶ 30-38 regarding which patents served as blocking patents, as well as the purported effect these "blocking patents" had on the competitive market for Restasis®. Mr. Hofmann does not cite to any of Petitioner's technical experts for his interpretation of the scope of the Ding '979 patent in ¶ 31. *See* Ex. 1041 at FN 55; Ex. 2084 at p. 66 line 21 to p. 67 line 17. His testimony is relevant because any conclusions Mr. Hofmann draws about certain patents acting as blocking patents stem from his own interpretation of the scope of the patent claims, for which he admits he is not qualified to offer an opinion.

Respectfully submitted,

Date:/July 20, 2017/

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on July 20, 2017, a complete and entire copy of this Patent Owner Allergan, Inc.'s Motion for Observations On the Cross-Examination Testimony of Ivan T. Hofmann was provided via electronic service, to the Petitioner by serving the correspondence address of record as follows:

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