UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SWISS PHARMA INTERNATIONAL AG,
Petitioner

v.

BIOGEN IDEC,
Patent Owner

Case IPR2016-00916
Patent 8,900,577

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

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
Ex. 2001	CURRENT TRENDS IN MONOCLONAL ANTIBODY DEVELOPMENT AND MANUFACTURING (Steven J. Shire, et al., eds., 2010)
Ex. 2002	Theodore W. Randolph & John F. Carpenter, *Engineering Challenges of Protein Formulations*, 53 AIChe J. 1902-07 (2007)
Ex. 2003	RATIONAL DESIGN OF STABLE PROTEIN FORMULATIONS: THEORY AND PRACTICE (John F. Carpenter & Mark C. Manning, eds., 2002)
Ex. 2004	Elizabeth R. Proos, et al., *Long-term Stability and in vitro Release of hPTH(1−34) from a Multi-reservoir Array*, 25(6) Pharm. Res. 1387-95 (2008)
Ex. 2005	HERCEPTIN® FDA Approved Drug Label, dated September 25, 1998
Ex. 2006	SYNAGIS®, *in* PHYSICIANS' DESK REFERENCE 2028-29 (2002)
Ex. 2007	XOLAIR® FDA Approved Drug Label, dated June 20, 2003
Ex. 2008	RAPTIVA® FDA Approved Drug Label, dated October 24, 2003
Ex. 2009	REMICADE® FDA Approved Drug Label, dated October 2, 2015
Ex. 2010	ENTYVIO® FDA Approved Drug Label, dated May 20, 2014
Ex. 2011	David Ouellette, et al., *Comparison of the* in vitro *and* in vivo *stability of a succinimide intermediate observed on a therapeutic IgG1 molecule*, 5(3) mAbs 432-44 (2013)
Ex. 2012	LH Stockwin & S Holmes, *Antibodies as therapeutic agents:* vive la renaissance!, 3(7) Expert Opin. Biol. Ther. 1133-52 (2003)
Ex. 2013	Robert G. Hamilton, THE HUMAN IGG SUBCLASSES (2001)
Ex. 2014	*The Generation of Antibody Diversity, in* MOLECULAR BIOLOGY OF THE CELL 1385-92 (Bruce Alberts, et al., eds., 4th ed. 2002)
Ex. 2015	PROTEIN FORMULATION AND DELIVERY (Eugene J. McNally, ed., 2000)
Ex. 2016	Wei Wang, *Instability, stabilization, and formulation of liquid protein pharmaceuticals*, 185 Int. J. Pharm. 129-88 (1999)
Ex. 2017	Samir Mitagotri, et al., *Overcoming the challenges in administering biopharmaceuticals: formulation and delivery strategies*, 13 Nat.

EXHIBIT	DESCRIPTION
	Rev. Drug Discov. 655-72 (2014)
Ex. 2018	Jeffrey L. Cleland, et al., *The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation, in* CRITICAL REVIEWS IN THERAPEUTIC DRUG CARRIER SYSTEMS 307-77 (Stephen D. Bruck, ed., 1993)
Ex. 2019	Romain Rouet, et al., *Stability engineering of the human antibody repertoire*, 588 FEBS Lett. 269-77 (2013)
Ex. 2020	PHARMACEUTICAL FORMULATION DEVELOPMENT OF PEPTIDES AND PROTEINS (Sven Frokjaer & Lars Hovgaard, eds., e-Library ed. 2003)
Ex. 2021	Shihong Li, Christian Schöneich, et al., *Chemical Instability of Proteins*, 2(5) Pharm. News 12-16 (1995)
Ex. 2022	Olivier Mozziconacci, Christian Schöneich, et al., *Comparative Evaluation of the Chemical Stability of 4 Well-Defined Immunoglobulin G1-Fc Glycoforms*, 105 J. Pharm. Sci. 575-87 (2016)
Ex. 2023	*United States Top 25 Neurological Therapies*, 49(11) Medical Marketing & Media 38 (2014)
Ex. 2024	*Tecfidera Will Be Leading MS Drug In 2015*, BMI Research, May 6, 2015
Ex. 2025	Ingrid Loma & Rock Heyman, *Multiple Sclerosis: Pathogenesis and Treatment*, 9 Curr. Neuropharmacol. 409-16 (2011)
Ex. 2026	Prosecution History of U.S. Patent No. 8,349,321
Ex. 2027	REMICADE® approval letter from the FDA, dated August 24, 1998
Ex. 2028	Sumit Goswami et al., *Developments and Challenges for mAb-Based Therapeutics*, 2 Antibodies 452-500 (2013)
Ex. 2029	SIMULECT®, *in* PHYSICIANS' DESK REFERENCE 2399-401 (2002)
Ex. 2030	Reed J. Harris, et al., *Commercial Manufacturing Scale Formulation and Analytical Characterization of Therapeutic Recombinant Antibodies*, 61 Drug Dev. Res. 137-54 (2004)
Ex. 2031	RITUXAN® FDA Approved Drug Label, dated November 26, 1997
Ex. 2032	WJ Pan, et al., *Pharmacology of AMG 181, a human anti- $\alpha_4\beta_7$ antibody that specifically alters trafficking of gut-homing T cells,*

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	169 Br. J. Pharmacol. 51-68 (2013)
Ex. 2033	Sampathkumar Krishnan, et al., *Development of Formulations for Therapeutic Monoclonal Antibodies and Fc Fusion Proteins*, *in* FORMULATION AND PROCESS DEVELOPMENT STRATEGIES FOR MANUFACTURING PHARMACEUTICALS 383-427 (Feroz Jameel & Susan Hershenson, eds., 2010)
Ex. 2034	Marco van de Weert & Theodore W. Randolph, *Physical Instability of Peptides and Proteins*, *in* PHARMACEUTICAL FORMULATION DEVELOPMENT OF PEPTIDES AND PROTEINS 107-29 (Lars Hovgaard, et al., eds., 2013)
Ex. 2035	Jasmin F. Sydow, et al., *Structure-Based Prediction of Asparagine and Aspartate Degradation Sites in Antibody Variable Regions*, 9(6) PLoS ONE e100736 (2014)
Ex. 2036	Josef Vlasak, et al., *Identification and characterization of asparagine deamidation in the light chain CDR1 of a humanized IgG1 antibody*, 392 Anal. Biochem. 14554 (2009)
Ex. 2037	*Genentech: Survivor Strutting Its Stuff*, The New York Times, Oct. 1, 2000
Ex. 2038	Jerry Cacia, et al., *Isomerization of an Aspartic Acid Residue in the Complementarity-Determining Regions of a Recombinant Antibody to Human IgE: Identification and Effect on Binding Affinity*, 35 Biochem. 1897-903 (1996)
Ex. 2039	Stuart Rudikoff, et al., *Single amino acid substitution altering antigen-binding specificity*, 79 Proc. Natl. Acad. Sci. USA 1979-83 (1982)
Ex. 2040	E. Morrey Atkinson & Wolfgang Klum, *Formulation Strategies for Biopharmaceuticals Ensuring Success to Market*, 4 IDrugs 557-60 (2001)
Ex. 2041	*Genentech, Xoma seeking FDA approval for psoriasis drug*, RBC News, Dec. 24, 2002
Ex. 2042	*CD18 trials disappoint again*, 18 Nature Biotechnology 817−20 (2000)
Ex. 2043	EP Patent Application No. 04709508.8, Grounds in Support of Appeal, Nov. 4, 2010
Ex. 2044	Wim Jiskoot, et al., *Protein Instability and Immunogenicity: Roadblocks to Clinical Application of Injectable Protein Delivery Systems for Sustained Release*, 101 J. Pharm. Sci. 946-54 (2012)

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