

Paper No. _____
Filed: November 17, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,
v.
REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2023-00462
Patent No. 10,464,992

PETITIONER'S UPDATED LIST OF EXHIBITS

Pursuant to 37 C. F. R. § 42.63(e), Petitioner hereby submits a current listing of its exhibits to counsel for Patent Owner. Exhibits 1048 and 1049 were filed on P-TACTS and served via email to Patent Owner’s counsel of record.

Exhibit No.	Description
1001	U.S. Patent No. 10,464,992 (“’992 <i>patent</i> ”)
1002	Declaration of Dr. Ralph Tarantino (“ <i>Tarantino</i> ”)
1003	Dr. Ralph Tarantino <i>curriculum vitae</i>
1004	File History of U.S. Application No. 16/159,269 (“’992 <i>Prosecution History</i> ”)
1005	James D. Andya et al., <i>Mechanisms of Aggregate Formation and Carbohydrate Excipient Stabilization of Lyophilized Humanized Monoclonal Antibody Formulations</i> , 5(2) AAPS PHARMSCI (Apr. 4, 2003) (“ <i>Andya 2003</i> ”)
1006	Byeong S. Chang & Susan Hershenson, <i>Practical Approaches to Protein Formulation Development</i> in RATIONALE DESIGN OF STABLE PROTEIN FORMULATIONS – THEORY AND PRACTICE, 1-25 (J.F. Carpenter and M.C. Manning eds., 2002) (“ <i>Chang 2002</i> ”)
1007	Eva Y. Chi et al., <i>Physical Stability of Proteins in Aqueous Solution: Mechanism and Driving Forces in Nonnative Protein Aggregation</i> , 20 PHARMACEUTICAL RESEARCH 9, 1325-1336 (Sept. 2003) (“ <i>Chi</i> ”)
1008	Napoleone Ferrara & Robert S. Kerbel, <i>Angiogenesis as a Therapeutic Target</i> , 438 NATURE 967-74 (Dec. 15, 2005) (“ <i>Ferrara 2005</i> ”)
1009	Hamish M. Fraser et al., <i>Single Injections of Vascular Endothelial Growth Factor Trap Block Ovulation in the Macaque and Produce a Prolonged, Dose-Related Suppression of Ovarian Function</i> , 90(2) J. CLIN. ENDOCRINOL. & METAB. 1114-1122 (Feb. 2005) (“ <i>Fraser</i> ”)

Exhibit No.	Description
1010	Jocelyn Holash et al., <i>VEGF-Trap: A VEGF Blocker with Potent Antitumor Effects</i> , 99 (17) PNAS 11393-11398 (Aug. 20, 2002) (“ <i>Holash</i> ”)
1011	Janeway et al., <i>The Structure of a Typical Antibody Molecule</i> in IMMUNOBIOLOGY: THE IMMUNE SYSTEM IN HEALTH AND DISEASE, 5th ed., 94-100 (2001) (“ <i>Janeway</i> ”)
1012	Leopold K. Kostanski et al., <i>Size-exclusion Chromatography – a Review of Calibration Methodologies</i> , 58 J. BIOCHEM. BIOPHYS. METHODS 159-186 (2004) (“ <i>Kostanski 2004</i> ”)
1013	Paul McGoff & David S. Scher., <i>Solution Formulation of Proteins/Peptides</i> in PROTEIN FORMULATION AND DELIVERY vol. 99, 139-58 (2000) (“ <i>McNally 2000</i> ”)
1014	Dave A. Parkins & Ulla T. Lashmar, <i>The Formulation of Biopharmaceutical Products</i> , 3(4) PHARM. SCI. & TECH. TODAY 129-137 (Apr. 4, 2000) (“ <i>Parkins</i> ”)
1015	J.S. Rudge et al., <i>VEGF Trap as a Novel Antiangiogenic Treatment Currently in Clinical Trials for Cancer and Eye Diseases, and VelociGene®-based Discovery of the Next Generation of Angiogenesis Targets</i> , 70 COLD SPRING HARBOR SYMPOSIA ON QUANTITATIVE BIOLOGY 411-418 (2005) (“ <i>Rudge</i> ”)
1016	Christine Wulff et al., <i>Prevention of Thecal Angiogenesis, Antral Follicular Growth, and Ovulation in the Primate by Treatment with Vascular Endothelial Growth Factor Trap R1R2</i> , 143(7) ENDOCRINOLOGY 2797-2807 (Jul. 2002) (“ <i>Wulff</i> ”)
1017	Florian M. Wurm, <i>Production of Recombinant Protein Therapeutics in Cultivated Mammalian Cells</i> , 22 NATURE BIOTECHNOLOGY 1393-1398 (Nov. 2004) (“ <i>Wurm</i> ”)
1018	U.S. Patent No. 6,171,586 to Lam et al. (“ <i>’586 Patent</i> ”)
1019	U.S. Patent No. 7,374,758 to Papadopoulos et al. (“ <i>’758 Patent</i> ”)
1020	Application for Extension of Patent Term to U.S. Patent No. 7,374,758 (“ <i>’758 PTE</i> ”)
1021	U.S. Patent No. 8,110,546 to Dix et al. (“ <i>Dix</i> ”)

Exhibit No.	Description
1022	Declaration Pursuant to 37 C.F.R. § 1.131 of Daniel B. Dix, Kelly Frye, and Susan Kautz in Support of U.S. Application No. 12/835,065 (“ <i>Declaration of Dix et al.</i> ”)
1023	Response to Office Action of July 13, 2011 in U.S. Application No. 12/835,065 (“ <i>Nov 22 OA Response</i> ”)
1024	U.S. Patent Publication No. 2003/0113316 to Kaisheva et al. (“ <i>Kaisheva ’316</i> ”)
1025	U.S. Patent Publication No. 2003/0138417 to Kaisheva et al. (“ <i>Kaisheva ’417</i> ”)
1026	U.S. Patent Publication No. 2004/0197324 to Liu et al. (“ <i>Liu</i> ”)
1027	U.S. Patent Publication No. 2004/0265309 to Kandel et al. (“ <i>’309 Publication</i> ”)
1028	U.S. Patent Publication No. 2005/0112061 to Holash et al. (“ <i>’061 Publication</i> ”)
1029	International Publication No. WO 00/75319 to Papadopoulos et al. (“ <i>’319 Publication</i> ”)
1030	International Publication No. WO 97/04801 to Andya et al. (“ <i>WO ’801</i> ”)
1031	<i>Vial</i> , Merriam-Webster.com, https://merriam-webster.com/dictionary/vial (last visited Jan. 16, 2023) (“ <i>Merriam Webster Vial Definition</i> ”)
1032	AVASTIN [®] , <i>Approved Labeling</i> , CENTER FOR DRUG EVALUATION AND RESEARCH (2004) (“ <i>AVASTIN Label</i> ”)
1033	RAPTIVA [®] , <i>Physicians’ Desk Reference</i> (59th ed. 2005) (“ <i>RAPTIVA Label</i> ”)
1034	REMICADE [®] , <i>Physicians’ Desk Reference</i> (59th ed. 2005) (“ <i>REMICADE Label</i> ”)
1035	SIMULECT [®] , <i>Physicians’ Desk Reference</i> (59th ed. 2005) (“ <i>SIMULECT Label</i> ”)
1036	HERCEPTIN [®] , <i>Physicians’ Desk Reference</i> (59th ed. 2005) (“ <i>HERCEPTIN Label</i> ”)

Exhibit No.	Description
1037	XOLAIR [®] label, <i>Physicians' Desk Reference</i> (59th ed. 2005) (" <i>XOLAIR Label</i> ")
1038	Food & Drug Administration, <i>Guidance for Industry, Container Closure Systems for Packaging Human Drugs and Biologics</i> (May 1999) (" <i>FDA Container Closure Guidance</i> ")
1039	Excerpts from Prosecution History of U.S. Application No. 11/818,463 (" <i>'463 Excerpts</i> ")
1040	Excerpts from Prosecution History of U.S. Application No. 12/560,885 (" <i>'885 Excerpts</i> ")
1041	Excerpts from Prosecution History of U.S. Application No. 12/833,417 (" <i>'417 Excerpts</i> ")
1042	Excerpts from Prosecution History of U.S. Application No. 13/329,770 (" <i>'770 Excerpts</i> ")
1043	Excerpts from Prosecution History of U.S. Application No. 13/914,996 (" <i>'996 Excerpts</i> ")
1044	Excerpts from Prosecution History of U.S. Application No. 14/330,096 (" <i>'096 Excerpts</i> ")
1045	Excerpts from Prosecution History of U.S. Application No. 15/095,606 (" <i>'606 Excerpts</i> ")
1046	Excerpts from Prosecution History of U.S. Application No. 15/879,294 (" <i>'294 Excerpts</i> ")
1047	U.S. Department of Health and Human Services, Food & Drug Administration, <i>Guidance for Industry, Guidance for Industry</i> (Aug. 1999) (" <i>FDA Specification Guidance</i> ")
1048	October 13, 2023, Oral Deposition of Dr. Ralph Tarantino (redacted)
1049	PROTECTIVE ORDER MATERIAL: October 13, 2023, Oral Deposition of Dr. Ralph Tarantino (Board and Parties only)

Respectfully submitted,

Dated: November 17, 2023

/ Lora M. Green /

Lora M. Green, Lead Counsel
Reg. No. 43,541

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petitioner's Updated List of Exhibits was served on November 17, 2023, on the Patent Owner at the following electronic correspondence addresses:

Adam R. Brausa ABrausa@mofo.com

Rebecca Weires RWeires@mofo.com

Kira A. Davis KiraDavis@mofo.com

Daralyn J. Durie DDurie@mofo.com

Regeneron-MoFo-IPR@mofo.com

Respectfully submitted,

Date: November 17, 2023

/ Lora M. Green /
Lora M. Green, Lead Counsel
USPTO Reg. No. 43,541