[redacted]

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case No. IPR2021-00816
U.S. Patent No. 9,220,631

DECLARATION OF DR. KENNETH S. GRAHAM

[redacted]

TABLE OF CONTENTS

[redacted]

EXHIBIT LIST

Ex. 1019	U.S. Pharmacopeia, *USP 789, Particulate Matter in Ophthalmic Solutions, USP 34 NF 29* (2011)
Ex. 1066	Australian Government, Department of Health and Ageing, Australian Public Assessment Report for Aflibercept, (July 2012)
Ex. 1137	REGITC00114439 – Regeneron Confidential Report Filed Under Seal
Ex. 1138	REGITC00042686 – Vetter Confidential Report Filed Under Seal
Ex. 1139	REGITC00264748 – Regeneron Confidential Report Filed Under Seal
Ex. 1140	REGITC00149282 – Regeneron Confidential Report Filed Under Seal
Ex. 1141	STERIS_00000489 – Steris Report Filed Under Seal
Ex. 1142	REGITC00122265 – Regeneron Confidential Report Filed Under Seal
Ex. 1143	REGITC00116953 – Vetter Confidential Report Filed Under Seal
Ex. 1144	REGITC01008782 – Vetter Confidential Report Filed Under Seal
Ex. 1145	REGITC00381349 – Regeneron Confidential Report Filed Under Seal
Ex. 1146	REGITC00255816 – Bayer Correspondence with EMEA Filed Under Seal
Ex. 1147	REGITC00883958 – Regeneron Confidential Memorandum Filed Under Seal
Ex. 1148	REGITC00264472 – Regeneron Confidential Memorandum Filed Under Seal
Ex. 1149	REGITC01066319 – Regeneron Confidential Memorandum Filed Under Seal
Ex. 1150	REGITC00149657 – EMA Assessment Report Filed Under Seal
Ex. 1151	REGITC00381924 – Regeneron Confidential Memorandum Filed Under Seal
Ex. 1152	REGITC00041726 – Regeneron Confidential Presentation Filed Under Seal
Ex. 1153	REG_SDNY_02214433 – EMA Correspondence Filed Under Seal
Ex. 1154	REGITC00160863 – Regeneron Confidential Memorandum Filed Under Seal
Ex. 1155	REGITC00110725 – Regeneron Confidential Emails Filed Under Seal
Ex. 1156	REGITC00117031 – Regeneron Confidential FDA Correspondence Filed Under Seal

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I, Kenneth S. Graham, declare as follows:

I. Introduction

1. I am Senior Director at Regeneron Pharmaceuticals, Inc. ("Regeneron") and I have been employed at Regeneron since January 21, 2002.

2. I earned a B.S. in Animal Bioscience from Penn State University in 1983 and an M.S. in Veterinary Science from Penn State University in 1986. I then earned a Ph.D in Bioorganic Chemistry from the California Institute of Technology in 1992.

3. I have worked on Regeneron's biologic drug EYLEA® (aflibercept) ("EYLEA") since 2003. My initial involvement was developing fit for purpose analytical methods that were used to characterize the protein and ensure its quality. While working in the Regeneron pilot manufacturing facility at Tarrytown, New York, I helped to produce and ensure the release of the first clinical batches that were used during development of the drug. In 2005, I transferred pilot manufacturing into pre-clinical development and joined the Formulation Development Group ("FDG").

4. In 2005, I became the FDG Program Lead of EYLEA and was responsible for the development of EYLEA in both vial and pre-filled syringe presentations. My role in the development of EYLEA pre-filled syringe included defining quality attributes, studying the stability of the product, evaluating syringe offerings and specifications from Vetter, evaluating particulate matter and

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siliconization, and evaluating and developing methods of terminally sterilizing the pre-filled syringes.

5. I have personal knowledge of the facts set forth below.

II. Exhibits

6. Exs. 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, and 1153 are true and correct copies of records that were either created or received by an employee of Regeneron as part of that employee's job duties relating to the development of EYLEA and regulatory submissions for EYLEA. The records were maintained by Regeneron in the ordinary course of business.

7. Exs. 1154 and 1155 are true and correct copies of records of email or letter correspondence sent by an employee of Regeneron as part of that employee's job duties relating to the development of EYLEA and regulatory submissions for EYLEA. The records were maintained by Regeneron in the ordinary course of business.

III. Development of EYLEA PFS

8. EYLEA is a biotherapeutic product developed for intravitreal injection that is designed to treat diseases of the eye, such as Wet Age-related Macular Degeneration ("wAMD").

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