UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owners

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

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DECLARATION OF JOHN E. DILLBERGER, DVM, PH.D., IN SUPPORT OF NOVARTIS'S PATENT OWNER RESPONSE

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I. INTRODUCTION

1. I, John E. Dillberger, DVM, Ph.D., submit this declaration on behalf of Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corp. (collectively, "Novartis"), regarding IPR2021-00816. I understand that Regeneron Pharmaceuticals, Inc., ("Petitioner") submitted its petition in IPR2021-00816 ("Petition") challenging the patentability of all claims of U.S. Patent No. 9,220,631 ("the '631 patent").

2. This declaration is the result of my review and analysis of the Petition, the declaration of Mr. Horst Koller (Ex. 1003), and other exhibits submitted in the above referenced IPR proceeding, as well as additional materials relied on herein.

II. BACKGROUND AND QUALIFICATIONS

3. I received a B.S. in Biology from the University of Georgia in 1975 and a D.V.M. degree from Iowa State University in 1979, completed a 3-year residency in Comparative Pathology at the University of Miami School of Medicine and Papanicolaou Cancer Research Institute in 1986, and received a Ph.D. degree in Pathology and Environmental Toxicology from Michigan State University in 1989 for research into the molecular mechanisms of carcinogenesis. I was certified as an expert in Veterinary Pathology by the American College of Veterinary Pathologists in 1987. I was certified as an expert in Toxicology by the American Board of Toxicology in 1992 and have been re-certified every five years

since then. In 2001, I became one of a handful of toxicologic pathologists accepted as a fellow in the International Academy of Toxicologic Pathology, and I served as Treasurer for the organization from 2006 to 2012. I have authored numerous scientific papers and a book chapter entitled "Nonclinical Development of Drugs and Biologics: Pharmacology and Toxicology," served as reviewer for Antimicrobial Agents and Chemotherapy, and served two terms on the editorial board of Veterinary Pathology.

4. I am currently employed full time as president and principal of J. Dillberger, LLC, a nonclinical development consulting company that I founded in 2000. I specialize in the application of toxicology, pathology, and pharmacology expertise to the safety evaluation of drugs, biologics, medical devices, imaging agents, diagnostic agents, and combination products. My clients include biopharmaceutical companies in the USA, Canada, UK, Denmark, Korea, Japan, Italy, Germany, Israel, Australia, and New Zealand; nonprofit foundations; and investment firms with pharmaceutical company portfolios.

5. I have over 30 years of product development experience in the pharmaceutical industry. Over that time, I have held positions of increasing responsibility at Marion Merrell Dow, GlaxoWellcome, Triangle Pharmaceuticals, and Charles River Laboratories, Inc. I served as Head of USA Pathology, Director of Safety Evaluation for USA-Based Development Projects, and Worldwide

Specialist in Oncology Drug Projects for GlaxoWellcome, Director of Toxicology at Triangle Pharmaceuticals, and Senior Director of Research at Charles River Laboratories, Inc. I have prepared or helped prepare safety evaluation packages for numerous clinical trial and marketing applications in the USA and Europe, including the successful NDAs for Coviracil®, Kapvay®, and Northera®, Triferic®, Auryxia®, Sovaldi®, and Pretomanid and CTDs for Thelin®, Tyvaso®, and Maxigesic®.

6. Safety evaluation involves finding existing information and generating new information about a product's potential harmful effects, which might derive from its active ingredient(s), inactive ingredient(s), device components, or packaging. Preparing a safety evaluation package involves critically reviewing and synthesizing this information in written form for use by a company developing the product and by regulatory authorities overseeing such development. Information about a product's potential harmful effects can be found in scientific publications, reviews by expert panels, and reviews by regulatory authorities of previous products that contained the same ingredient or device component or that used the same packaging. Information about a product's potential harmful effects also can be generated by designing, executing, and analyzing the results from studies in cells, tissues, and animals in order to discover and understand the product's effects before it is tested in human subjects or

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