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 Owner

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Case IPR2020-01317 & IPR2020-1318
Patent 9,220,631

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DECLARATION OF KARL R. LEINSING, PE, IN SUPPORT OF NOVARTIS'S PATENT OWNER PRELIMINARY RESPONSE

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I. INTRODUCTION

1. I, Karl R. Leinsing, MSME, PE, submit this declaration on behalf of Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corp. (collectively, "Patent Owner" or "Novartis"), regarding IPR2020-1317 and IPR2020-1318. I understand that Regeneron Pharmaceuticals, Inc. ("Petitioner" or "Regeneron") initiated these proceedings by filing Petitions seeking cancellation of all claims of U.S. Patent No. 9,220,631 ("the '631 patent").

2. The subject of my declaration is the validity of the '631 patent. This declaration is the result of my review and analysis of the petitions, declarations, and prior art submitted by the Petitioner in the above referenced IPR proceedings, as well as additional materials identified herein.

II. BACKGROUND AND QUALIFICATIONS

3. I received a Bachelor of Science (B.S.) degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science (M.S.) degree in mechanical engineering from North Carolina A&T State University in 1995. I am also licensed as a Registered Professional Engineer in the state of New Hampshire.

4. I have been a medical device engineer since 1992 and worked extensively with medical device disposables, including syringes of all types, since that date. I have extensive expertise in the mechanical design and manufacturing

of medical devices. My areas of expertise include full life-cycle product development of medical devices, including conception, patent applications, manufacturing, testing, verification, validation, packaging, bioburden testing, sterility assurance testing, biocompatibility, bacterial contamination testing, labeling, clinical trials, regulatory approval, marketing, and sales training.

5. Since 2006, I have been President of ATech Designs, Inc., where I have worked in the development of various medical devices, including cardiovascular, surgical, intravenous, endoluminal, and percutaneous devices. More specifically, I have consulted in the development of various drug delivery devices, such as auto-injectors, pen injectors, syringes, safety syringes, and insulin pumps, among others.

6. Previously, from 2005 to 2006, I worked as a Director of Biomedical Engineering at Mitralign, Inc., developing implants for heart valve repair. From 2002 to 2005, I worked as a Manager of Design Engineering at ONUX Medical, Inc., developing fixation devices for abdominal aortic aneurysm repair.

7. From 1992 to 2002, I worked as a Senior Principal Design Engineer at IVAC, which was a subsidiary of Eli Lilly & Company. There, I developed a number of medical drug infusion products, including disposable sets and components, IV and syringe pump systems, injection systems, vial adapters, syringes, and needle-free valves for the delivery of drugs. My work involved both

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