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 Owners.

Patent Number: 9,220,631

REPLY DECLARATION OF DR. SZILÁRD KISS

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I. Introduction

1. I have been retained by Petitioner Regeneron Pharmaceuticals, Inc. ("Petitioner" or "Regeneron"), as an independent expert witness in the above-captioned *inter partes* review ("IPR"), in which Regeneron has requested that the U.S. Patent and Trademark Office cancel as unpatentable all claims of U.S. Patent No. 9,220,631 ("the '631 patent"). I previously submitted a declaration in this matter, which I understand was submitted as Ex. 1031.

2. I provide this declaration to respond to certain issues raised in the declarations of Dr. Andrew Calman (Ex. 2204) and Dr. Jeremey Wolfe (Ex. 2206). I also provide this declaration to explain that certain ophthalmology-related subject matter disclosed and claimed in the '631 patent was well-known prior to 2012, and also to specifically opine on the obviousness of proposed substitute claims 50-52.

3. For purposes of this declaration, I have assumed that claim 1 of the '631 patent has separately been shown to be obvious based on the prior art and the Declaration of Horst Koller (Ex. 1003). I have also assumed that proposed substitute claim 27 of the '631 patent has separately been shown to be obvious based on the prior art and the Second Declaration of Horst Koller (Ex. 1105).

II. Qualifications and Compensation

4. The declaration I previously submitted in this matter sets forth my qualifications and compensation. *See* Ex. 1031.

III. Person of Ordinary Skill in the Art

5. As noted in my initial declaration, I reviewed and adopted the definition of a person of ordinary skill in the art ("POSITA") as of July 2012 set forth in the Koller Decl. (Ex. 1003). Specific to claims 24-26, Mr. Koller opined that a POSITA would be an ophthalmologist with some experience administering VEGF-antagonist drugs to patients via the intravitreal route, because claims 24-26 relate to methods of treating a patient suffering from eye disease by administering an ophthalmic solution using a pre-filled syringe.

6. I understand that Novartis and its expert Mr. Leinsing have set forth the following definition for a POSITA:

> A POSA would have had an advanced degree (i.e., an M.S., a Ph.D., or equivalent) in mechanical engineering, biomedical engineering, materials science, chemistry, chemical engineering, or a related field, and at least 2–3 years of professional experience, including in the design of a PFS and/or the development of ophthalmologic drug products or drug delivery devices. Such a person would have been a member of a product development team and would have drawn upon not only his or her own skills, but also the specialized skills of team members in complementary fields including ophthalmology, microbiology and toxicology.

Ex. 2201, ¶ 16. I understand that Dr. Calman has further opined that the product development team would have included someone "who would have had an M.D.

with a specialty in clinical ophthalmology and some experience administering VEGF-antagonist intravitreal injections." Ex. 2204, ¶ 25. As I explained in my initial declaration, I have served as a principal investigator in over three-dozen prospective clinical trials and laboratory investigations related to ophthalmologic drug products or drug delivery devices. I am therefore qualified to provide testimony from the perspective of an individual having specialized skills in ophthalmology that has been involved in the development of ophthalmologic drug products or drug delivery devices. I also have the requisite experience identified by Dr. Calman—namely that I am an M.D. with a specialty in clinical ophthalmology who has experience administering VEGF-antagonist intravitreal injections. Ex. 2204, ¶¶ 25, 40.

7. My opinions regarding the obviousness of claims 24-26 are the same under either definition of a POSITA. In particular, it is my opinion that it would have been obvious to use the syringe of Claim 1 of the '631 Patent according to the method steps recited in claims 24-26 under the definition of a POSITA offered by either Mr. Leinsing and Dr. Calman, or Mr. Koller. Similarly, it is my opinion that it would have been obvious to use the syringe of proposed substitute Claim 27 of the '631 Patent according to the method steps recited in claims 50-52 under the definition of a POSITA offered by either Mr. Leinsing and Dr. Calman, or Mr. Koller.

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