UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX, INC.
Petitioners

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner

Inter Partes Review No.: IPR2021-00881[1]
U.S. Patent No. 9,254,338 B2

EXPERT DECLARATION OF DR. MARY E. GERRITSEN, Ph.D.
IN SUPPORT OF PETITIONER'S REPLY

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[1] IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

TABLE OF CONTENTS

1. My name is Dr. Mary E. Gerritsen and I have been retained by counsel for Mylan Pharmaceuticals, Inc. ("Mylan" or "Petitioner"), to provide my opinions in support of Petitioner's Reply. I am the same Dr. Gerritsen who wrote declarations in support of Mylan's Petition for *Inter Partes* Review of U.S. Patent Nos. 9,669,069 B2 ("'069 patent") and 9,254,338 B2 ("'338 patent"), instituted as IPR2021-00880 and IPR2021-00881, respectively. I also have been asked to reply to the opinions and views of Patent Owner's declarants, Lucian V. Del Priore, M.D., Ph.D., and Alexander M. Klibanov, Ph.D.

I. QUALIFICATIONS AND BACKGROUND.

A. Education and Experience.

2. My qualifications, education, and experience are set forth in my previous report, Ex.1003,[2] and my *curriculum vitae* is attached as Exhibit 1061. I incorporate both as if set forth herein.

B. Bases for Opinions and Materials Considered.

3. In addition to my education, knowledge of the relevant published art, training, and experience, in forming the opinions I provide in this declaration, I have also considered the exhibits cited herein and in Exhibits 2048 and 2049.

[2] Unless otherwise noted, all citations to exhibits refer to exhibits filed in IPR2021-00881.

C. Scope of Work.

4. I have been retained by Petitioner as an expert in this matter to provide various opinions regarding the '069 patent (IPR2021-00880 Ex.1001) and '338 patent (IPR2021-00881 Ex.1001). I receive $350 per hour for my services. No part of my compensation is dependent upon my opinions given or the outcome of this case. I have no financial interest in this matter.

II. LEGAL STANDARDS.

5. For my opinions in this declaration, I understand that it requires applying various legal principles. As I am not an attorney, I have been informed about various legal principles that govern my analysis. I have used my understanding of those principles in forming my opinions. I summarized my understanding of those legal principles in my previous report, Exhibit 1003, and I incorporate that understanding as if set forth herein.

III. PERSON OF ORDINARY SKILL IN THE ART.

6. It is my opinion that a person of ordinary skill in the art ("POSA") would have: (1) knowledge regarding the diagnosis and treatment of angiogenic eye disorders, including the administration of therapies to treat said disorders; and (2) the ability to understand results and findings presented or published by others in the field, including the publications discussed herein. Typically, such a person would

have an advanced degree, such as an M.D. or Ph.D. (or equivalent, or less education but considerable professional experience in the medical, biotechnological, or pharmaceutical field), with practical academic or medical experience in: (i) developing treatments for angiogenic eye disorders, such as age-related macular degeneration ("AMD"), including through the use of VEGF antagonists, or (ii) treating of same, including through the use of VEGF antagonists.

7. I understand that Patent Owner contends that the skilled artisan is an ophthalmologist with experience in treating angiogenic eye disorders, including through the use of VEGF antagonists.

8. My opinions set forth in this declaration remain the same under either Patent Owner's or Petitioner's definition.

IV. THE PRIOR ART DISCLOSED VEGF TRAP-EYE/AFLIBERCEPT.

A. Regeneron Informed the Patent Office that VEGF Trap-Eye Was Encoded by the Sequences in the Prior Art.

9. I have reviewed the declarations of Drs. Klibanov and Del Priore. (Ex.2049, Klibanov Decl.; Ex.2048, Del Priore Decl.). They provide opinions that amount to speculation about what a POSA could have believed about VEGF Trap-Eye and aflibercept. I have also reviewed Regeneron's Patent Owner Response, where they too present arguments that the sequence of VEGF Trap-Eye could have been uncertain to a POSA. (Paper 38, Patent Owner Response, 24-35). I disagree.

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