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.: IPR2021-00880[1]
U.S. Patent No. 9,669,069 B2

EXPERT DECLARATION OF DR. THOMAS A. ALBINI IN SUPPORT OF PETITIONER'S REPLY

[1] IPR2022-00257 and IPR2022-00301 have been joined with this proceeding.

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1. My name is Dr. Thomas A. Albini and I have been retained by counsel for Mylan Pharmaceuticals, Inc. ("Mylan" or "Petitioner"), to provide my opinions in support of Mylan's Petitioner Reply. I am the same Dr. Albini who provided declarations in support of Mylan's Petition for *Inter Partes* Review of U.S. Patent Nos. 9,669,069 B2 ("the '069 patent") and 9,254,338 B2, 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, Diana V. Do, M.D., David M. Brown, M.D., 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, Exhibit 1002, and my *curriculum vitae* is attached as Exhibit 1038. 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, 2049, 2050, and 2051.

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. I receive $500 per hour for my services.

No part of my compensation is dependent upon my opinions given or the outcome of this case. I do not have any current or past affiliation with Regeneron, or any of the named inventors on the '069 patent.

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 1002, 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 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 AMD, including

through the use of VEGF antagonists, or (ii) treating of same, including through the use of VEGF antagonists. (*See* Ex.1002, Albini, ¶¶26-28).

7. Although I disagree with Patent Owner's definition of the POSA, my opinions set forth in this declaration remain the same under either Patent Owner's or Petitioner's definition.

IV. CLAIM CONSTRUCTION.

8. I understand that the Board has found "that no construction of [the claim terms "initial dose," "secondary dose," "tertiary dose," "4 weeks," "*pro re nata* (PRN)," "VEGFR1 Component," "VEGFR2 Component," and "Multimerization Component"] is necessary for the purposes of this Decision to Institute a trial." (Paper 21, Institution Decision, 7). I further understand that "Patent Owner does not advance claim construction positions for these terms at this time because construction of these terms is not necessary to resolve the arguments presented in its Preliminary Response." (*Id*.). However, if the Board decides that it is necessary to construe these terms in this IPR, it should do so consistently with the constructions that I have proposed in my opening declaration, IPR2021-00880, Ex.1002.

9. I understand that Patent Owner has taken the position that the phrase "assessed by a physician or other qualified medical professional" is a positive claim limitation. (*See* Paper 21, Institution Decision, 31 n.12). I have been asked whether

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