UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner

_____

Case IPR2021-00880[1]
Patent 9,669,069 B2

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Case IPR2021-00881
Patent 9,254,338 B2

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EXPERT DECLARATION OF ALEXANDER M. KLIBANOV, Ph.D.

CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER

[1] IPR2022-00257, IPR2022-00258, IPR2022-00298, and IPR2022-00301 have been joined with this proceeding.

Mylan v. Regeneron
IPR2021-00880
U.S. Pat. 9,669,069
Exhibit 2049

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B. Adis R&D Profile (Ex. 1007)....14

C. Regeneron (8-May-2008) (Ex. 1013)....16

D. NCT-795 and NCT-377 (Ex. 1014 and Ex. 1015)....17

E. Heier-2009 (Ex. 1020)....17

F. Regeneron (30-April-2009) (Ex. 1028)....18

X. The Challenged Claims Are Not Anticipated....18

A. The Prior Art Did Not Disclose That VEGF Trap-Eye Necessarily Has the Same Amino Acid Sequence as Aflibercept....18

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1. A POSA would not understand Dixon's phrase "molecular structure" to necessarily correspond to the amino acid sequence 19
2. A POSA would understand that VEGF Trap-Eye could encompass a genus of protein sequences 28
3. None of Petitioner's references discloses that VEGF Trap Eye corresponds to—and only to—the recited sequences.....38
B. Knowledge of the Amino Acid Sequence of VEGF Trap-Eye Alone Would Not Necessarily Result in Treatment.....41

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I, Alexander Klibanov, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained by counsel for Regeneron Pharmaceuticals, Inc. ("Regeneron") as a technical expert in connection with the above-captioned proceeding. I have been asked to provide my opinions and views on the materials I have reviewed in relation to the Petition for *Inter Partes* review of U.S. Patent No. 9,254,338 ("the '338 Patent") (Ex. 1001)[2] and the Petition for *Inter Partes* review of U.S. Patent No. 9,669,069 ("the '069 Patent") (Ex. 1019). In particular, I have been asked to comment on the state of the relevant art as of the earliest filing date ("priority date") of the '338 and '069 Patents and to respond to the opinions and views of Petitioner's declarant, Thomas A. Albini, M.D. I submit this declaration in support of Regeneron's Patent Owner Responses ("PORs").

2. I am being paid for my time spent working on this matter at my usual and customary hourly rate. I have no personal or financial stake in, or affiliation with, the petitioner, real-parties-in-interest, or the patent owner. My compensation is not dependent upon the outcome of, or my testimony in, the present proceeding.

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

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II. QUALIFICATIONS AND EXPERIENCE

3. I am currently a Professor Emeritus of Chemistry and Bioengineering at the Massachusetts Institute of Technology ("M.I.T."), where I taught and conducted research for over 40 years. From 2014 to 2019 (and also from 2007 to 2012), I held the Novartis Endowed Chair Professorship at M.I.T. From 2012 to 2014, I held the Roger and Georges Firmenich Endowed Chair Professorship in Chemistry. Prior to that, I was a Professor of Chemistry and a Professor of Bioengineering at M.I.T., positions I held from 1988 and 2000, respectively. From 1979 to 1988, I was an Assistant Professor, then Associate Professor, and thereafter a Full Professor of Applied Biochemistry in the Department of Applied Biological Sciences (formerly the Department of Nutrition and Food Science) at M.I.T.

4. I obtained my M.S. degree in Chemistry from Moscow University in Russia in 1971 and Ph.D. in Chemical Enzymology from the same University in 1974. Thereafter, I was a Research Chemist at Moscow University's Department of Chemistry for three years. From 1977 to 1979, following my immigration to the United States, I was a Post-Doctoral Associate at the Department of Chemistry, University of California in San Diego.

5. Over the last 50 years as a practicing chemist, I have extensively researched, published, taught, and lectured in many areas of chemistry, including biological, protein, medicinal, and formulation chemistry.

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