

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

Case No. IPR2021-00881¹
U.S. Patent No. 9,254,338 B2

**EXPERT DECLARATION OF IVAN T. HOFMANN
IN SUPPORT OF PETITIONER REPLY**

¹ I understand that IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

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I, Ivan T. Hofmann, hereby declare as follows

I. INTRODUCTION

1. I am over the age of eighteen and am competent to make this declaration.

2. I have been retained as an independent expert on behalf of Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) to provide economic analysis in the above-captioned *inter partes* review (“IPR”).

3. I understand that this IPR involves U.S. Patent No. 9,254,338 B2 (the “’338 Patent” or the “Patent-at-Issue”).² The Patent-at-Issue is entitled “Use of a VEGF Antagonist to Treat Angiogenic Eye Disorders,” issued on February 9, 2016, I understand claims priority to a provisional application filed on January 13, 2011, and expires on or about May 22, 2032.³ I understand that George D. Yancopoulos is the named inventor on the ’338 Patent and that, according to United States Patent and Trademark Office (“USPTO”) records, the ’338 Patent is assigned to Regeneron

² EX 1001 (’338 Patent).

³ EX 1001 (’338 Patent); and EX 1166 (<https://purplebooksearch.fda.gov/patent-list>, accessed May 13, 2022).

Pharmaceuticals, Inc. (“Regeneron”).⁴ I understand that the ’338 Patent claims a method for treating an angiogenic eye disorder in a patient by sequentially administering a single initial dose of a vascular endothelial growth factor (“VEGF”) antagonist, followed by one or more secondary doses of the VEGF antagonist two to four weeks after the immediately preceding dose, followed by one or more tertiary doses of the VEGF antagonist at least eight weeks after the immediately preceding dose.⁵ I further understand that the VEGF antagonist claimed in the ’338 Patent is aflibercept.⁶

4. I have been asked to review and respond to the Expert Declaration of Richard Manning, Ph.D., dated February 11, 2022 (the “Manning Declaration”)⁷ as

⁴ EX 1001 (’338 Patent).

⁵ EX 1002 (Expert Declaration of Dr. Thomas A. Albini in Support of Petition for *Inter Partes* Review of U.S. Patent No. 9,254,338 B2, dated May 4, 2021 (the “Albini Declaration”), pars. 36-37).

⁶ EX 1002 (Albini Declaration, par. 44). I understand that VEGF Trap-Eye is aflibercept. (*Id.*).

⁷ EX 2052 (Manning Declaration).

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