Exhibit 15

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED** **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**

REPLY EXPERT REPORT
OF BERNHARDT L. TROUT, PH.D.

I declare that the following is, to the best of my knowledge and belief, true and correct.

Dated: March 30, 2023

Bernhardt L. Trout, Ph.D.

TABLE OF CONTENTS

I. Introduction

1. I have been asked by counsel for Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff") to serve as an expert and provide my professional opinions regarding certain issues relating to U.S. Patent Nos. 11,084,865 (the "'865 patent") and 11,253,572 (the "'572 patent").

2. I understand Defendant Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant") seeks FDA approval of Biologics License Application ("BLA") No. 761274 to manufacture and sell a biosimilar version of Regeneron's EYLEA® (aflibercept) product ("M710").

3. On February 2, 2023, I submitted an expert report in which I explained the bases for my opinion that Mylan infringes claims 4, 7, 9, 11, and 14-18 (i.e., the asserted claims of the '865 patent, the "'865 Asserted Claims") of the '865 patent.

4. In this report, I have been asked by counsel for Regeneron to respond to the opinions expressed in the Responsive Expert Report of Gregory MacMichael Regarding Noninfringement dated March 2, 2023.

II. M710 infringes at least claims 4, 7, 9, 11, and 14-18 of the '865 patent

5. In my Opening Report, I opined that M710 infringes claims 4, 7, 9, 11, and 14-18 of the '865 patent. Opening Report ¶ 4.

6. Dr. MacMichael has not offered any response or otherwise disagreed with my opinion that M710 meets the specific limitations set forth in dependent claims 7, 9, 11, and 14-17 of the '865 patent. The only limitations addressed by Dr. MacMichael are "organic co-solvent" (as recited in claim 1, from which the '865 Asserted Claims depend), "native conformation" (as recited in claim 1), and "wherein said formulation does not contain phosphate" (as recited in claim 18). MacMichael Responsive ¶¶ 38-96.

7. The '865 Asserted Claims, and the claims from which they depend, are set forth below:

> 1. A vial comprising an ophthalmic formulation suitable for intravitreal administration that comprises:
>
> a vascular endothelial growth factor (VEGF) antagonist
>
> an organic co-solvent,
>
> a buffer, and
>
> a stabilizing agent,
>
> wherein said VEGF antagonist fusion protein is glycosylated and comprises amino acids 27-457 of SEQ ID NO:4; and
>
> wherein at least 98% of the VEGF antagonist is present in native conformation following storage at 5° C. for two months as measured by size exclusion chromatography.
>
> 2. The vial of claim 1, wherein the concentration of said VEGF antagonist fusion protein is 40 mg/ml, and wherein said organic co-solvent comprises polysorbate.
>
> 4. The vial of claim 2, wherein said organic co-solvent comprises about 0.03% to about 0.1% polysorbate 20.
>
> 5. The vial of claim 2, wherein said organic co-solvent comprises 0.01% to 3% polysorbate 20.
>
> 7. The vial of claim 5, wherein said buffer comprises 5-25 mM buffer.
>
> 9. The vial of claim 5, wherein said buffer comprises a pH about 6.2-6.3.
>
> 10. The vial of claim 5, wherein said stabilizing agent comprises a sugar.
>
> 11. The vial of claim 10, wherein said sugar is selected from the group consisting of sucrose, sorbitol, glycerol, trehalose, and mannitol.
>
> 14. The vial of claim 5, wherein said VEGF antagonist fusion protein is glycosylated at asparagine residues corresponding to asparagine residues 62, 94, 149, 222 and 308 of SEQ ID NO: 4.

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