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

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No.: 1:22-cv-00061-TSK

MYLAN PHARMACEUTICALS INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant") by and through its undersigned attorneys, hereby submits its Answer, Defenses, and Counterclaims to the Complaint of Plaintiff, Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff"), as follows:

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Mylan denies each and every allegation in the Complaint, whether express or implied, except those specifically and expressly admitted below. Any factual allegation admitted below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculation that may arguably follow from the admitted facts. To the extent any allegation in the Complaint is vague and/or ambiguous, Mylan denies such allegations. Mylan denies that Plaintiff is entitled to the relief requested or any other relief.

The headings and subheadings in Mylan's Answer are used solely for purposes of convenience and organization to mirror those appearing in the Complaint; to the extent that any headings or other non-numbered statements in the Complaint contain or imply any allegations,

Mylan denies each and every allegation therein. Each of the numbered paragraphs in the Answer below corresponds to the same-numbered paragraphs in the Complaint.

RESPONSES TO ALLEGATIONS PERTAINING TO NATURE OF THE ACTION

1. Regeneron is a leading science-based American biotechnology company dedicated to improving human health and tackling the most urgent medical issues facing the Nation. Founded and led for over 30 years by physician-scientists, Regeneron has developed life-transforming medicines for people with serious diseases, including cancer, atopic dermatitis, asthma, eye diseases, cardiovascular and metabolic diseases, Ebola, and COVID-19, the latter of which has been used across the country, including by the former President. Regeneron's cutting-edge scientific advances were supported, in large part, by its ophthalmic product, Eylea®, which FDA approved in 2011.

ANSWER: Mylan admits that, according to the online records of the Food and Drug Administration ("FDA"), the "Original Approval" date for Biologic License Application ("BLA") No. 125387 for Eylea® (aflibercept), is identified as on or about November 18, 2011. Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 1 of the Complaint and, on that basis, denies all remaining allegations of this paragraph.

2. Eylea® has been administered millions of times to treat certain ophthalmic disorders that, if left untreated, can lead to permanent blindness. Its active ingredient is a genetically engineered fusion protein called aflibercept. It works by blocking the overproduction of a naturally occurring protein in the eye that can cause the formation of new blood vessels, leading to vision loss. Based on extensive clinical testing by Regeneron, FDA approved Eylea® in 2011 to treat an ophthalmic disorder called neovascular age-related macular degeneration. As a result of

Regeneron's additional clinical testing, Eylea® is now also approved for use in treating other serious disorders of the eye: diabetic macular edema, macular edema following retinal vein occlusion, and diabetic retinopathy. And other clinical trials are ongoing, including to treat a retinal disease in premature babies called retinopathy of prematurity. In addition to benefitting the many patients it has been used to treat, Eylea® is also a critical source of research and development funding for Regeneron.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that aflibercept is the active ingredient in Eylea®; that aflibercept can inhibit certain proteins that promote angiogenesis (or formation of blood vessels) in the eye; that, according to FDA's online records, the "Approval Date" for BLA No. 125387 for Eylea® (aflibercept), is identified as on or about November 18, 2011; and that, according to the currently approved label for Eylea® (aflibercept), available from the online records of FDA, FDA has approved Eylea® (aflibercept) for the following indications:

INDICATIONS AND USAGE

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD) (1.1)
- Macular Edema Following Retinal Vein Occlusion (RVO) (1.2)
- Diabetic Macular Edema (DME) (1.3)
- Diabetic Retinopathy (DR) (1.4)

Mylan lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 2 of the Complaint and, on that basis, denies all remaining allegations of this paragraph.

3. Last October, Mylan filed for FDA approval under the BPCIA to commercialize a "biosimilar" copy of Eylea®. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for a substantially abbreviated regulatory approval pathway for biosimilars by letting applicants rely on the extensive clinical testing previously conducted, at great expense, by the

innovator company that developed the medicine the applicant wants to copy. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017).

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval process for biologic products, known as biosimilar products, that are "highly similar to the reference product" and exhibit "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i); *see also* 42 U.S.C. § 262(k). Answering further, Mylan admits that, on or about October 29, 2021, Mylan Pharmaceuticals Inc. submitted Biologic License Application (or BLA) No. 761274 to FDA, seeking approval of M710 (or YESAFILI), a proposed biosimilar to EYLEA®. To the extent that there are other allegations contained in paragraph 3 not expressly admitted above, such allegations are denied.

4. On December 28, 2021, FDA notified Mylan that its application—i.e., its abbreviated Biologic License Application, or "aBLA" No. 761274—for M710 had been accepted for review. Mylan's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e).

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, pursuant to 42 U.S.C. § 262(k), Mylan Pharmaceuticals Inc. submitted its BLA No. 761274 to FDA seeking approval of M710, a proposed biosimilar to EYLEA® ("Mylan's Proposed BLA Product"). Mylan further admits that FDA notified Mylan that its BLA had been accepted for review on or about December 28, 2021. To the extent that there are other allegations contained in paragraph 4 not expressly admitted above, such allegations are denied.

5. By statute, Regeneron could not immediately file a lawsuit for Mylan's § 271(e) infringement. The BPCIA prohibits filing such a suit until certain requirements of 42 U.S.C. § 262(*l*), commonly called the "patent dance," are satisfied. In the patent dance, the BPCIA directs exchanges of certain information between the innovator company (or "reference product sponsor") and the biosimilar (or "subsection (k)") applicant. At the end of the patent dance, the reference product sponsor is authorized to initiate litigation against the biosimilar applicant within thirty days in a venue of its choosing. Mylan, the subsection (k) applicant, and Regeneron, the reference product sponsor, completed the final step of the patent dance—the exchange of lists of patents pursuant to § 262(*l*)(5)—on July 5. Regeneron then promptly brought this action as required by § 262(*l*)(6) to address Mylan's patent infringement under § 271(e).

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that "[t]he BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017) (citing 42 U.S.C. § 262(*l*)). Mylan further admits that the BPCIA scheme includes multiple steps, including disclosure of information, potential resolution of patent disputes, and if necessary and appropriate, the commencement of a patent infringement action. Answering further, Mylan admits that, on July 5, 2022, pursuant to 42 U.S.C. § 262(*l*)(5)(B)(i), the parties exchanged the lists of patents that each party believed should be the subject of an action for patent infringement. Mylan denies any remaining allegations contained in paragraph 5 of the Complaint, including that Regeneron "promptly" filed the current patent infringement action against Mylan.

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