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 FIRST AMENDED ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Mylan Pharmaceuticals Inc. ("Mylan" or "Defendant") by and through its undersigned attorneys, hereby submits its First Amended Answer, Defenses, and Counterclaims ("First Amended Answer") 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 First Amended 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 First Amended 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.

RESPONSES TO ALLEGATIONS PERTAINING TO THE PARTIES, JURISDICTION, AND VENUE

6. Regeneron Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York, with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases. Regeneron owns each of the patents asserted in this Complaint: U.S. Patent Nos. 7,070,959; 9,222,106; 9,254,338; 9,669,069; 9,816,110; 10,130,681; 10,406,226; 10,415,055; 10,464,992; 10,669,594; 10,857,205; 10,888,601; 10,927,342; 10,973,879; 11,053,280; 11,066,458; 11,084,865; 11,104,715; 11,174,283; 11,186,625; 11,253,572; 11,299,532; 11,306,135; and 11,332,771 (collectively, the "asserted patents" or the "patents in suit").

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the electronic records of the United States Patent and Trademark Office ("PTO") identify Regeneron as the purported "assignee" of U.S. Patent Nos. 7,070,959 ("the '959 patent"), 9,222,106 ("the '106 patent"), 9,254,338 ("the '338 patent"), 9,669,069 ("the '069 patent"), 9,816,110 ("the '110 patent"), 10,130,681 ("the '681 patent"), 10,406,226 ("the '226 patent"), 10,415,055 ("the '055 patent"), 10,464,992 ("the '992 patent"), 10,669,594 ("the '594 patent"), 10,857,205 ("the '205 patent"), 10,888,601 ("the '601 patent"), 10,927,342 ("the '342 patent"), 10,973,879 ("the '879 patent"), 11,053,280 ("the '280 patent"), 11,066,458 ("the '458 patent"), 11,084,865 ("the '865 patent"), 11,104,715 ("the '715 patent"), 11,174,283 ("the '283 patent"), 11,186,625 ("the '625 patent"), 11,253,572 ("the '572 patent"), 11,299,532 ("the '532 patent"), 11,306,135 ("the '135 patent"), and 11,332,771 ("the '771 patent") (collectively, "the Patents-in-Suit"). Mylan lacks sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 6 of the

Complaint and, on that basis, denies them.

7. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Viatris Inc. ("Viatris").

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that it is a West Virginia corporation with a place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505. Answering further, Mylan admits that it is an indirect wholly-owned subsidiary of Viatris Inc. To the extent there are allegations contained in paragraph 7 not expressly admitted above, such allegations are denied.

8. On information and belief, Mylan develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state, including West Virginia, either directly or indirectly.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Mylan admits that it develops, manufactures and sells pharmaceutical and biologic drug products. To the extent there are allegations contained in paragraph 8 not expressly admitted above, such allegations are denied.

9. Regeneron's claims for patent infringement arise under the patent laws of the United States, Titles 35 and 42 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that Regeneron purports to bring suit under 35 U.S.C. § 271(e). To the extent there are allegations contained in paragraph 9 not expressly

admitted above, such allegations are denied.

10. Mylan and its development partners have publicly announced their intention to ignore Regeneron's patent rights and launch an aflibercept biosimilar product before the expiration of the patents asserted in this action.

ANSWER: Denied.

11. On information and belief, Momenta Pharmaceuticals Inc. is or was Mylan's development partner for its proposed aflibercept biosimilar product. In August 2020, Momenta publicly announced that it "believe[d]" its collaboration with Mylan to market an aflibercept biosimilar product "has the potential to launch in the 2023 time frame,"[1] before the expiry of the asserted patents.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent and answer is required, Mylan admits that Momenta Pharmaceuticals Inc., Form 10-Q, at 26 (Aug. 10, 2020), https://seekingalpha.com/filings/pdf/14323380, states:

> While we have terminated all future development of any new or early stage biosimilar and complex generic products, we have retained our commercial partnership with Sandoz AG, or Sandoz, for our generic versions of COPAXONE and LOVENOX, which are approved products. We believe that Sandoz's sales of GLATOPA, our generic version of COPAXONE, can generate cash flow to help fund our novel pipeline. Enoxaparin Sodium Injection, our generic version of LOVENOX, is not currently marketed by Sandoz. In addition, we are developing an EYLEA biosimilar, in collaboration with Mylan Ireland Limited, or Mylan, a wholly-owned indirect subsidiary of Mylan N.V., which is currently conducting a clinical trial in patients. If the results from this study are supportive, we believe this program has the potential to launch in the 2023 time frame and help fund our novel portfolio.

To the extent there are allegations contained in paragraph 11 not expressly admitted above, such allegations are denied.

12. Viatris later announced its intention to become the "first to market" an aflibercept biosimilar product. Rajiv Malik, the president of Viatris, explained that becoming "the first to

[1] Momenta Pharmaceuticals Inc., Form 10-Q, at 26 (Aug. 10, 2020), https://seekingalpha.com/filings/pdf/14323380.

market [an aflibercept biosimilar product] is becoming [sic] decisive advantage. And that's where we're going to focus on that how can we be the first to market."[2]

ANSWER: Mylan admits that Goldman Sachs 42nd Annual Global Healthcare Conference, Viatris Inc. Presentation (June 10, 2021), https://seekingalpha.com/article/4434224-viatris-inc-vtrs-management-presents-goldman-sachs-42nd-annual-global-healthcare-conference, states:

> opportunity like -- now I'm excited by Eylea. I think we are still -- because as you have seen by this time, not in USA, everywhere else also, the first to market is becoming decisive advantage. And that's where we're going to focus on that how can we be the first to the market. And Eylea is, you know, we just had successful readout for

To the extent there are allegations contained in paragraph 12 not expressly admitted above, such allegations are denied.

13. This Court has personal jurisdiction over Mylan because it is incorporated in the State of West Virginia; because Mylan is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of M710 in the United States, including in the State of West Virginia; and because, if its product receives FDA approval, Mylan intends to market, distribute, offer for sale, and/or sell it in the United States, including in the State of West Virginia, deriving substantial revenue therefrom.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for the purposes of this litigation only, Mylan does not contest personal jurisdiction in this judicial District. To the extent there are allegations contained

[2] Goldman Sachs 42nd Annual Global Healthcare Conference, Viatris Inc. Presentation (June 10, 2021), https://seekingalpha.com/article/4434224-viatris-inc-vtrs-management-presents-goldman-sachs-42nd-annual-global-healthcare-conference.

in paragraph 13 not expressly admitted above, such allegations are denied.

14. In addition, Mylan has consented to jurisdiction in the State of West Virginia in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Mylan pharmaceutical products in the United States, including in the State of West Virginia.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for the purposes of this litigation only, Mylan does not contest personal jurisdiction in this judicial District. To the extent there are allegations contained in paragraph 14 not expressly admitted above, such allegations are denied.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and § 1400(b). Venue is proper because Mylan Pharmaceuticals Inc. is incorporated in the State of West Virginia and resides in this judicial district.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for the purposes of this litigation only, Mylan does not contest venue under 28 U.S.C. § 1400(b) in this judicial District. To the extent there are allegations contained in paragraph 15 not expressly admitted above, such allegations are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO FACTUAL BASIS FOR RELIEF

16. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is "biosimilar" to a previously licensed "reference product" such as Eylea®. 42 U.S.C. § 262(k). In order to be approved, biosimilars must be "highly similar to the reference product notwithstanding minor differences in clinically inactive components," with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *Id.* § 262(i)(2)(A)-(B).

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that the BPCIA created an abbreviated approval process for 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). To the extent that there are other allegations contained in paragraph 16 not expressly admitted above, such allegations are denied.

17. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Mylan to rely on most of the prior clinical testing that Regeneron conducted to establish the safety and efficacy of the reference product (Eylea®). Regeneron, the reference product sponsor, invested many years of effort into its design and development of Eylea® and received numerous patents rewarding this research. In exchange for this accelerated and far less expensive application process, the BPCIA obligates a biosimilar applicant to address a reference product sponsor's relevant patents in a manner that permits adjudication of patent rights before commercialization of the biosimilar product. The BPCIA does so, *inter alia*, through its patent dance.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the BPCIA describes a process whereby the reference product sponsor and the biosimilar applicant exchange information in advance of a specific and statutorily prescribed action for patent infringement, often referred to as the "patent dance." To the extent that there are other allegations contained in paragraph 17 not expressly admitted above, such allegations are denied.

18. The patent dance between Regeneron and Mylan proceeded substantially as follows within the timeframes specified in the BPCIA. Mylan informed Regeneron that its aBLA for M710

was accepted for FDA review on December 28, 2021. Mylan provided Regeneron access to Mylan's aBLA through an online review platform. Under § 262(*l*)(3)(A), Regeneron next provided Mylan with a list of patents for which "a claim of patent infringement could reasonably be asserted" if Mylan commercialized its product. Under § 262(*l*)(7), Regeneron also provided to Mylan a "supplement to the list" for several additional patents that issued following Regeneron's service of its original patent list provided under § 262(*l*)(3)(A).

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that it alerted Regeneron that its BLA was accepted for review on or about December 28, 2021; that Mylan provided Regeneron with access to Mylan's BLA and other information that describes the process or processes used to manufacture Mylan's Proposed BLA Product pursuant to 42 U.S.C. § 262(*l*)(2)(A) on or about January 17, 2022; that Regeneron purported to provide a list pursuant to § 262(*l*)(3)(A) on or about February 22, 2022; and that Regeneron purported to provide supplements to its § 262(*l*)(3)(A) list through the mechanism provided by § 262(*l*)(7). To the extent that there are other allegations contained in paragraph 18 not expressly admitted above, such allegations are denied.

19. Upon receiving Regeneron's patent lists, Mylan served "detailed statements" for the patents on the original or supplemental list. By statute, a biosimilar applicant's detailed statements must either represent that it will not begin commercial marketing of its biosimilar product before the patent expires (under § 262(*l*)(3)(B)(ii)(II)) or allege that the patent is invalid, unenforceable, or not infringed (under § 262(*l*)(3)(B)(ii)(I)). Remarkably, Mylan's "detailed statements" respected not one of Regeneron's patents; rather, according to Mylan, every one of Regeneron's listed patents is not infringed, invalid, and unenforceable.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) states:

> a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application.

42 U.S.C. § 262(*l*)(3)(B)(ii)(I). Mylan further admits that on or about April 14, 2022, Mylan provided Regeneron with detailed statements pursuant to § 262(*l*)(3)(B)(ii)(I) and on or about May 5 and June 16, 2022, Mylan provided detailed statements in response to Regeneron's § 262(*l*)(7) supplements, setting forth Mylan's description of the factual and legal bases as to why the listed patents are invalid, unenforceable, or not infringed. Mylan further admits that its detailed statements satisfied all statutory requirements. To the extent that there are other allegations contained in paragraph 19 not expressly admitted above, such allegations are denied.

20. Under § 262(*l*)(3)(C), Regeneron provided its detailed responses to Mylan's contentions, setting forth particular grounds for infringement based on the confidential information in Mylan's aBLA and rebutting Mylan's noninfringement, invalidity and unenforceability allegations. Regeneron did not contend infringement on one of the patents on its list and informed Mylan it did not plan to assert that patent.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that Regeneron informed Mylan that it did not intend to assert U.S. Patent No. 10,828,345. To the extent that there are other allegations contained in paragraph 20 not expressly admitted above, such allegations are denied.

21. Next, under § 262(*l*)(4)(A), Regeneron initiated negotiations over which patents on Regeneron's list should be litigated in a § 271(e) infringement action. Regeneron proposed litigating a targeted subset of the listed patents, in order to facilitate the Court's adjudication of the parties' primary disputes on a full record before approval of Mylan's product. Mylan refused to do

so. Instead, it proposed to litigate twenty-five of the listed patents. Next, under § 262(*l*)(5)(B), the parties exchanged the lists of patents that each believed should be part of the infringement action under § 271(e). Mylan listed twenty-five patents, whereas Regeneron listed twelve (each of which was also on Mylan's list).

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that it listed twenty-five patents and Regeneron listed twelve patents on the parties' respective § 262(*l*)(5)(B) lists. To the extent that there are other allegations contained in paragraph 21 not expressly admitted above, such allegations are denied.

22. If the parties disagree on the patents that should be part of the litigation, § 262(*l*)(6)(B) requires the innovator company to bring suit on every patent selected by either party. Thus, despite Regeneron's efforts to focus this case on a targeted subset of asserted patents, Mylan's expansive listing of patents requires Regeneron by statute to include each one of those patents in this Complaint. Regeneron therefore brings this action for infringement of twenty-four patents,[3] while remaining amenable to approaches for streamlining this proceeding in conformity with the BPCIA's goal of adjudicating patent disputes before approval or commercialization of the proposed biosimilar product.[4]

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that Plaintiff's Complaint alleges infringement of

[3] The twenty-four patents include each of Mylan's listed patents minus the one patent for which Regeneron did not serve contentions and no longer asserts against Mylan.

[4] The infringement allegations in this Complaint do not reference any specific content of Mylan's aBLA, which Mylan has designated as confidential under an agreement pursuant to 42 U.S.C. § 262(*l*)(1)(A). To be clear, Regeneron has already served upon Mylan hundreds of pages of detailed contentions setting forth and putting Mylan on notice of the factual and legal basis for the allegations made in this lawsuit.

twenty-four (24) patents. To the extent there are allegations contained in paragraph 22 not expressly admitted above, such allegations are denied.

RESPONSES TO ALLEGATIONS PERTAINING TO FIRST CAUSE OF ACTION (THE '959 PATENT)

23. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

24. United States Patent No. 7,070,959 (the "'959 patent") (Exhibit 1 hereto), was duly and legally issued on July 4, 2006.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '959 patent indicates that it issued on or about July 4, 2006, and that Regeneron purports to attach a copy of the '959 patent as Exhibit 1 to the Complaint. Mylan denies any suggestion that the '959 patent was duly and legally issued, as well as any suggestion or implication that the '959 patent is valid or enforceable or that Mylan infringes any claim of the '959 patent. To the extent there are allegations contained in paragraph 24 not expressly admitted above, such allegations are denied.

25. Regeneron is the owner of all right, title, and interest in the '959 patent.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '959 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 25 not expressly admitted above, such allegations are denied.

26. The '959 patent has not yet expired.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining

allegations of paragraph 26, and therefore denies the same.

27. The '959 patent claims a method of producing aflibercept and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '959 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 27 not expressly admitted above, such allegations are denied.

28. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '959 patent is an act of infringement of one or more claims of the '959 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

29. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 11 of the '959 patent.

ANSWER: Denied.

30. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '959 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

31. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '959 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

32. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '959 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO SECOND CAUSE OF ACTION (THE '106 PATENT)

33. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

34. United States Patent No. 9,222,106 (the "'106 patent") (Exhibit 2 hereto), was duly and legally issued on December 29, 2015.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '106 patent indicates that it issued on or about December 29, 2015, and that Regeneron purports to attach a copy of the '106 patent as Exhibit 2 to the Complaint. Mylan denies any suggestion that the '106 patent was duly and legally issued, as well as any suggestion or implication that the '106 patent is valid or enforceable or that Mylan infringes any claim of the '106 patent. To the extent there are allegations contained in paragraph 34 not expressly admitted above, such allegations are denied.

35. Regeneron is the owner of all right, title, and interest in the '106 patent.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '106 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 35 not expressly admitted above, such allegations are denied.

36. The '106 patent has not yet expired.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 36, and therefore denies the same.

37. The '106 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '106 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 37 not expressly admitted above, such allegations are denied.

38. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '106 patent is an act of infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

39. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 20 of the '106 patent.

ANSWER: Denied.

40. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '106 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

41. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '106 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

42. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '106 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THIRD CAUSE OF ACTION (THE '338 PATENT)

43. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

44. United States Patent No. 9,254,338 (the "'338 patent") (Exhibit 3 hereto), was duly and legally issued on February 9, 2016.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '338 patent indicates that it issued on or about February 9, 2016, and that Regeneron purports to attach a copy of the '338 patent as Exhibit 3 to the Complaint. Mylan denies any suggestion that the '338 patent was duly and legally issued, as well as any suggestion or implication that the '338 patent is valid or enforceable or that Mylan infringes any claim of the '338 patent. To the extent there are allegations contained in paragraph 44 not expressly admitted above, such allegations are denied.

45. Regeneron is the owner of all right, title, and interest in the '338 patent.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '338 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 45 not expressly admitted above, such allegations are denied.

46. The '338 patent has not yet expired.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 46, and therefore denies the same.

47. The '338 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that the '338 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 47 not expressly admitted above, such allegations are denied.

48. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '338 patent is an act of infringement of one or more claims of the '338 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

49. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '338 patent.

ANSWER: Denied.

50. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '338 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

51. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '338 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

52. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '338 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO FOURTH CAUSE OF ACTION (THE '069 PATENT)

53. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

54. United States Patent No. 9,669,069 (the "'069 patent") (Exhibit 4 hereto), was duly and legally issued on June 6, 2017.

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '069 patent indicates that it issued on or about June 6, 2017, and that Regeneron purports to attach a copy of the '069 patent as Exhibit 4 to the Complaint. Mylan denies any suggestion that the '069 patent was duly and legally issued, as well as any suggestion or implication that the '069 patent is valid or enforceable or that Mylan infringes any claim of the '069 patent. To the extent there are allegations contained in paragraph 54 not expressly admitted above, such allegations are denied.

55. Regeneron is the owner of all right, title, and interest in the '069 patent.

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. Mylan admits that, on its face, the '069 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 55 not expressly admitted above, such allegations are denied.

56. The '069 patent has not yet expired.

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 56, and therefore denies the same.

57. The '069 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 57 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '069 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 57 not expressly admitted above, such allegations are denied.

58. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '069 patent is an act of infringement of one or more claims of the '069 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

59. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '069 patent.

ANSWER: Denied.

60. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '069 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

61. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '069 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

62. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '069 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO FIFTH CAUSE OF ACTION (THE '110 PATENT)

63. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

64. United States Patent No. 9,816,110 (the "'110 patent") (Exhibit 5 hereto), was duly and legally issued on November 14, 2017.

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '110 patent indicates that it issued on or about November 14, 2017, and that Regeneron purports to attach a copy of the '110 patent as Exhibit 5 to the Complaint. Mylan denies any suggestion that the '110 patent was duly

and legally issued, as well as any suggestion or implication that the '110 patent is valid or enforceable or that Mylan infringes any claim of the '110 patent. To the extent there are allegations contained in paragraph 64 not expressly admitted above, such allegations are denied.

65. Regeneron is the owner of all right, title, and interest in the '110 patent.

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '110 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 65 not expressly admitted above, such allegations are denied.

66. The '110 patent has not yet expired.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 66, and therefore denies the same.

67. The '110 patent claims methods related to manufacturing a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '110 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 67 not expressly admitted above, such allegations are denied.

68. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710

before the expiration of the '110 patent is an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

69. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 18 of the '110 patent.

ANSWER: Denied.

70. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '110 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

71. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '110 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

72. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '110 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO SIXTH CAUSE OF ACTION (THE '681 PATENT)

73. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

74. United States Patent No. 10,130,681 (the "'681 patent") (Exhibit 6 hereto), was duly and legally issued on November 20, 2018.

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '681 patent indicates that it issued on or about November 20, 2018, and that Regeneron purports to attach a copy of the '681 patent as Exhibit 6 to the Complaint. Mylan denies any suggestion that the '681 patent was duly and legally issued, as well as any suggestion or implication that the '681 patent is valid or enforceable or that Mylan infringes any claim of the '681 patent. To the extent there are allegations contained in paragraph 74 not expressly admitted above, such allegations are denied.

75. Regeneron is the owner of all right, title, and interest in the '681 patent.

ANSWER: Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '681 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 75 not expressly admitted above, such allegations are denied.

76. The '681 patent has not yet expired.

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 76, and therefore denies the same.

77. The '681 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also

was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '681 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 77 not expressly admitted above, such allegations are denied.

78. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '681 patent is an act of infringement of one or more claims of the '681 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

79. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '681 patent.

ANSWER: Denied.

80. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '681 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

81. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '681 patent will

cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

82. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '681 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO SEVENTH CAUSE OF ACTION (THE '226 PATENT)

83. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

84. United States Patent No. 10,406,226 (the "'226 patent") (Exhibit 7 hereto), was duly and legally issued on September 10, 2019.

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '226 patent indicates that it issued on or about September 10, 2019, and that Regeneron purports to attach a copy of the '226 patent as Exhibit 7 to the Complaint. Mylan denies any suggestion that the '226 patent was duly and legally issued, as well as any suggestion or implication that the '226 patent is valid or enforceable or that Mylan infringes any claim of the '226 patent. To the extent there are allegations contained in paragraph 84 not expressly admitted above, such allegations are denied.

85. Regeneron is the owner of all right, title, and interest in the '226 patent.

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that, on its face, the '226 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 85 not expressly admitted above, such allegations are denied.

86. The '226 patent has not yet expired.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 86, and therefore denies the same.

87. The '226 patent claims methods of manufacturing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '226 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 87 not expressly admitted above, such allegations are denied.

88. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '226 patent is an act of infringement of one or more claims of the '226 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

89. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 3 of the '226 patent.

ANSWER: Denied.

90. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '226 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

91. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '226 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

92. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '226 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO EIGHTH CAUSE OF ACTION (THE '055 PATENT)

93. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

94. United States Patent No. 10,415,055 (the "'055 patent") (Exhibit 8 hereto), was duly and legally issued on September 17, 2019.

ANSWER: Paragraph 94 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that, on its face, the '055 patent indicates that it issued on or about September 17, 2019, and that Regeneron purports to attach a copy of the '055 patent as Exhibit 8 to the Complaint. Mylan denies any suggestion that the '055 patent was duly and legally issued, as well as any suggestion or implication that the '055 patent is valid or enforceable or that Mylan infringes any claim of the '055 patent. To the extent there are allegations contained in paragraph 94 not expressly admitted above, such allegations are denied.

95. Regeneron is the owner of all right, title, and interest in the '055 patent.

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '055 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 95 not expressly admitted above, such allegations are denied.

96. The '055 patent has not yet expired.

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 96, and therefore denies the same.

97. The '055 patent claims methods of making proteins and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '055 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations

contained in paragraph 97 not expressly admitted above, such allegations are denied.

98. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '055 patent is an act of infringement of one or more claims of the '055 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

99. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 23 of the '055 patent.

ANSWER: Denied.

100. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '055 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

101. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '055 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

102. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '055 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO NINTH CAUSE OF ACTION (THE '992 PATENT)

103. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

104. United States Patent No. 10,464,992 (the "'992 patent") (Exhibit 9 hereto), was duly and legally issued on November 5, 2019.

ANSWER: Paragraph 104 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '992 patent indicates that it issued on or about November 5, 2019, and that Regeneron purports to attach a copy of the '992 patent as Exhibit 9 to the Complaint. Mylan denies any suggestion that the '992 patent was duly and legally issued, as well as any suggestion or implication that the '992 patent is valid or enforceable or that Mylan infringes any claim of the '992 patent. To the extent there are allegations contained in paragraph 104 not expressly admitted above, such allegations are denied.

105. Regeneron is the owner of all right, title, and interest in the '992 patent.

ANSWER: Paragraph 105 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '992 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 105 not expressly admitted above, such allegations are denied.

106. The '992 patent has not yet expired.

ANSWER: Paragraph 106 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 106, and therefore denies the same.

107. The ’992 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the ’992 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 107 not expressly admitted above, such allegations are denied.

108. The submission of Mylan’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the ’992 patent is an act of infringement of one or more claims of the ’992 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

109. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’992 patent.

ANSWER: Denied.

110. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the ’992 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

111. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '992 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

112. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '992 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TENTH CAUSE OF ACTION (THE '594 PATENT)

113. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

114. United States Patent No. 10,669,594 (the "'594 patent") (Exhibit 10 hereto), was duly and legally issued on June 2, 2020.

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '594 patent indicates that it issued on or about June 2, 2020, and that Regeneron purports to attach a copy of the '594 patent as Exhibit 10 to the Complaint. Mylan denies any suggestion that the '594 patent was duly and legally issued, as well as any suggestion or implication that the '594 patent is valid or enforceable or that Mylan infringes any claim of the '594 patent. To the extent there are allegations contained in paragraph 114 not expressly admitted above, such allegations are denied.

115. Regeneron is the owner of all right, title, and interest in the '594 patent.

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '594 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 115 not expressly admitted above, such allegations are denied.

116. The '594 patent has not yet expired.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 116, and therefore denies the same.

117. The '594 patent claims methods of detecting biological contaminants and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 117 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '594 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 117 not expressly admitted above, such allegations are denied.

118. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '594 patent is an act of infringement of one or more claims of the '594 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

119. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '594 patent.

ANSWER: Denied.

120. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '594 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

121. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '594 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

122. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '594 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO ELEVENTH CAUSE OF ACTION (THE '205 PATENT)

123. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

124. United States Patent No. 10,857,205 (the "'205 patent") (Exhibit 11 hereto), was duly and legally issued on December 8, 2020.

ANSWER: Paragraph 124 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '205 patent indicates that it issued on or about December 8, 2020, and that Regeneron purports to attach a copy of the '205 patent as Exhibit 11 to the Complaint. Mylan denies any suggestion that the '205 patent was duly and legally issued, as well as any suggestion or implication that the '205 patent is valid or enforceable or that Mylan infringes any claim of the '205 patent. To the extent there are allegations contained in paragraph 124 not expressly admitted above, such allegations are denied.

125. Regeneron is the owner of all right, title, and interest in the '205 patent.

ANSWER: Paragraph 125 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '205 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 125 not expressly admitted above, such allegations are denied.

126. The '205 patent has not yet expired.

ANSWER: Paragraph 126 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 126, and therefore denies the same.

127. The '205 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 127 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that the '205 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 127 not expressly admitted above, such allegations are denied.

128. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '205 patent is an act of infringement of one or more claims of the '205 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

129. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '205 patent.

ANSWER: Denied.

130. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '205 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

131. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '205 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

132. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '205 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TWELFTH CAUSE OF ACTION (THE '601 PATENT)

133. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

134. United States Patent No. 10,888,601 (the "'601 patent") (Exhibit 12 hereto), was duly and legally issued on January 12, 2021.

ANSWER: Paragraph 134 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '601 patent indicates that it issued on or about January 12, 2021, and that Regeneron purports to attach a copy of the '601 patent as Exhibit 12 to the Complaint. Mylan denies any suggestion that the '601 patent was duly and legally issued, as well as any suggestion or implication that the '601 patent is valid or enforceable or that Mylan infringes any claim of the '601 patent. To the extent there are allegations contained in paragraph 134 not expressly admitted above, such allegations are denied.

135. Regeneron is the owner of all right, title, and interest in the '601 patent.

ANSWER: Paragraph 135 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '601 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 135 not expressly admitted above, such allegations are denied.

136. The ’601 patent has not yet expired.

ANSWER: Paragraph 136 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 136, and therefore denies the same.

137. The ’601 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 137 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the ’601 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 137 not expressly admitted above, such allegations are denied.

138. The submission of Mylan’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the ’601 patent is an act of infringement of one or more claims of the ’601 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

139. For example, the sale of M710 pursuant to the label proposed in Mylan’s aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the ’601 patent.

ANSWER: Denied.

140. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the ’601 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C.

§ 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

141. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '601 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

142. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '601 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO THIRTEENTH CAUSE OF ACTION (THE '342 PATENT)

143. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

144. United States Patent No. 10,927,342 (the "'342 patent") (Exhibit 13 hereto), was duly and legally issued on February 23, 2021.

ANSWER: Paragraph 144 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '342 patent indicates that it issued on or about February 23, 2021, and that Regeneron purports to attach a copy of the '342 patent as Exhibit 13 to the Complaint. Mylan denies any suggestion that the '342 patent was duly

and legally issued, as well as any suggestion or implication that the '342 patent is valid or enforceable or that Mylan infringes any claim of the '342 patent. To the extent there are allegations contained in paragraph 144 not expressly admitted above, such allegations are denied.

145. Regeneron is the owner of all right, title, and interest in the '342 patent.

ANSWER: Paragraph 145 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '342 patent lists the assignee as Regeneran [sic] Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 145 not expressly admitted above, such allegations are denied.

146. The '342 patent has not yet expired.

ANSWER: Paragraph 146 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 146, and therefore denies the same.

147. The '342 patent claims methods of cultivating biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 147 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '342 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 147 not expressly admitted above, such allegations are denied.

148. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710

before the expiration of the '342 patent is an act of infringement of one or more claims of the '342 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

149. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '342 patent.

ANSWER: Denied.

150. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '342 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

151. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '342 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

152. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '342 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO FOURTEENTH CAUSE OF ACTION (THE '879 PATENT)

153. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

154. United States Patent No. 10,973,879 (the "'879 patent") (Exhibit 14 hereto), was duly and legally issued on April 13, 2021.

ANSWER: Paragraph 154 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '879 patent indicates that it issued on or about April 13, 2021, and that Regeneron purports to attach a copy of the '879 patent as Exhibit 14 to the Complaint. Mylan denies any suggestion that the '879 patent was duly and legally issued, as well as any suggestion or implication that the '879 patent is valid or enforceable or that Mylan infringes any claim of the '879 patent. To the extent there are allegations contained in paragraph 154 not expressly admitted above, such allegations are denied.

155. Regeneron is the owner of all right, title, and interest in the '879 patent.

ANSWER: Paragraph 155 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '879 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 155 not expressly admitted above, such allegations are denied.

156. The '879 patent has not yet expired.

ANSWER: Paragraph 156 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 156, and therefore denies the same.

157. The '879 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also

was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 157 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '879 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 157 not expressly admitted above, such allegations are denied.

158. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '879 patent is an act of infringement of one or more claims of the '879 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

159. For example, the sale of M710 while the reference product is approved for the uses patented in the '879 patent will contribute to and induce infringement of, *inter alia*, claim 1 of the '879 patent.

ANSWER: Denied.

160. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '879 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

161. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '879 patent will

cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

162. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '879 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO FIFTEENTH CAUSE OF ACTION (THE '280 PATENT)

163. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

164. United States Patent No. 11,053,280 (the "'280 patent") (Exhibit 15 hereto), was duly and legally issued on July 6, 2021.

ANSWER: Paragraph 164 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '280 patent indicates that it issued on or about July 6, 2021, and that Regeneron purports to attach a copy of the '280 patent as Exhibit 15 to the Complaint. Mylan denies any suggestion that the '280 patent was duly and legally issued, as well as any suggestion or implication that the '280 patent is valid or enforceable or that Mylan infringes any claim of the '280 patent. To the extent there are allegations contained in paragraph 164 not expressly admitted above, such allegations are denied.

165. Regeneron is the owner of all right, title, and interest in the '280 patent.

ANSWER: Paragraph 165 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that, on its face, the '280 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 165 not expressly admitted above, such allegations are denied.

166. The '280 patent has not yet expired.

ANSWER: Paragraph 166 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 166, and therefore denies the same.

167. The '280 patent claims methods of producing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 167 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '280 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 167 not expressly admitted above, such allegations are denied.

168. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '280 patent is an act of infringement of one or more claims of the '280 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

169. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '280 patent.

ANSWER: Denied.

170. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '280 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

171. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '280 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

172. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '280 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO SIXTEENTH CAUSE OF ACTION (THE '458 PATENT)

173. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

174. United States Patent No. 11,066,458 (the "'458 patent") (Exhibit 16 hereto), was duly and legally issued on July 20, 2021.

ANSWER: Paragraph 174 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that, on its face, the '458 patent indicates that it issued on or about July 20, 2021, and that Regeneron purports to attach a copy of the '458 patent as Exhibit 16 to the Complaint. Mylan denies any suggestion that the '458 patent was duly and legally issued, as well as any suggestion or implication that the '458 patent is valid or enforceable or that Mylan infringes any claim of the '458 patent. To the extent there are allegations contained in paragraph 174 not expressly admitted above, such allegations are denied.

175. Regeneron is the owner of all right, title, and interest in the '458 patent.

ANSWER: Paragraph 175 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '458 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 175 not expressly admitted above, such allegations are denied.

176. The '458 patent has not yet expired.

ANSWER: Paragraph 176 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 176, and therefore denies the same.

177. The '458 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 177 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '458 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations

contained in paragraph 177 not expressly admitted above, such allegations are denied.

178. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '458 patent is an act of infringement of one or more claims of the '458 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

179. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '458 patent.

ANSWER: Denied.

180. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '458 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

181. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '458 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

182. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '458 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO SEVENTEENTH CAUSE OF ACTION (THE '865 PATENT)

183. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

184. United States Patent No. 11,084,865 (the "'865 patent") (Exhibit 17 hereto), was duly and legally issued on August 10, 2021.

ANSWER: Paragraph 184 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '865 patent indicates that it issued on or about August 10, 2021, and that Regeneron purports to attach a copy of the '865 patent as Exhibit 17 to the Complaint. Mylan denies any suggestion that the '865 patent was duly and legally issued, as well as any suggestion or implication that the '865 patent is valid or enforceable or that Mylan infringes any claim of the '865 patent. To the extent there are allegations contained in paragraph 184 not expressly admitted above, such allegations are denied.

185. Regeneron is the owner of all right, title, and interest in the '865 patent.

ANSWER: Paragraph 185 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '865 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 185 not expressly admitted above, such allegations are denied.

186. The '865 patent has not yet expired.

ANSWER: Paragraph 186 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 186, and therefore denies the same.

187. The ’865 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 187 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the ’865 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 187 not expressly admitted above, such allegations are denied.

188. The submission of Mylan’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the ’865 patent is an act of infringement of one or more claims of the ’865 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

189. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’865 patent.

ANSWER: Denied.

190. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the ’865 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

191. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '865 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

192. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '865 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO EIGHTEENTH CAUSE OF ACTION (THE '715 PATENT)

193. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

194. United States Patent No. 11,104,715 (the "'715 patent") (Exhibit 18 hereto), was duly and legally issued on August 31, 2021.

ANSWER: Paragraph 194 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '715 patent indicates that it issued on or about August 31, 2021, and that Regeneron purports to attach a copy of the '715 patent as Exhibit 18 to the Complaint. Mylan denies any suggestion that the '715 patent was duly and legally issued, as well as any suggestion or implication that the '715 patent is valid or enforceable or that Mylan infringes any claim of the '715 patent. To the extent there are allegations contained in paragraph 194 not expressly admitted above, such allegations are denied.

195. Regeneron is the owner of all right, title, and interest in the '715 patent.

ANSWER: Paragraph 195 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '715 patent lists the assignee as Regeneran [sic] Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 195 not expressly admitted above, such allegations are denied.

196. The '715 patent has not yet expired.

ANSWER: Paragraph 196 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 196, and therefore denies the same.

197. The '715 patent claims methods of producing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 197 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '715 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 197 not expressly admitted above, such allegations are denied.

198. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '715 patent is an act of infringement of one or more claims of the '715 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

199. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '715 patent.

ANSWER: Denied.

200. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '715 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

201. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '715 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

202. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO NINETEENTH CAUSE OF ACTION (THE '283 PATENT)

203. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

204. United States Patent No. 11,174,283 (the "'283 patent") (Exhibit 19 hereto), was duly and legally issued on November 16, 2021.

ANSWER: Paragraph 204 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '283 patent indicates that it issued on or about November 16, 2021, and that Regeneron purports to attach a copy of the '283 patent as Exhibit 19 to the Complaint. Mylan denies any suggestion that the '283 patent was duly and legally issued, as well as any suggestion or implication that the '283 patent is valid or enforceable or that Mylan infringes any claim of the '283 patent. To the extent there are allegations contained in paragraph 204 not expressly admitted above, such allegations are denied.

205. Regeneron is the owner of all right, title, and interest in the '283 patent.

ANSWER: Paragraph 205 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '283 patent lists the assignee as Regeneran [sic] Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 205 not expressly admitted above, such allegations are denied.

206. The '283 patent has not yet expired.

ANSWER: Paragraph 206 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 206, and therefore denies the same.

207. The '283 patent claims methods of producing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 207 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that the '283 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 207 not expressly admitted above, such allegations are denied.

208. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '283 patent is an act of infringement of one or more claims of the '283 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

209. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '283 patent.

ANSWER: Denied.

210. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '283 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

211. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '283 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

212. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '283 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TWENTIETH CAUSE OF ACTION (THE '625 PATENT)

213. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

214. United States Patent No. 11,186,625 (the "'625 patent") (Exhibit 20 hereto), was duly and legally issued on November 30, 2021.

ANSWER: Paragraph 214 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '625 patent indicates that it issued on or about November 30, 2021, and that Regeneron purports to attach a copy of the '625 patent as Exhibit 20 to the Complaint. Mylan denies any suggestion that the '625 patent was duly and legally issued, as well as any suggestion or implication that the '625 patent is valid or enforceable or that Mylan infringes any claim of the '625 patent. To the extent there are allegations contained in paragraph 214 not expressly admitted above, such allegations are denied.

215. Regeneron is the owner of all right, title, and interest in the '625 patent.

ANSWER: Paragraph 215 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '625 patent lists the assignee as Regeneran [sic] Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 215 not expressly admitted above, such allegations are denied.

216. The ’625 patent has not yet expired.

ANSWER: Paragraph 216 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 216, and therefore denies the same.

217. The ’625 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 217 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the ’625 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 217 not expressly admitted above, such allegations are denied.

218. The submission of Mylan’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the ’625 patent is an act of infringement of one or more claims of the ’625 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

219. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 and/or M710 drug substance will infringe, *inter alia*, claim 1 of the ’625 patent.

ANSWER: Denied.

220. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '625 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

221. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '625 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

222. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '625 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TWENTY-FIRST CAUSE OF ACTION (THE '572 PATENT)

223. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

224. United States Patent No. 11,253,572 (the "'572 patent") (Exhibit 21 hereto), was duly and legally issued on February 22, 2022.

ANSWER: Paragraph 224 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '572 patent indicates that it

issued on or about February 22, 2022, and that Regeneron purports to attach a copy of the '572 patent as Exhibit 21 to the Complaint. Mylan denies any suggestion that the '572 patent was duly and legally issued, as well as any suggestion or implication that the '572 patent is valid or enforceable or that Mylan infringes any claim of the '572 patent. To the extent there are allegations contained in paragraph 224 not expressly admitted above, such allegations are denied.

225. Regeneron is the owner of all right, title, and interest in the '572 patent.

ANSWER: Paragraph 225 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '572 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 225 not expressly admitted above, such allegations are denied.

226. The '572 patent has not yet expired.

ANSWER: Paragraph 226 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 226, and therefore denies the same.

227. The '572 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 227 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '572 patent was included in the list Regeneron purported to provide under § 262(*l*)(3)(A) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 227 not expressly admitted above, such allegations are denied.

228. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '572 patent is an act of infringement of one or more claims of the '572 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

229. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '572 patent.

ANSWER: Denied.

230. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '572 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

231. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '572 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

232. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '572 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TWENTY-SECOND CAUSE OF ACTION (THE '532 PATENT)

233. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

234. United States Patent No. 11,299,532 (the "'532 patent") (Exhibit 22 hereto), was duly and legally issued on April 12, 2022.

ANSWER: Paragraph 234 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '532 patent indicates that it issued on or about April 12, 2022, and that Regeneron purports to attach a copy of the '532 patent as Exhibit 22 to the Complaint. Mylan denies any suggestion that the '532 patent was duly and legally issued, as well as any suggestion or implication that the '532 patent is valid or enforceable or that Mylan infringes any claim of the '532 patent. To the extent there are allegations contained in paragraph 234 not expressly admitted above, such allegations are denied.

235. Regeneron is the owner of all right, title, and interest in the '532 patent.

ANSWER: Paragraph 235 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '532 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 235 not expressly admitted above, such allegations are denied.

236. The '532 patent has not yet expired.

ANSWER: Paragraph 236 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 236, and therefore denies the same.

237. The ’532 patent claims methods of manufacturing biological products and was included in a supplemental notice provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(7) on May 5, 2022. The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 237 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the ’532 patent was purportedly included by Regeneron in a supplement provided under § 262(*l*)(7) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 237 not expressly admitted above, such allegations are denied.

238. The submission of Mylan’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the ’532 patent is an act of infringement of one or more claims of the ’532 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

239. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’532 patent.

ANSWER: Denied.

240. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the ’532 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

241. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '532 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

242. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '532 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TWENTY-THIRD CAUSE OF ACTION (THE '135 PATENT)

243. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

244. United States Patent No. 11,306,135 (the "'135 patent") (Exhibit 23 hereto), was duly and legally issued on April 19, 2022.

ANSWER: Paragraph 244 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '135 patent indicates that it issued on or about April 19, 2022, and that Regeneron purports to attach a copy of the '135 patent as Exhibit 23 to the Complaint. Mylan denies any suggestion that the '135 patent was duly and legally issued, as well as any suggestion or implication that the '135 patent is valid or enforceable or that Mylan infringes any claim of the '135 patent. To the extent there are allegations contained in paragraph 244 not expressly admitted above, such allegations are denied.

245. Regeneron is the owner of all right, title, and interest in the '135 patent.

ANSWER: Paragraph 245 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '135 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 245 not expressly admitted above, such allegations are denied.

246. The '135 patent has not yet expired.

ANSWER: Paragraph 246 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 246, and therefore denies the same.

247. The '135 patent claims biological products and was included in a supplemental notice provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(7) on May 5, 2022. The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 247 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the '135 patent was purportedly included by Regeneron in a supplement provided under § 262(*l*)(7) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 247 not expressly admitted above, such allegations are denied.

248. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '135 patent is an act of infringement of one or more claims of the '135 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

249. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '135 patent.

ANSWER: Denied.

250. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '135 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

251. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '135 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

252. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '135 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

RESPONSES TO ALLEGATIONS PERTAINING TO TWENTY-FOURTH CAUSE OF ACTION (THE '771 PATENT)

253. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

ANSWER: Mylan incorporates by reference its responses to paragraphs 1-22 as if fully set forth herein.

254. United States Patent No. 11,332,771 (the "'771 patent") (Exhibit 24 hereto), was duly and legally issued on May 17, 2022.

ANSWER: Paragraph 254 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '771 patent indicates that it issued on or about May 17, 2022, and that Regeneron purports to attach a copy of the '771 patent as Exhibit 24 to the Complaint. Mylan denies any suggestion that the '771 patent was duly and legally issued, as well as any suggestion or implication that the '771 patent is valid or enforceable or that Mylan infringes any claim of the '771 patent. To the extent there are allegations contained in paragraph 254 not expressly admitted above, such allegations are denied.

255. Regeneron is the owner of all right, title, and interest in the '771 patent.

ANSWER: Paragraph 255 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, on its face, the '771 patent lists the assignee as Regeneron Pharmaceuticals, Inc. To the extent there are allegations contained in paragraph 255 not expressly admitted above, such allegations are denied.

256. The '771 patent has not yet expired.

ANSWER: Paragraph 256 contains legal conclusions to which no answer is required. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of paragraph 256, and therefore denies the same.

257. The '771 patent claims methods of producing biological products and was included in a supplemental notice provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(7) on June 16, 2022. The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

ANSWER: Paragraph 257 contains legal conclusions to which no answer is required. To

the extent an answer is required, Mylan admits that the '771 patent was purportedly included by Regeneron in a supplement provided under § 262(*l*)(7) and the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5). To the extent there are allegations contained in paragraph 257 not expressly admitted above, such allegations are denied.

258. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '771 patent is an act of infringement of one or more claims of the '771 patent under 35 U.S.C. § 271(e)(2)(C)(i).

ANSWER: Denied.

259. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '771 patent.

ANSWER: Denied.

260. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '771 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

ANSWER: Denied.

261. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '771 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

ANSWER: Denied.

262. The submission of Mylan's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 before the expiration of the '771 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ANSWER: Denied.

GENERAL DENIAL

Any allegation in Plaintiff's Complaint not expressly admitted is hereby denied.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

Mylan denies that Plaintiff is entitled to any relief sought in paragraphs (a) through (i) of the Complaint ("Prayer for Relief"), or to any relief whatsoever, and further requests that the Court: (a) dismiss Regeneron's Complaint with prejudice; (b) enter judgment in favor of Mylan; (c) award Mylan reasonable attorneys' fees and costs incurred in defending this action pursuant to, *inter alia*, 35 U.S.C. § 285; and, (d) award Mylan such further relief as the Court deems just and appropriate.

SEPARATE DEFENSES

Without prejudice to the denials set forth in the Answer, and without admitting any allegation of the Complaint not expressly admitted, Mylan asserts the following separate defenses to the Complaint, without assuming the burden of proof of any such defense that would otherwise rest with Plaintiff.

FIRST SEPARATE DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE
(Lack of Subject Matter Jurisdiction)

The Court does not have subject matter jurisdiction for an action brought pursuant to 35 U.S.C. § 271(a), (b), (c) and/or (g).

THIRD THROUGH TWENTY-SIXTH SEPARATE DEFENSES
(No Infringement)

Mylan has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of U.S. Patent Nos. 7,070,959; 9,222,106; 9,254,338; 9,669,069; 9,816,110; 10,130,681; 10,406,226; 10,415,055; 10,464,992; 10,669,594; 10,857,205; 10,888,601; 10,927,342; 10,973,879; 11,053,280; 11,066,458; 11,084,865; 11,104,715; 11,174,283; 11,186,625; 11,253,572; 11,299,532; 11,306,135; and 11,332,771.

TWENTY-SEVENTH THROUGH FIFTIETH SEPARATE DEFENSES
(Invalidity)

The claims of U.S. Patent Nos. 7,070,959; 9,222,106; 9,254,338; 9,669,069; 9,816,110; 10,130,681; 10,406,226; 10,415,055; 10,464,992; 10,669,594; 10,857,205; 10,888,601; 10,927,342; 10,973,879; 11,053,280; 11,066,458; 11,084,865; 11,104,715; 11,174,283; 11,186,625; 11,253,572; 11,299,532; 11,306,135; and 11,332,771 patents are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTY-FIRST SEPARATE DEFENSE
(Safe Harbor)

To the extent Regeneron claims that Mylan's activities performed in relation to Mylan's Proposed BLA product related to the development and submission of information to the FDA is an act of infringement, Mylan is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e).

FIFTY-SECOND SEPARATE DEFENSE
(No Willfulness)

The Complaint fails to state a claim for willful infringement.

FIFTY-THIRD SEPARATE DEFENSE
(No Recovery of Costs)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

FIFTY-FOURTH SEPARATE DEFENSE
(No Exceptional Case)

Mylan's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285 or 35 U.S.C. § 271(e)(4).

FIFTY-FIFTH SEPARATE DEFENSE
(No Equitable Relief)

Plaintiff is not entitled to any preliminary or permanent equitable relief.

FIFTY-SIXTH SEPARATE DEFENSE
(No Standing)

Plaintiff lacks standing to assert one or more Patents-in-Suit.

FIFTY-SEVENTH SEPARATE DEFENSE
(BPCIA Compliance by Mylan)

Mylan has complied with the procedures of the BPCIA.

FIFTY-EIGHTH SEPARATE DEFENSE
(Waiver, Estoppel)

Plaintiff's Complaint, and each of its purported causes of action, is barred in whole or in part by the doctrines of waiver and/or estoppel.

FIFTY-NINTH SEPARATE DEFENSE
(Failure to Mitigate)

Plaintiff has failed to mitigate the harm it claims to have sustained, if any.

SIXTIETH SEPARATE DEFENSE
(Unclean Hands)

Plaintiff's Complaint, and each of its purported causes of action, is barred by Plaintiff's unclean hands, in view of at least the reasons relating to Regeneron's inequitable conduct.

SIXTY-FIRST SEPARATE DEFENSE
(Inequitable Conduct)

Plaintiff's Complaint, and each of its purported causes of action, is barred by Plaintiff's inequitable conduct.

OTHER DEFENSES RESERVED

As Mylan's investigation is ongoing and discovery has not yet been begun or been completed, Mylan is without complete information regarding the existence or non-existence of other facts or acts that would constitute a defense to the purported causes of action in Plaintiff's Complaint. Accordingly, Mylan reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case. Mylan further reserves the right to supplement and/or amend these defenses.

COUNTERCLAIMS

Defendant/Counterclaim Plaintiff, Mylan Pharmaceuticals Inc. ("Mylan"), by and through its undersigned attorneys, hereby asserts the following counterclaims against Plaintiff/Counterclaim Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Counterclaim Defendant") for declaratory judgment that the claims of U.S. Patent Nos. 7,070,959 ("the '959 patent"), 9,222,106 ("the '106 patent"), 9,254,338 ("the '338 patent"), 9,669,069 ("the '069 patent"), 9,816,110 ("the '110 patent"), 10,130,681 ("the '681 patent"), 10,406,226 ("the '226 patent"), 10,415,055 ("the '055 patent"), 10,464,992 ("the '992 patent"), 10,669,594 ("the '594 patent"), 10,857,205 ("the '205 patent"), 10,888,601 ("the '601 patent"), 10,927,342 ("the '342 patent"), 10,973,879 ("the '879 patent"), 11,053,280 ("the '280 patent"), 11,066,458 ("the '458 patent"), 11,084,865 ("the '865 patent"), 11,104,715 ("the '715 patent"), 11,174,283 ("the '283 patent"), 11,186,625 ("the '625 patent"), 11,253,572 ("the '572 patent"), 11,299,532 ("the '532 patent"), 11,306,135 ("the '135 patent"), and 11,332,771 ("the '771 patent") are not infringed

and/or invalid.

PARTIES

1. Counterclaimant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 3711 Collins Ferry Road, Morgantown, WV 26505.

2. On information and belief, Counterclaim Defendant Regeneron claims and purports to be a corporation organized and existing under the laws of the State of New York, with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591.

JURISDICTION AND VENUE

3. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. The Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 because Counterclaim Defendant commenced and continues to maintain this action in this judicial district.

5. The Court has personal jurisdiction over Counterclaim Defendant for purposes of these counterclaims because Counterclaim Defendant commenced and continues to maintain this action in this judicial district.

6. Venue is proper in this judicial district for purposes of these counterclaims because Counterclaim Defendant commenced and continues to prosecute this action in this judicial district.

BACKGROUND

7. On information and belief, Counterclaim Defendant has alleged in the instant action that it owns the ’959, ’106, ’338, ’069, ’110, ’681, ’226, ’055, ’992, ’594, ’205, ’601, ’342, ’879, ’280, ’458, ’865, ’715, ’283, ’625, ’572, ’532, ’135, and ’771 patents.

8. On information and belief, Counterclaim Defendant holds Biologics License Application (BLA) Number 125387 for aflibercept, referred to as "Eylea®."

9. Mylan submitted BLA No. 761274 to FDA seeking approval for its aflibercept product ("Mylan's Proposed BLA Product").

10. Counterclaim Defendant filed the present action against Mylan for alleged infringement of the '959, '106, '338, '069, '110, '681, '226, '055, '992, '594, '205, '601, '342, '879, '280, '458, '865, '715, '283, '625, '572, '532, '135, and '771 patents.

BPCIA

11. The BPCIA created a new, abbreviated approval pathway for FDA to review and approve biosimilar biologic products, as well as a new mechanism to potentially resolve and address patent disputes that may arise with respect to such products.

12. The BPCIA reflects a careful and critical balance between innovation and price competition. On one side, Congress created an abbreviated licensure pathway that allows applicants to file BLAs under 42 U.S.C. § 262(k) for biological products shown to be biosimilar to, or interchangeable with, a licensed reference product. In exchange, Congress granted reference product sponsors certain periods of exclusivity which prevent applicants from filing a BLA for a biosimilar product for four (4) years from the date the reference product was licensed, and which delay ultimate eligibility for licensure of a BLA product pursuant to § 262(k) for twelve (12) years from the date the reference product was licensed.

13. A "biosimilar" is a "biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

14. To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the "reference product" and that "there are

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)(2); *see also id.* § 262(k). Specifically, FDA determines if "the biological product is biosimilar to a reference product based upon data derived from" required studies, including:

> a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product.

Id. § 262(k)(2)(A)(i).

15. Recognizing that patent disputes between the reference product sponsor and the biosimilar applicant may exist, the "BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Sandoz*, 137 S. Ct. at 1670 (citing 42 U.S.C. § 262(*l*)).

16. Specifically, the BPCIA describes a series of optional steps to exchange information between the parties that begins with the biosimilar applicant providing "a copy of the application submitted . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). Optionally, the applicant additionally "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." *Id.* § 262(*l*)(2)(B).

17. The reference product sponsor must specifically identify "recipients of information" pursuant to § 262(*l*)(1)(B)(ii) with the understanding that such individuals must agree that "confidential access to the information required to be produced" is subject to at least the confidentiality requirements of § 262(*l*).

18. The reference product sponsor must then provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted" if the biosimilar applicant engages "in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A) (referred to herein as the "3(A) List"). The biosimilar applicant then provides to the reference product sponsor:

> a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application.

Id. § 262(*l*)(3)(B)(ii)(I) (referred to herein as the "3(B) Statement"). Alternatively, the biosimilar applicant may provide a statement that it does not intend to begin commercial marketing of its biological product before the date that the patents identified on the 3(A) List expire. *Id*. § 262(*l*)(3)(B)(ii)(II).

19. The reference product sponsor then:

> shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

42 U.S.C. § 262(*l*)(3)(C) (referred to herein as the "3(C) Statement").

20. If following the reference product sponsor's disclosure of its 3(A) List to the biosimilar applicant, the reference product sponsor obtains a newly issued or licensed patent that it believes "a claim of patent infringement could reasonably be asserted by the reference product sponsor" against the biosimilar applicant:

> not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent.

42 U.S.C. § 262(*l*)(7)(B). Thus, the 3(A) List and the remaining scheme set forth for the exchange of information pursuant to § 262(*l*) must be supplemented to include the newly issued or licensed patent. Accordingly, "not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B)." *Id*. § 262(*l*)(7)(B).

21. Following the exchange of information detailed above, the parties may engage in "good faith negotiations to agree on which, if any, patents . . . shall be the subject of an action for patent infringement." 42 U.S.C. § 262(*l*)(4)(A). If the parties cannot reach an agreement, the BPCIA provides a mechanism by which the patents that will be the subject of any litigation are determined by a further exchange of patent lists. *Id*. § 262(*l*)(5). Regardless of the mechanism employed, no later than thirty (30) days following the parties' negotiations, the reference product sponsor can bring an action for patent infringement with respect to each patent either agreed to between the parties or identified on the parties' § 262(*l*)(5) lists. 42 U.S.C. § 262(*l*)(6).

22. If a reference product sponsor fails to bring suit within thirty (30) days following the completion of the parties negotiations pursuant to either § 262(*l*)(4) or § 262(*l*)(5), "a reasonable royalty" shall be the "sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent." 35 U.S.C. § 271(e)(6).

23. The BPCIA also provides that the biosimilar applicant shall provide "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product" that is the subject of its biosimilar application. 42 U.S.C. § 262(*l*)(8).

24. Once notice is received pursuant to 42 U.S.C. § 262(*l*)(8), there is no limitation under the BPCIA on an applicant's right to bring an action under 28 U.S.C. § 2201 for a declaration of non-infringement, invalidity or unenforceability of any patent included in a reference product sponsor's 3(A) List (including any supplements pursuant to § 262(*l*)(7)). 42 U.S.C. § 262(*l*)(9).

THE PARTIES' EXCHANGES PURSUANT TO 42 U.S.C. § 262(*l*)

25. On October 29, 2021, Mylan Pharmaceuticals Inc. submitted BLA No. 761274 to FDA pursuant to 42 U.S.C. § 262(k) ("Mylan's BLA"), seeking approval of MYL-1701P, Solution for Intravitreal Injection, a proposed biosimilar to Eylea® (aflibercept). On January 5, 2022, Mylan notified Regeneron that Mylan's BLA had been accepted for review by FDA and began negotiating with Regeneron the terms of access to Mylan's confidential information pursuant to 42 U.S.C. § 262(*l*)(1).

26. On or about January 17, 2022, the parties finalized a Confidentiality Agreement, and on that same day, Mylan provided Regeneron's counsel with access to a database that contained a searchable copy of its entire BLA and other information described in § 262(*l*)(2)(A). Mylan's production comprised over 1000 documents, totaling over 560,000 pages, which included confidential information concerning "the process or processes used to manufacture" Mylan's Proposed BLA Product, among other information.

27. On February 22, 2022, Regeneron provided a patent list under 42 U.S.C. § 262(*l*)(3)(A) ("3A List") identifying 29 patents that it alleged could reasonably be asserted against a person engaged in the making, using, offering to sell, selling, or importing into the United States the biological product that is the subject of Mylan's BLA. Regeneron, however, conceded that with respect to seven (7) of these listed patents, identified with an asterisk, they "do not contend that these patents would be infringed by making, using, offering to sell, selling or

importing into the United States the particular product that is made according to the labeling, processes, and specifications of the version of Mylan's BLA No. 761274 that you have placed on the online review platform." Notably, this subset of seven (7) patents includes U.S. Patent No. 10,973,879 ("879 Patent"), which is currently one of the Patents-in-Suit. Regeneron also stated that it was "not currently prepared to license any of the [listed patents] to Mylan in connection with the biological product described in [Mylan's BLA]."

28. On April 14, 2022, Mylan provided to Regeneron its detailed statements under 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) ("3(B) Statements"), in which Mylan set forth over a thousand pages of preliminary factual and legal bases for its opinion that each of the patents in Regeneron's 3A List is invalid, unenforceable, and/or will not be infringed by the commercial marketing of Mylan's biological product. In effort to narrow the issues between the parties, Mylan provided detailed descriptions of Mylan's positions with respect to each of the 29 listed patents, on a claim-by-claim basis, which included pinpoint citations to Mylan's BLA, descriptions of the prior art, and particularized facts to support its invalidity and/or unenforceability defenses. Mylan also reserved all rights to further develop and discover new defenses in litigation in the ordinary course of fact and expert discovery.

29. On May 5, 2022, Mylan provided detailed statements with respect to two (2) additional patents that Regeneron had added to its 3A List through the mechanism provided by 42 U.S.C. § 262(*l*)(7) on April 13 and April 19, 2022. On June 16, 2022, Mylan provided a detailed statement with respect to an additional patent that Regeneron had added to its 3A List through the § 262(*l*)(7) mechanism on May 17, 2022. As before, each of these statements set forth detailed descriptions of Mylan's positions with respect to each of the supplemental patents, on a claim-by-

claim basis, which included pinpoint citations to Mylan's BLA, descriptions of the prior art, and particularized facts to support its invalidity and/or unenforceability defenses.

30. On June 10, 2022, approximately 57 days after receiving Mylan's 3(B) Statements, Regeneron provided what it purported to be its detailed statement under 42 U.S.C. § 262(*l*)(3)(C) ("3(C) Statements"). Among other deficiencies, these 3(C) Statements failed to provide a "detailed" statement "on a claim by claim basis" with respect to the factual and legal basis for Regeneron's infringement contentions. In addition, Regeneron failed to adequately respond to the detailed invalidity contentions provided by Mylan, in many cases providing only conclusory assertions of validity without addressing the detailed bases provided in Mylan's 3(B) Statements. As just one example, in response to Mylan's 71-page 3(B) Statement regarding the '959 patent, Regeneron provided a 6-page 3(C) Statement. Therein, Regeneron provided purported infringement contentions for only claims 8 and 11. Further, in response to Mylan's thirty-six (36) pages of detailed invalidity contentions, Regeneron provided only a page and a half response comprising single paragraphs of conclusory statements that the claims are valid, without directly addressing any of Mylan's detailed invalidity bases. This trend continued through Regeneron's other 3(C) Statements as well. For the patents in Regeneron's dosing patent family, Regeneron pushed meritless arguments before the Patent Trial and Appeal Board ("PTAB") that the claim preambles should be read to incorporate "a high level of efficacy, that is not inferior to the existing standard-of-care." However, Regeneron's 3(C) Statement infringement contentions were silent on that additional claim limitation, and Regeneron made no effort to identify how Mylan purportedly would infringe under Regeneron's interpretation of the preamble, asserting instead that merely conducting the steps of the dosing patents is sufficient to show infringement. Thus, Regeneron's 3(C) Statements directed to the dosing family patents were deficient for at least this additional

reason, and also illustrate Regeneron's inconsistent and contradictory approaches when litigating the claims in different venues.

31. Moreover, Regeneron did not provide any infringement or validity contentions in response to Mylan's 3(B) Statements directed to the '532, '135 or '771 patents.

32. Between June 15, 2022 and June 30, 2022, the parties engaged in negotiations pursuant to 42 U.S.C. § (*l*)(4)(A). During these negotiations, Regeneron proposed to immediately litigate only twelve (12) of the thirty-one (31) patents included on its initial 3A List and as supplemented through Section (*l*)(7) disclosures. In response, Mylan stated its willingness and desire to minimize the number of patents and disputes to be included in the (*l*)(6) litigation, but, in an effort to establish a level of certainty going forward, asked Regeneron for covenants not to sue or equivalent assurances with respect to the nineteen (19) remaining patents. In seeking these assurances, Mylan relied upon, among other things, its 3B Statement disclosures setting forth detailed non-infringement defenses to the Patents-in-Suit, including supporting citations to Mylan's BLA. Despite this, Regeneron refused to provide any such covenants or assurances, refused to withdraw any of its listed patents (except for U.S. Patent No. 10,828,345), and refused to provide any explanation for how it intended to proceed with respect to the nineteen (19) remaining patents. This includes the seven (7) patents that Regeneron had already conceded would not be infringed by Mylan's BLA No. 761274.

33. Because Regeneron was unwilling to provide Mylan with any level of certainty with respect to the nineteen (19) patents that Regeneron was proposing to hold in reserve for later litigation, the timing and circumstances of which Regeneron was unwilling to offer any details for, on June 30, 2022, Mylan notified Regeneron that it intended to identify 25 patents for (*l*)(6)

litigation, with the exception of six (6) of the patents that Regeneron conceded were not infringed by Mylan's BLA No. 761274.

34. 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's list included twenty-five (25) patents. Regeneron's list included twelve (12) patents.

35. On August 2, 2022, Regeneron filed suit, including twenty-four (24) of the twenty-five (25) patents that had been included on Mylan's 42 U.S.C. § 262(*l*)(5)(B)(i) list.

COUNT 1
Non-Infringement and Invalidity of U.S. Patent No. 7,070,959

36. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

37. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '959 patent.

38. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '959 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

39. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '959 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

40. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '959 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related

to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

41. The claims of the '959 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

42. Mylan is entitled to a judgment that the claims of the '959 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 2
Non-Infringement and Invalidity of U.S. Patent No. 9,222,106

43. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

44. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '106 patent.

45. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '106 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

46. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '106 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

47. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '106 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

48. The claims of the '106 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

49. Mylan is entitled to a judgment that the claims of the '106 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 3
Non-Infringement and Invalidity of U.S. Patent No. 9,254,338

50. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

51. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '338 patent.

52. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '338 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

53. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '338 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

54. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '338 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

55. The claims of the '338 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

56. The claims of the '338 patent are unenforceable due to Regeneron's inequitable conduct during prosecution of the application(s) that led to the '338 patent's issuance, and the positions that Regeneron has taken before the PTAB. During the prosecution of the '338 patent, Regeneron made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office. For example, while arguing to the PTO during prosecution of U.S. Patent Application No. 13/940,370 that the disclosures of Heier 2012, (*see, e.g.*, '338 patent prosecution history ("PH"), 9/11/2015 Applicant Remarks), supported the patentability of the pending claims, Regeneron knew that the VIEW and Phase 2 dosing regimens were widely disclosed in the prior art, including in its own prior art press releases, (*e.g.*, Press Release, Regeneron, Regeneron and Bayer Healthcare Announce VEGF Trap-Eye Achieved

Durable Improvement in Vision Over 52 Weeks in a Phase 2 Study in Patients with Age Related Macular Degeneration (Aug. 19, 2008), https://investor.regeneron.com/news-releases/news-release-details/regeneron-and-bayer-healthcare-announce-vegf-trap-eye-achieved?ReleaseID=394056 ("8-19-2008 Regeneron Press Release"), Press Release, Regeneron, VEGF Trap-Eye Final Phase 2 Results in Age-related Macular Degeneration Presented at 2008 Retina Society Meeting (Sept. 28, 2008), https://investor.regeneron.com/news-releases/news-release-details/vegf-trap-eye-final-phase-2-results-age-related-macular?ReleaseID=393906 ("9-28-2008 Regeneron Press Release"), Press Release, Regeneron, Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD) (Sept. 14, 2009), https://investor.regeneron.com/news-releases/news-release-details/enrollment-completed-regeneron-and-bayer-healthcare-phase-3?ReleaseID=408872 ("9-14-2009 Regeneron Press Release"), 10-Q forms, and 10-K forms, as well as industry publications, which were withheld from the PTO. Thus, Regeneron, and/or its agents, withheld the fact that the same dosing regimen it was relying upon in the 2012 reference to show unexpected results was also disclosed in the prior art. Moreover, Regeneron made arguments to the PTO which were intentionally misleading and inaccurate, including Regeneron's statements regarding the purported "standard of care" and the state of the art. (*See, e.g.*, '338 patent PH, 9/11/2015 Applicant Remarks; IPR2021-00881, Petition for *Inter Partes* Review of U.S. Patent No. 9,254,338 at 66-69). Further, Regeneron was aware of the materiality of references disclosing the VIEW and Phase 2 dosing regimens, which is evidenced by its representations to the PTO during prosecution and its subsequent decisions to submit a subset of said references to the PTO in connection with other pending and related applications. (*See, e.g.*, '338 patent PH, 9/11/2015 Applicant Remarks; '069 patent PH, 1/30/2017 Remarks; '681 patent PH, 6/25/2018

Applicant Remarks; '681 patent PH, 5/26/2017 Information Disclosure Statement). Further, upon information and belief, Regeneron was aware of the misleading and inaccurate statements made to the PTO during prosecution, and given that many of the prior art references were Regeneron's own publications, Regeneron had knowledge of the invalidating disclosures of the prior art. (*See, e.g.*, '338 patent PH, 9/11/2015 Applicant Remarks; '681 patent PH, 6/25/2018 Applicant Remarks; '681 patent PH, 7/26/2018 Notice of Allowability). In addition, the most reasonable inference to be drawn from Regeneron's withholding of the above references from the PTO, and misleading and inaccurate statements made to the PTO, is that the actions were done with the specific intent to deceive. Also, during at least PGR2021-00117, IPR2021-00880, and IPR2021-00881, Regeneron has taken positions that it knows to be misleading, inaccurate, and without merit, including, but not limited to, with respect to the identity of the claimed molecule, and its amino acid sequence and nucleotide sequence. (*See, e.g.*, IPR2021-00881, Patent Owner Response, Paper 41 at 24-35). Further, Regeneron has obstructed the PTAB proceedings at least through its continued pursuit of the above arguments, and its meritless claim construction arguments. In addition, the most reasonable inference to be drawn from Regeneron's withholding of the disclosures of the above references from the PTO and misleading and inaccurate statements made to the PTO, is that the actions were done with the intent to deceive. Because of the clearly invalidating disclosures of the prior art, which set forth the exact same dosing regimen that Regeneron later claimed in its dosing patents, Regeneron's omissions and misleading arguments to the PTO were material, because but for said omissions and misleading arguments, the claims would not have issued.

57. Mylan is entitled to a judgment that the claims of the '338 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of

that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 4
Non-Infringement and Invalidity of U.S. Patent No. 9,669,069

58. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

59. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '069 patent.

60. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '069 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

61. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '069 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

62. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '069 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

63. The claims of the '069 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or

112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

64. The claims of the '069 patent are unenforceable due to Regeneron's inequitable conduct during prosecution of the application(s) that led to the '069 patent's issuance and the positions that Regeneron has taken before the PTAB. For example, while arguing to the PTO during prosecution of U.S. Patent Application No. 14/972,560 that the disclosures of Heier 2012, (*see, e.g.*, '069 patent PH, 1/30/2017 Remarks) supported the patentability of the pending claims, Regeneron knew that the VIEW and Phase 2 dosing regimens were widely disclosed in the prior art, including in its own prior art press releases, (*e.g.*, 8-19-2008 Regeneron Press Release; 9-28-2008 Regeneron Press Release; 9-14-2009 Regeneron Press Release), 10-Q forms, and 10-K forms, as well as industry publications, which were withheld from the PTO. Thus, Regeneron, and/or its agents, withheld the fact that the same dosing regimen it was relying upon in the 2012 reference to show unexpected results was also disclosed in the prior art. Moreover, Regeneron made arguments to the PTO which were intentionally misleading and inaccurate, including Regeneron's statements regarding the purported "standard of care" and the state of the art. (*See, e.g.*, '069 patent PH, 1/30/2017 Remarks; '338 patent PH, 9/11/2015 Applicant Remarks; IPR2021-00880, Petition for *Inter Partes* Review of U.S. Patent No. 9,669,069 at 69-72; IPR2021-00881, Petition for *Inter Partes* Review of U.S. Patent No. 9,254,338 at 66-69). Further, Regeneron was aware of the materiality of references disclosing the VIEW and Phase 2 dosing regimens, which is evidenced by its representations to the PTO during prosecution and its subsequent decisions to submit a subset of said references to the PTO in connection with other pending and related applications. (*See, e.g.*, '069 patent PH, 1/30/2017 Remarks; '338 patent PH, 9/11/2015 Applicant Remarks; '681 patent PH, 6/25/2018 Applicant Remarks; '681 patent PH,

5/26/2017 Information Disclosure Statement). Further, upon information and belief, Regeneron was aware of the misleading and inaccurate statements made to the PTO during prosecution, and given that many of the prior art references were Regeneron's own publications, Regeneron had knowledge of the invalidating disclosures of the prior art. (*See, e.g.*, '338 patent PH, 9/11/2015 Applicant Remarks; '681 patent PH, 6/25/2018 Applicant Remarks; '681 patent PH, 7/26/2018 Notice of Allowability). Also, during at least PGR2021-00117, IPR2021-00880, and IPR2021-00881, Regeneron has taken positions that it knows to be misleading, inaccurate, and without merit, including, but not limited to, with respect to the identity of the claimed molecule, and its amino acid sequence and nucleotide sequence. (*See, e.g.*, IPR2021-00881, Patent Owner Response, Paper 41 at 24-35). Further, Regeneron has obstructed the PTAB proceedings at least through its continued pursuit of the above arguments and its meritless claim construction arguments. In addition, the most reasonable inference to be drawn from Regeneron's withholding of the disclosures of the above references from the PTO and misleading and inaccurate statements made to the PTO, is that the actions were done with the intent to deceive. Because of the clearly invalidating disclosures of the prior art, which set forth the exact same dosing regimen that Regeneron later claimed in its dosing patents, Regeneron's omissions and misleading arguments to the PTO were material, because but for said omissions and misleading arguments, the claims would not have issued. Further, given the applicant's failure to provide relevant disclosures to the Examiner, and the misleading and inaccurate statements made to the PTO, during at least the prosecution of the applications leading to the '338 patent and '069 patent; given Regeneron's knowledge of the materiality of those actions; given that the most reasonable inference to be drawn from those actions is that they were done with the intent to deceive; and given the close relation of the claims at issue in the '338 patent to the other issued claims in the patent family; each member

of the patent family, including the '069 patent, is unenforceable for inequitable conduct. *See, e.g.*, *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580 (D. Del. 2006).

65. Mylan is entitled to a judgment that the claims of the '069 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 5
Non-Infringement and Invalidity of U.S. Patent No. 9,816,110

66. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

67. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '110 patent.

68. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '110 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

69. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '110 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

70. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '110 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related

to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

71. The claims of the ’110 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

72. Mylan is entitled to a judgment that the claims of the ’110 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 6
Non-Infringement and Invalidity of U.S. Patent No. 10,130,681

73. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

74. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the ’681 patent.

75. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the ’681 patent, as set forth in Plaintiff’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

76. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’681 patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

77. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '681 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

78. The claims of the '681 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

79. The claims of the '681 patent are unenforceable due to Regeneron's inequitable conduct during prosecution of the application(s) that led to the '681 patent's issuance and the positions that Regeneron has taken before the PTAB. For example, while arguing to the PTO during prosecution of U.S. Patent Application No. 14/972,560 that the disclosures of Heier 2012 supported the patentability of the pending claims, Regeneron knew that the VIEW and Phase 2 dosing regimens were widely disclosed in the prior art, including in its own prior art press releases, (*e.g.*, 8-19-2008 Regeneron Press Release; 9-28-2008 Regeneron Press Release; 9-14-2009 Regeneron Press Release), 10-Q forms, and 10-K forms, as well as industry publications, which were withheld from the PTO. Thus, Regeneron, and/or its agents, withheld the fact that the same dosing regimen it was relying upon in the 2012 reference to show unexpected results was also disclosed in the prior art. Moreover, Regeneron made arguments to the PTO which were, upon information and belief, intentionally misleading and inaccurate, including Regeneron's statements regarding the purported "standard of care" and the state of the art. (*See, e.g.*, '681 patent PH,

6/25/2018 Applicant Remarks; IPR2021-00880, Petition for *Inter Partes* Review of U.S. Patent No. 9,669,069 at 69-72; IPR2021-00881, Petition for *Inter Partes* Review of U.S. Patent No. 9,254,338 at 66-69). Further, Regeneron was aware of the materiality of references disclosing the VIEW and Phase 2 dosing regimens, which is evidenced by its representations to the PTO during prosecution and its subsequent decisions to submit a subset of said references to the PTO in connection with other pending related applications. (*See, e.g.*, '681 patent PH, 6/25/2018 Applicant Remarks; '681 patent PH, 5/26/2017 Information Disclosure Statement). Further, upon information and belief, Regeneron was aware of the materiality of the misleading and inaccurate statements made to the PTO during prosecution, and given that many of the prior art references were Regeneron's own publications, Regeneron had knowledge of the invalidating disclosures of the prior art. (*See, e.g.*, '681 patent PH, 6/25/2018 Applicant Remarks; '681 patent PH, 7/26/2018 Notice of Allowability). In addition, during at least PGR2021-00117, IPR2021-00880, and IPR2021-00881, Regeneron has taken positions that it knows to be misleading, inaccurate, and without merit, including, but not limited to, with respect to the identity of the claimed molecule, and its amino acid sequence and nucleotide sequence. (*See, e.g.*, IPR2021-00881, Patent Owner Response, Paper 41 at 24-35). Further, Regeneron has obstructed the PTAB proceedings at least through its continued pursuit of the above arguments, and its meritless claim construction arguments. In addition, the most reasonable inference to be drawn from Regeneron's withholding of the disclosures of the above references from the PTO and misleading and inaccurate statements made to the PTO, is that the actions were done with the intent to deceive. Because of the clearly invalidating disclosures of the prior art, which set forth the exact same dosing regimen that Regeneron later claimed in its dosing patents, Regeneron's omissions and misleading arguments to the PTO were material, because but for said omissions and misleading arguments, the claims

would not have issued. Further, given the applicant's failure to provide relevant disclosures to the Examiner, and the misleading and inaccurate statements made to the PTO, during at least the prosecution of the applications leading to the '338 patent and the '069 patent; given Regeneron's knowledge of the materiality of those actions; given that the most reasonable inference to be drawn from those actions is that they were done with the intent to deceive; and given the close relation of the claims at issue in the '338 and '069 patents to the other issued claims in the patent family; each member of the patent family, including the '681 patent, is unenforceable for inequitable conduct. *See, e.g., eSpeed*, 417 F. Supp. 2d 580.

80. Mylan is entitled to a judgment that the claims of the '681 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 7
Non-Infringement and Invalidity of U.S. Patent No. 10,406,226

81. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

82. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '226 patent.

83. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '226 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

84. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’226 patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

85. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’226 patent because particular activities related to Mylan’s Proposed BLA Product, such as the manufacture or testing of Mylan’s Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

86. The claims of the ’226 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

87. Mylan is entitled to a judgment that the claims of the ’226 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 8
Non-Infringement and Invalidity of U.S. Patent No. 10,415,055

88. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

89. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the ’055 patent.

90. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '055 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

91. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '055 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

92. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '055 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

93. The claims of the '055 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

94. Mylan is entitled to a judgment that the claims of the '055 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 9
Non-Infringement and Invalidity of U.S. Patent No. 10,464,992

95. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

96. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '992 patent.

97. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '992 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

98. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '992 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

99. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '992 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

100. The claims of the '992 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

101. Mylan is entitled to a judgment that the claims of the '992 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of

that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 10
Non-Infringement and Invalidity of U.S. Patent No. 10,669,594

102. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

103. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '594 patent.

104. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '594 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

105. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '594 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

106. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '594 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

107. The claims of the '594 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or

112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

108. Mylan is entitled to a judgment that the claims of the '594 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 11
Non-Infringement and Invalidity of U.S. Patent No. 10,857,205

109. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

110. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '205 patent.

111. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '205 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

112. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '205 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

113. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '205 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related

to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

114. The claims of the ’205 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

115. The claims of the ’205 patent are unenforceable due to Regeneron’s inequitable conduct during prosecution of the application(s) that led to the ’338 and ’069 patents’ issuance and the positions that Regeneron has taken before the PTAB as outlined above for the ’338 and ’069 patents, counts 3 and 4, incorporated herein in its entirety.

116. Mylan is entitled to a judgment that the claims of the ’205 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 12
Non-Infringement and Invalidity of U.S. Patent No. 10,888,601

117. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

118. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the ’601 patent.

119. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the ’601 patent, as set forth in Plaintiff’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

120. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '601 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

121. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '601 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

122. The claims of the '601 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

123. The claims of the '601 patent are unenforceable due to Regeneron's inequitable conduct during prosecution of the application(s) that led to the '338 and '069 patents' issuance and the positions that Regeneron has taken before the PTAB as outlined above for the '338 and '069 patents, counts 3 and 4, incorporated herein in its entirety.

124. Mylan is entitled to a judgment that the claims of the '601 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 13
Non-Infringement and Invalidity of U.S. Patent No. 10,927,342

125. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

126. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '342 patent.

127. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '342 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

128. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '342 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

129. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '342 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

130. The claims of the '342 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

131. Mylan is entitled to a judgment that the claims of the '342 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of

that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 14
Non-Infringement and Invalidity of U.S. Patent No. 10,973,879

132. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

133. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '879 patent.

134. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '879 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

135. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '879 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Moreover, EYLEA® (aflibercept) has not been approved for a condition of use (e.g., indication, dosing regimen) that would be covered by the claims of the '879 patent. Under 42 U.S.C. § 262(k)(2)(A)(i)(III) and FDA's regulations and policies, a biosimilar applicant cannot obtain approval for a condition of use for which the reference product has not previously been approved. Thus, the proposed label for Mylan's Proposed BLA Product, a draft of which was provided to Regeneron in Mylan's § 262(*l*)(2)(A) BLA production and can be found in Module 1 of Mylan's BLA No. 761274, and which is incorporated by reference herein in its entirety, does not seek approval for any condition of use that would be covered by the claims of the '879 patent; nor does it encourage, promote, or recommend, or otherwise provide any instruction, to engage in administration of the drug in a

manner that would be covered by the claims of the '879 patent. Further, Regeneron conceded during the patent dance that it "do[es] not contend that th[is] patent[] would be infringed by making using, offering to sell, selling or importing into the United States the particular product that is made according to the labeling, processing, and specifications of the version of Mylan's BLA No. 761274 . . . placed on the online review platform."

136. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '879 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

137. The claims of the '879 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

138. Mylan is entitled to a judgment that the claims of the '879 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 15
Non-Infringement and Invalidity of U.S. Patent No. 11,053,280

139. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

140. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the ’280 patent.

141. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the ’280 patent, as set forth in Plaintiff’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

142. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’280 patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

143. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’280 patent because particular activities related to Mylan’s Proposed BLA Product, such as the manufacture or testing of Mylan’s Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

144. The claims of the ’280 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

145. Mylan is entitled to a judgment that the claims of the ’280 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 16
Non-Infringement and Invalidity of U.S. Patent No. 11,066,458

146. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

147. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '458 patent.

148. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '458 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

149. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '458 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

150. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '458 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

151. The claims of the '458 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

152. Mylan is entitled to a judgment that the claims of the '458 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of

that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 17
Non-Infringement and Invalidity of U.S. Patent No. 11,084,865

153. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

154. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '865 patent.

155. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '865 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

156. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '865 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

157. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '865 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

158. The claims of the '865 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or

112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

159. Mylan is entitled to a judgment that the claims of the '865 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 18
Non-Infringement and Invalidity of U.S. Patent No. 11,104,715

160. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

161. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '715 patent.

162. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '715 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

163. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '715 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

164. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '715 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related

to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

165. The claims of the '715 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

166. Mylan is entitled to a judgment that the claims of the '715 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 19
Non-Infringement and Invalidity of U.S. Patent No. 11,174,283

167. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

168. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '283 patent.

169. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '283 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

170. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '283 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

171. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '283 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

172. The claims of the '283 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

173. Mylan is entitled to a judgment that the claims of the '283 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 20
Non-Infringement and Invalidity of U.S. Patent No. 11,186,625

174. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

175. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '625 patent.

176. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '625 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

177. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’625 patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

178. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’625 patent because particular activities related to Mylan’s Proposed BLA Product, such as the manufacture or testing of Mylan’s Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

179. The claims of the ’625 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

180. Mylan is entitled to a judgment that the claims of the ’625 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 21
Non-Infringement and Invalidity of U.S. Patent No. 11,253,572

181. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

182. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the ’572 patent.

183. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '572 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

184. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '572 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

185. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '572 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

186. The claims of the '572 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

187. The claims of the '572 patent are unenforceable due to Regeneron's inequitable conduct during prosecution of the application(s) that led to the '338 and '069 patents' issuance and the positions that Regeneron has taken before the PTAB as outlined above for the '338 and '069 patents, counts 3 and 4, incorporated herein in its entirety.

188. Mylan is entitled to a judgment that the claims of the '572 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C.

§ 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 22
Non-Infringement and Invalidity of U.S. Patent No. 11,299,532

189. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

190. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the ’532 patent.

191. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the ’532 patent, as set forth in Plaintiff’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

192. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’532 patent, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

193. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’532 patent because particular activities related to Mylan’s Proposed BLA Product, such as the manufacture or testing of Mylan’s Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

194. The claims of the ’532 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

195. Mylan is entitled to a judgment that the claims of the '532 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 23
Non-Infringement and Invalidity of U.S. Patent No. 11,306,135

196. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

197. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '135 patent.

198. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '135 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

199. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '135 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

200. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '135 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

201. The claims of the '135 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

202. Mylan is entitled to a judgment that the claims of the '135 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 24
Non-Infringement and Invalidity of U.S. Patent No. 11,332,771

203. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

204. Plaintiff has alleged that Regeneron is the owner of all right, title, and interest in the '771 patent.

205. A case or controversy exists because Plaintiff has alleged that Mylan has infringed and will infringe one or more claims of the '771 patent, as set forth in Plaintiff's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

206. Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '771 patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

207. Under 35 U.S.C. § 271(e)(1), Mylan has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '771 patent because particular activities related to Mylan's Proposed BLA Product, such as the manufacture or testing of Mylan's Proposed

BLA Product related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use, or sale of drugs.

208. The claims of the '771 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

209. Mylan is entitled to a judgment that the claims of the '771 patent are invalid and/or unenforceable, and that Mylan has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Mylan's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT 25
Declaratory Judgment of No Lost Profits or Injunctive Relief For Certain Patents

210. Mylan realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

211. This claim arises under the BPCIA, 42 U.S.C. § 262(*l*), the Patent Act, 35 U.S.C. § 271(e), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

212. When a biosimilar applicant elects to participate and uphold its obligations under the patent dance, the biosimilar applicant "has substantial control over the timing and scope" of the ensuing patent litigation(s). *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1666 (2017). This carefully calibrated scheme is designed to incentivize the biosimilar applicant to make substantial pre-suit disclosures of its regulatory application, manufacturing information, and defenses in exchange for certain statutory protections.

213. Central to the BPCIA's multi-step information exchange scheme is the selection of the patents to be *immediately* litigated within 30-days of completion of the patent dance and, if applicable, the identification of any remaining patents to be resolved in a subsequent phase of litigation. Any patents to be immediately litigated pursuant to subsection (*l*)(6) are included in patent lists exchanged by the reference product sponsor and the biosimilar applicant pursuant to subsection (*l*)(4) or (*l*)(5).

214. Under the BPCIA, when there is no agreement on which patents to immediately litigate, the biosimilar applicant has the express statutory right to control the *scope* (e.g., number of patents) of the immediate litigation. 42 U.S.C. § 262 (*l*)(5); *see also*, *Sandoz*, 137 S. Ct. at 1671 ("[t]his process gives the applicant substantial control over the scope of the first phase of litigation"). For any remaining patent disputes following the first phase of litigation, it is the biosimilar applicant who also has the statutory right to control the *timing* of any second phase of litigation. 42 U.S.C. § 262(*l*)(8)(A), (9)(A); *see also Sandoz*, 137 S. Ct. at 1672 ("Because the applicant (subject to certain constraints) chooses when to begin commercial marketing and when to give notice, it wields substantial control over the timing of the second phase of litigation.").

215. Once the patents have been identified for immediate litigation, the BPCIA directs the reference product sponsor to bring an action under subsection (*l*)(6) for patent infringement no later than thirty (30) days after agreement of a patent list under (*l*)(4) or the exchange of patent lists under (*l*)(5). 42 U.S.C. § 262(*l*)(6).

216. To reinforce the reference product sponsor's incentive to adhere to the patent lists exchanged under (*l*)(4) or (*l*)(5)—and thus the scope of the first phase of litigation selected by the biosimilar applicant—the BPCIA dictates consequences to the reference product sponsor for (1) any untimely suits filed "after the expiration of the 30-day period" or (2) timely suits filed "before

the expiration of the 30-day period" but which were "dismissed without prejudice or [were] not prosecuted to judgment in good faith." 35 U.S.C. § 271(e)(6)(A)(ii)(I), (II). In such instances, the BPCIA unambiguously limits the infringement remedies available to the reference product sponsor: "the sole and exclusive remedy that may be granted by a court, upon [a finding of infringement], shall be a reasonable royalty." 35 U.S.C. § 271(e)(6)(B).

217. During the patent dance, Regeneron and Mylan collectively identified a total of twenty-five (25) patents on the lists exchanged pursuant to 42 U.S.C. § 262(*l*)(5)(B)(i) ("the (*l*)(5) Patent List"). Within thirty (30) days of completion of the patent dance, Regeneron filed suit on twenty-four (24) of the patents included in the (*l*)(5) Patent List, which reasonably signaled its intent to immediately litigate or otherwise resolve the dispute with respect to each of these patents. (Dkt. No. 1). At no point during the patent dance, did Regeneron ever indicate that it would request an expedited trial date on only a subset of the Patents-in-Suit, leaving the bulk of the patents included in the (*l*)(5) Patent List to be litigated in a later phase after resolution of the patents selected for trial.

218. On August 5, 2022, a mere three (3) days after filing suit, Regeneron filed a motion for an expedited status conference, stating for the first time its request for a June 2023 trial on only half of the twenty-four (24) Patents-in-Suit. (Dkt. No. 7, at 5, 6). Regeneron did not include a proposal to resolve patent disputes with respect to the other half of the Patents-in-Suit. Mylan was given no opportunity to select any of the twelve (12) patents chosen by Regeneron for immediate litigation.

219. On September 28, 2022, on its own accord, Regeneron volunteered during a scheduling conference with the Court to further reduce the number of patents for immediate litigation down to six (6) patents. (Transcript at 22). Despite several meet and confers and written

exchanges in advance of the scheduling conference, Regeneron gave no advance notice of its plans to withhold the bulk of the patents included in the (*l*)(5) Patent List from the first wave of litigation.

220. When asked, Regeneron declined to provide any plan as to how to resolve the patent disputes with respect to any of the remaining unselected, but still asserted patents included in the (*l*)(5) Patent List—only informing the Court that it would evaluate and potentially assert some of these patents after adjudication of the first phase of patents depending on the outcome of the first phase. (*Id.* at 25, 33) (Regeneron's counsel stating "I will submit that with respect to the rest of those patents, Your Honor, we don't know exactly what will happen with them. But it is likely that there won't need to be another trial with respect to those patents. If we prevail on these patents that we're proposing to move forward with now, this small subset of patents, then it's very unlikely that we would feel the need to move forward again with respect to those other patents.").

221. On September 29, 2022, Regeneron submitted a proposed scheduling order voluntarily reducing the twenty-four (24) Patents-in-Suit to a total of six (6) patents, with a further subsequent reduction down to three (3) patents for trial and adjudication. (Dkt. No. 78-1).

222. On October 25, 2022, presumably based on Regeneron's representations that it would voluntarily narrow the patents for trial, the Court entered a Scheduling Order setting trial for June 2023. (Dkt. No. 87, at 2).

223. On October 28, 2022, Regeneron filed a stipulation unilaterally "elect[ing] six patents from three patent families to proceed in the first stage of litigation." (Dkt. No. 88, at 1). The stipulation did not contain any details with regard to when the parties would litigate or otherwise resolve the patent disputes with respect to the other eighteen (18) Patents-in-Suit: '959 patent, '106 patent, '338 patent, '069 patent, '110 patent, '681 patent, '226 patent, '055 patent,

'992 patent, '594 patent, '205 patent, '342 patent, '879 patent, '458 patent, '283 patent, '625 patent, '135 patent, and '771 patent (collectively, "the Remainder 18 Patents").

224. Each of the Remainder 18 Patents were included in the (*l*)(5) Patent List and are the subject of this suit filed under 42 U.S.C. § 262(*l*)(6).

225. Regeneron has failed to comply with its obligations under the BPCIA and its violations have injured Mylan by depriving it of the procedural protections to which it is entitled under the statute.

226. Regeneron's voluntary, unilateral reduction of the (*l*)(5) Patent List down to an eventual three (3) patents, while reserving the right to litigate the Remainder 18 Patents, at its own discretion, at some unknown time, and depending on the outcome of trial, effectively dismisses those patents without prejudice from the (*l*)(6) suit.

227. Regeneron has not prosecuted each of the patents included in its (*l*)(5) Patent List to judgement in good faith. Regeneron's choice to assert the twenty-four (24) Patents-in-Suit while only actually litigating three (3) of those patents at trial, is nothing more than a self-serving act to reserve the right to seek lost profits and injunctive relief on the Remainder 18 Patents well after the statutory 30-day window to begin litigation under subsection (*l*)(6), and to circumvent the limitations on damages contemplated by 35 U.S.C. § 271(e)(6).

228. Regeneron's effective dismissal of the Remainder 18 Patents without prejudice and/or failure to prosecute the Remainder 18 Patents to judgement in good faith has wholly negated Mylan's decision to make substantial pre-suit disclosures and participate in the extensive patent dance procedures for over 200 days prior to suit.

229. Regeneron's unilateral actions have stripped Mylan of its statutory right to control the scope of the (*l*)(6) litigation and have not only deprived Mylan of a full and fair opportunity to

immediately litigate the invalidity, unenforceability, and/or non-infringement of each of the Remainder 18 Patents, but have also entirely vitiated Mylan's statutory right to participate in the selection of the patents to immediately litigate. Regeneron's unilateral actions have also usurped Mylan's statutory right to control the timing of any second phase of litigation by allowing Regeneron to dictate when and under what circumstances each of the Remainder 18 Patents are to be litigated.

230. There is a real and justiciable controversy between Regeneron and Mylan regarding scope of available remedies that may be granted upon a finding of infringement of the Remainder 18 Patents.

231. Mylan is entitled to a judgment declaring that, if Mylan infringes any valid claim of the Remainder 18 Patents, the sole and exclusive remedy that Regeneron is entitled to is a reasonable royalty since these patents have been effectively dismissed without prejudice and/or Regeneron has not prosecuted these patents to judgment in good faith. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Mylan respectfully requests that the Court enter judgment:

A. adjudging and decreeing that Plaintiff be denied all forms of relief requested in its Complaint;

B. dismissing the Complaint in its entirety with prejudice;

C. declaring that the claims of the Patents-in-Suit have not been and will not be infringed by Mylan;

D. declaring that the claims of the Patents-in-Suit are invalid;

E. declaring that the claims of the Patents-in-Suit are unenforceable;

F. finding that this is an exceptional case under 35 U.S.C. § 285;

G. awarding attorneys' fees, costs, and expenses to Mylan;

H. declaring that the sole and exclusive remedy for any infringement of the Remainder 18 Patents is a reasonable royalty under 35 U.S.C. § 271(e)(6)(B); and

I. granting such other and further relief as this Court deems just and proper.

Date: December 9, 2022

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