UNITED STATES DISTRICT COURT
EASTERN DISTRICT NEW YORK

ALLERGAN, INC. and ABBVIE INC., *Plaintiffs*, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC and AMNEAL EU, LIMITED, *Defendants*.	C.A. No. 2:23-cv-06208-NJC-ST [redacted] [redacted]

DEFENDANTS AMNEAL PHARMACEUTICALS OF NEW YORK, LLC'S AND AMNEAL EU, LIMITED'S ANSWER AND COUNTERCLAIMS

Defendants Amneal Pharmaceuticals of New York, LLC ("Amneal NY") and Amneal EU, Limited ("Amneal EU" and collectively with Amneal NY, "Amneal"), by their undersigned attorneys, hereby answer the Complaint of Plaintiffs Allergan, Inc. ("Allergan") and AbbVie Inc. ("AbbVie" and collectively with Allergan, "Plaintiffs"), as set forth below. This pleading is based upon Amneal's knowledge as to its own activities, and upon information and belief as to the activities of others. Amneal denies all allegations except those specifically admitted below. *See* Fed. R. Civ. P. 8(b)(3).

RESPONSES TO "NATURE OF THE ACTION"

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, arises from Amneal's submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Plaintiffs' successful pharmaceutical product LUMIGAN® 0.01% prior to the expiration of U.S. Patent Nos. 7,851,504 ("'504 Patent"); 8,278,353 ("'353 Patent"); 8,299,118 ("'118 Patent"); 8,309,605 ("'605 Patent"); 8,338,479 ("'479 Patent"); 8,524,777 ("'777 Patent");

8,586,630 ("'630 Patent"); 8,772,338 ("'338 Patent"); 8,933,120 ("'120 Patent"); 8,933,127 ("'127 Patent"); 9,155,716 ("'716 Patent"); and 9,241,918 ("'918 Patent") (collectively the "patents-in-suit"), which are each listed for LUMIGAN® 0.01% in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book").

ANSWER:

Paragraph 1 states a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that Plaintiffs purport to bring an action for patent infringement under the patent laws of the United States. Amneal further admits that it filed ANDA No. 217289 with the FDA for approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products prior to the expiration of U.S. Patent Nos. 7,851,504 ("'504 Patent"); 8,278,353 ("'353 Patent"); 8,299,118 ("'118 Patent"); 8,309,605 ("'605 Patent"); 8,338,479 ("'479 Patent"); 8,524,777 ("'777 Patent"); 8,586,630 ("'630 Patent"); 8,772,338 ("'338 Patent"); 8,933,120 ("'120 Patent"); 8,933,127 ("'127 Patent"); 9,155,716 ("'716 Patent"); and 9,241,918 ("'918 Patent") (collectively the "patents-in-suit"). Amneal denies any remaining allegations of this paragraph.

2. Amneal has infringed one or more claims of each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by filing its ANDA No. 217289 ("Amneal's ANDA") seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic version of LUMIGAN® 0.01% ("Amneal's ANDA Product") prior to the expiration of the patents-in-suit. Amneal will infringe one or more claims of each of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Amneal's ANDA Product prior to the expiration of the patents-in-suit.

ANSWER:

Denied.

RESPONSES TO "LUMIGAN®"

3. Open angle glaucoma is a chronic, progressive optic neuropathy that can result in blindness. Elevated intraocular pressure presents a major risk factor for glaucomatous field loss. The higher the level of intraocular pressure, the greater the likelihood of optic nerve damage and visual field loss.

ANSWER:

Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

4. LUMIGAN® 0.01% safely and effectively reduces intraocular pressure in patients suffering from open angle glaucoma and ocular hypertension.

ANSWER:

Amneal admits that Section 12.1 "Mechanism of Action" in the label for LUMIGAN® 0.1% states that "[b]imatoprost is believed to lower intraocular pressure (IOP) in humans by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes. Elevated IOP presents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss." Amneal denies any remaining allegations in Paragraph 4.

5. The FDA approved LUMIGAN® 0.01% on August 31, 2010, pursuant to New Drug Application ("NDA") No. 22184. A true and correct copy of the prescribing label for LUMIGAN® 0.01% is attached as Exhibit A.

ANSWER:

Amneal admits that Exhibit A to the Complaint appears to be a copy of the prescribing label for LUMIGAN® 0.01%. Amneal further admits that the prescribing information references NDA 022184 and lists an "Initial U.S. Approval" in 2001. Amneal denies any remaining allegations in Paragraph 5.

6. Plaintiffs developed LUMIGAN® 0.01% and market and sell it in this judicial district and throughout the United States.

ANSWER:

Amneal admits that LUMIGAN® 0.01% is marketed and sold in this judicial district. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 6, and therefore denies them.

7. The '504 Patent, which expires June 13, 2027, is listed in the Orange Book with

respect to LUMIGAN® 0.01% and NDA No. 22184.

ANSWER:

Amneal admits that the '504 Patent is listed in the Orange Book with respect to LUMIGAN® 0.01% and NDA No. 22184. Amneal denies any remaining allegations in Paragraph 7.

8. The rest of the patents-in-suit, each of which expires March 16, 2025, are listed in the Orange Book with respect to LUMIGAN® 0.01% and NDA No. 22184.

ANSWER:

Amneal admits that the '353 Patent, the '118 Patent, the '605 Patent, the '479 Patent, the '777 Patent, the '630 Patent, the '338 Patent, the '120 Patent, the '127 Patent, the '716 Patent, and the '918 Patent are listed in the Orange Book with respect to LUMIGAN® 0.01% and NDA No. 22184. Amneal denies any remaining allegations in Paragraph 8.

9. LUMIGAN® 0.01% has been the subject of prior ANDA litigation. *See Allergan, Inc. v. Sandoz, Inc.*, C.A. No. 6:11-cv-441 (E.D. Tex.). In the litigation against Sandoz, Inc., the district court held a bench trial and found all asserted patents—the '504, '353, '118, '605, and '479 Patents—valid and infringed and entered a permanent injunction. *See Allergan, Inc. v. Sandoz, Inc.*, C.A. No. 6:11-cv-441, at D.I. 303; *see also id.*, 2014 WL 12622277, at *12, 37-38 (E.D. Tex. Jan. 13, 2014). The district court's decision was affirmed in all respects on appeal. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293 (Fed. Cir. 2015).

ANSWER:

Amneal admits that LUMIGAN® 0.01% has been the subject of prior ANDA litigation. Amneal further avers that the decisions referenced in Paragraph 9 speak for themselves. Amneal denies any remaining allegations in Paragraph 9.

10. LUMIGAN® 0.01% is also the subject of concurrent ANDA litigation. *See Allergan, Inc. v. Mankind Pharma Ltd.*, C.A. No. 1:23-cv-00272 (D. Del.). Defendant Mankind Pharma Limited has limited its challenge to the '504 Patent and to date has not contested the validity of that patent.

ANSWER:

Amneal admits that LUMIGAN® 0.01% is the subject of litigation in *Allergan, Inc. v. Mankind Pharma Ltd.*, C.A. No. 1:23-cv-00272 (D. Del.). Amneal lacks knowledge or information

sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10, and therefore denies them.

RESPONSES TO "THE PARTIES"

11. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. AbbVie's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including eye diseases.

ANSWER:

Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 11, and therefore denies them.

12. AbbVie holds NDA No. 22184 for LUMIGAN® 0.01%. *See* Exhibit B.

ANSWER:

Admitted.

13. Plaintiff Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. Allergan is the assignee of the patents-in-suit. Allergan is an indirectly wholly owned subsidiary of AbbVie.

ANSWER:

Amneal lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 13, and therefore denies them.

14. On information and belief, Defendant Amneal Pharmaceuticals of New York, LLC, is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, NY 11719. On further information and belief, Amneal Pharmaceuticals of New York, LLC, is the U.S. agent for Amneal EU, Limited.

ANSWER:

Admitted.

15. On information and belief, Defendant Amneal EU, Limited is a corporation organized and existing under the laws of Ireland, having its principal place of business at 70 Sir Rogerson's Quay, D02 R296 Dublin, Ireland.

ANSWER:

Amneal admits that Amneal EU is a limited liability company organized and existing under the laws of Ireland, having its principal place of business at Cahir Road, Cashel, Co. Tipperary, E25 ZD51, Ireland. Amneal denies any remaining allegations in Paragraph 15.

16. On information and belief, Defendant Amneal Pharmaceuticals Private Limited is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 882/1-871 Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, District: Ahmedabad-382220, Gujarat, India.

ANSWER:

In accordance with Dkt. No. 6, all claims against Amneal Pharmaceuticals Private Limited have been dismissed, and therefore no response is required as to allegations pertaining to Amneal Pharmaceuticals Private Limited. Otherwise, denied.

17. On information and belief, Defendants prepared and submitted ANDA No. 217289 and continue to seek FDA approval for that application.

ANSWER:

Amneal admits that Amneal NY, which is the Authorized U.S. Agent for Amneal EU, prepared and filed ANDA No. 217289 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 17.

18. On information and belief, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), Amneal prepared and sent to Plaintiffs a letter dated July 5, 2023 (the "Notice Letter"), purporting to inform Plaintiffs that "Amneal Pharmaceuticals of New York, LLC, U.S. Agent for Amneal EU, Limited" had "filed an [ANDA]" with a Paragraph IV certification to the FDA with respect to the patents- in-suit.

ANSWER:

Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the

patents-in-suit. Amneal denies the remaining allegations in Paragraph 18.

19. On information and belief, Defendants stand to benefit from the approval of Amneal's ANDA. On information and belief, Amneal Pharmaceuticals of New York, LLC; Amneal EU, Limited; and Amneal Pharmaceuticals Private Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, and regularly enter into agreements with each other that are nearer than arm's length. Furthermore, on information and belief, Defendants intend to commercially manufacture, market, offer for sale, and sell Amneal's ANDA Product throughout the United States, including in the State of New York, in the event the FDA approves Amneal's ANDA.

ANSWER:

Amneal admits that it submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 19, and therefore denies them.

RESPONSES TO "JURISDICTION AND VENUE"

20. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

21. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271, specifically. Therefore, subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest subject matter jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 21.

22. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, *inter alia*, have continuous and systematic contacts with New York, regularly

conduct business in New York, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos, have purposefully availed themselves of the privilege of doing business in New York, and intend to sell Amneal's ANDA Product in New York upon approval of Amneal's ANDA. Furthermore, Amneal Pharmaceutical of New York, LLC, has its principal place of business in this judicial district: 50 Horseblock Road, Brookhaven, NY 11719.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 22.

23. Additionally, this Court has personal jurisdiction over Amneal EU, Limited and Amneal Pharmaceuticals Private Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Amneal EU, Limited and Amneal Pharmaceuticals Private Limited are both foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Amneal EU, Limited and Amneal Pharmaceuticals Private Limited both have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Amneal's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Amneal EU, Limited and Amneal Pharmaceuticals Private Limited satisfies due process.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 23.

24. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Defendants manufacture, distribute, market and/or sell throughout the United States and in this judicial district.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it is in the business of, among other things, manufacturing,

importing, distributing, and selling pharmaceutical drug products. Amneal further states that, solely for the limited purpose of this action only, Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 24.

25. On information and belief, Defendants are licensed to sell generic and proprietary pharmaceutical products in New York, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 25.

26. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the patents-in-suit that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by the Notice Letter sent by Amneal Pharmaceuticals of New York, LLC to Allergan, Inc. pursuant to 21 U.S.C. § 355(j)(2)(b), Defendants prepared and filed Amneal's ANDA with the intention of seeking to market Amneal's ANDA Product nationwide, including within this judicial district.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal further states that Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 26.

27. On information and belief, if the FDA approves ANDA No. 217289, Defendants intend to market, offer for sale, sell, and/or distribute Amneal's ANDA Product in New York and to residents of New York, list Amneal's ANDA Product on New York's prescription drug formulary, and seek Medicaid reimbursements for sales of Amneal's ANDA Product in the State of New York, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos. Defendants will derive substantial revenue from the use or consumption of Amneal's ANDA Product

in New York.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 27.

28. On information and belief, Defendants know and intend that Amneal's ANDA Product will be distributed and sold in New York and will thereby displace sales of LUMIGAN® 0.01%, causing injury to Plaintiffs. Defendants intend to take advantage of their established channels of distribution in New York for the sale of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest jurisdiction in the Eastern District of New York, but otherwise denies the allegations in Paragraph 28.

29. Venue is proper in this district for Amneal Pharmaceuticals Private Limited pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, Amneal Pharmaceuticals Private Limited is a corporation organized and existing under the laws of Republic of India and as such may be sued in any judicial district.

ANSWER:

In accordance with Dkt. No. 6, all claims against Amneal Pharmaceuticals Private Limited have been dismissed, and therefore no response is required as to allegations pertaining to Amneal Pharmaceuticals Private Limited. Otherwise, denied.

30. Venue is proper in this district for Amneal EU, Limited pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, Amneal EU, Limited is a corporation organized and existing under the laws of Ireland and as such may be sued in any judicial district.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an

answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest venue in the Eastern District of New York, but otherwise denies the allegations in Paragraph 30.

31. Venue is proper in this district for Amneal Pharmaceuticals of New York, LLC, pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Amneal Pharmaceuticals of New York, LLC: (1) has committed acts of infringement in this judicial district and (2) has a regular and established place of business in this judicial district, in particular, its principal place of business, located at 50 Horseblock Road, Brookhaven, NY 11719. Furthermore, on information and belief, Amneal Pharmaceuticals of New York, LLC, has an additional regular and established place of business in this judicial district through its facility at 85 Adams Avenue, Hauppauge, NY 11788.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal states that, solely for the limited purpose of this action only, Amneal does not contest venue in the Eastern District of New York, but otherwise denies the allegations in Paragraph 31.

32. On information and belief, Amneal Pharmaceuticals of New York, LLC has infringed one or more claims of each of the patents-in-suit from within this judicial district at least by submitting Amneal's ANDA with a Paragraph IV certification, thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the patents-in-suit, an act which violates 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

33. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the patents-in-suit would infringe one or more claims of the patents-in-suit under 35 U.S.C. § 271(a), and/or Amneal Pharmaceuticals of New York, LLC, would induce or contribute to infringement of one or more claims of the patents- in-suit under 35 U.S.C. § 271(b) and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Amneal's ANDA Product prior to the expiration of the patents-in-suit.

ANSWER:

Denied.

RESPONSES TO "THE PATENTS-IN-SUIT"

34. The '504 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on December 14, 2010. A true and correct copy of the '504 Patent is attached as Exhibit C.

ANSWER:

Amneal admits that Exhibit C to the Complaint appears to be a copy of the '504 Patent, which indicates on its face an issue date of December 14, 2010. Amneal further admits that the '504 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 34.

35. The '353 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on October 2, 2012. A true and correct copy of the '353 Patent is attached as Exhibit D.

ANSWER:

Amneal admits that Exhibit D to the Complaint appears to be a copy of the '353 Patent, which indicates on its face an issue date of October 2, 2012. Amneal further admits that the '353 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 35.

36. The '118 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on October 30, 2012. A true and correct copy of the '118 Patent is attached as Exhibit E.

ANSWER:

Amneal admits that Exhibit E to the Complaint appears to be a copy of the '118 Patent, which indicates on its face an issue date of October 30, 2012. Amneal further admits that the '118 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 36.

37. The '605 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on November 13, 2012. A true and correct copy of the '605 Patent is attached as Exhibit F.

ANSWER:

Amneal admits that Exhibit F to the Complaint appears to be a copy of the '605 Patent, which indicates on its face an issue date of November 13, 2012. Amneal further admits that the '605 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 37.

38. The '479 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on December 25, 2012. A true and correct copy of the '479 Patent is attached as Exhibit G.

ANSWER:

Amneal admits that Exhibit G to the Complaint appears to be a copy of the '479 Patent, which indicates on its face an issue date of December 25, 2012. Amneal further admits that the '479 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 38.

39. The '777 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on September 3, 2013. A true and correct copy of the '777 Patent is attached as Exhibit H.

ANSWER:

Amneal admits that Exhibit H to the Complaint appears to be a copy of the '777 Patent, which indicates on its face an issue date of September 3, 2012. Amneal further admits that the '777 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 39.

40. The '630 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on November 19, 2013. A true and correct copy of the '630 Patent is attached as Exhibit I.

ANSWER:

Amneal admits that Exhibit I to the Complaint appears to be a copy of the '630 Patent, which indicates on its face an issue date of November 19, 2013. Amneal further admits that the '630 Patent

is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 40.

41. The '338 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on July 8, 2014. A true and correct copy of the '338 Patent is attached as Exhibit J.

ANSWER:

Amneal admits that Exhibit J to the Complaint appears to be a copy of the '338 Patent, which indicates on its face an issue date of July 8, 2014. Amneal further admits that the '338 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 41.

42. The '120 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on January 13, 2015. A true and correct copy of the '120 Patent is attached as Exhibit K.

ANSWER:

Amneal admits that Exhibit K to the Complaint appears to be a copy of the '120 Patent, which indicates on its face an issue date of January 13, 2015. Amneal further admits that the '120 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 42.

43. The '127 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on January 13, 2015. A true and correct copy of the '127 Patent is attached as Exhibit L.

ANSWER:

Amneal admits that Exhibit L to the Complaint appears to be a copy of the '127 Patent, which indicates on its face an issue date of January 13, 2015. Amneal further admits that the '127 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 43.

44. The '716 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on October 13, 2015. A true and correct copy of the '716 Patent is attached as Exhibit

M.

ANSWER:

Amneal admits that Exhibit M to the Complaint appears to be a copy of the '716 Patent, which indicates on its face an issue date of October 13, 2015. Amneal further admits that the '716 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 44.

45. The '918 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on January 26, 2016. A true and correct copy of the '918 Patent is attached as Exhibit N.

ANSWER:

Amneal admits that Exhibit N to the Complaint appears to be a copy of the '918 Patent, which indicates on its face an issue date of January 26, 2016. Amneal further admits that the '918 Patent is titled "Enhanced Bimatoprost Ophthalmic Solution." Amneal denies any remaining allegations in Paragraph 45.

46. All of the patents-in-suit, except for the '504 Patent, expire on March 16, 2025. The United States Patent & Trademark Office awarded 819 days of patent term adjustment to the '504 Patent. The '504 Patent expires June 13, 2027.

ANSWER:

Amneal admits that the '353 Patent, '118 Patent, '605 Patent, '479 Patent, '777 Patent, '630 Patent, '338 Patent, '120 Patent, '127 Patent, '716 Patent, and '918 Patent expire March 16, 2025. Amneal denies that the '504 Patent expires June 13, 2027. The PTO improperly granted the '504 Patent a Type C patent term adjustment because the '504 Patent was not "issued under a decision in the review," and thus should not be entitled to an adjustment under 35 U.S.C. § 154(b)(1)(C)(iii). Amneal denies any remaining allegations in Paragraph 46.

47. Allergan is the assignee of all of the patents-in-suit.

ANSWER:

Amneal admits that Allergan is listed as the "Assignee" on the face of the patents-in-suit. Amneal denies any remaining allegations in Paragraph 47.

RESPONSES TO "AMNEAL'S ANDA"

48. On information and belief, Amneal through its actions and/or through the actions of its agents and subsidiaries, prepared and submitted Amneal's ANDA to the FDA. Amneal's ANDA seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States, including New York, of Amneal's ANDA Product, a generic version of LUMIGAN® 0.01%, before the expiration of the patents-in-suit.

ANSWER:

Amneal admits that it submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 48, and therefore denies them.

49. On information and belief, following FDA approval of the ANDA, Amneal will commercially manufacture, use, sell, offer for sale, and/or import Amneal's ANDA Product throughout the United States, including within the State of New York.

ANSWER:

Amneal admits that it submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 49, and therefore denies them.

50. On information and belief, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), Amneal prepared and sent to Plaintiffs the Notice Letter, purporting to inform Plaintiffs that Amneal had filed a certification to the FDA with respect to the '504 Patent, '353 Patent, '118 Patent, '605 Patent, '479 Patent, '777 Patent, '630 Patent, '338 Patent, '120 Patent, '127 Patent, '716 Patent, and '918 Patent.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval

to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 50.

RESPONSE TO "CLAIM FOR RELIEF COUNT I: [ALLEGED] INFRINGEMENT OF THE '504 PATENT BY AMNEAL"

51. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

52. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 52.

53. On information and belief, Amneal's ANDA Product infringes one or more claims of the '504 Patent.

ANSWER:

Denied.

54. Amneal has infringed one or more claims of the '504 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '504 Patent.

ANSWER:

Denied.

55. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '504 Patent would infringe one or more claims

of the '504 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '504 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

56. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 200 ppm of benzalkonium chloride," as required by Claim 1 of the '504 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 200 ppm benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '504 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '504 Patent.

ANSWER:

Denied.

57. Amneal had actual and constructive notice of the '504 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '504 Patent would constitute an act of infringement of the '504 Patent.

ANSWER:

To the extent Paragraph 57 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '504 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 57.

58. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '504 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO "COUNT II:
[ALLEGED] INFRINGEMENT OF THE '353 PATENT BY AMNEAL"

59. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

60. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 60.

61. On information and belief, Amneal's ANDA Product infringes one or more claims of the '353 Patent.

ANSWER:

Denied.

62. Amneal has infringed one or more claims of the '353 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '353 Patent.

ANSWER:

Denied.

63. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '353 Patent would infringe one or more claims of the '353 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '353 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

64. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 0.02% w/v benzalkonium chloride," as required by Claim 1 of the '353 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 0.02% w/v benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '353 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '353 Patent.

ANSWER:

Denied.

65. Amneal had actual and constructive notice of the '353 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '353 Patent would constitute an act of infringement of the '353 Patent.

ANSWER:

To the extent Paragraph 65 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '353 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 65.

66. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '353 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO "COUNT III:
[ALLEGED] INFRINGEMENT OF THE '118 PATENT BY AMNEAL"

67. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

68. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 68.

69. On information and belief, Amneal's ANDA Product infringes one or more claims of

the ’118 Patent.

ANSWER:

Denied.

70. Amneal has infringed one or more claims of the ’118 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal’s ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the ’118 Patent.

ANSWER:

Denied.

71. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal’s ANDA Product prior to the expiration of the ’118 Patent would infringe one or more claims of the ’118 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the ’118 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

72. For example, Amneal’s Notice Letter disputes that Amneal’s ANDA Product contains “about 0.02% w/v benzalkonium chloride,” as required by Claim 1 of the ’118 Patent. However, Amneal’s ANDA seeks approval to market a product that contains “about 0.02% w/v benzalkonium chloride.” Amneal does not dispute that the other limitations of Claim 1 of the ’118 Patent are met by Amneal’s ANDA Product. Accordingly, upon information and belief, Amneal’s ANDA Product meets every limitation of at least Claim 1 of the ’118 Patent.

ANSWER:

Denied.

73. Amneal had actual and constructive notice of the ’118 Patent prior to filing Amneal’s ANDA and was aware that the filing of Amneal’s ANDA with the request for FDA approval prior to the expiration of the ’118 Patent would constitute an act of infringement of the ’118 Patent.

ANSWER:

To the extent Paragraph 73 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the ’118 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 73.

74. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’118 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants,

a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSES TO "COUNT IV:
[ALLEGED] INFRINGEMENT OF THE '605 PATENT BY AMNEAL"

75. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

76. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 76.

77. On information and belief, Amneal's ANDA Product infringes one or more claims of the '605 Patent.

ANSWER:

Denied.

78. Amneal has infringed one or more claims of the '605 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '605 Patent.

ANSWER:

Denied.

79. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '605 Patent would infringe one or more claims of the '605 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '605 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

80. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 200 ppm benzalkonium chloride," as required by Claim 1 of the '605 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 200 ppm benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '605 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '605 Patent.

ANSWER:

Denied.

81. Amneal had actual and constructive notice of the '605 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '605 Patent would constitute an act of infringement of the '605 Patent.

ANSWER:

To the extent Paragraph 81 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '605 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 81.

82. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '605 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT V: [ALLEGED] INFRINGEMENT OF THE '479 PATENT BY AMNEAL"

83. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

84. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 84.

85. On information and belief, Amneal's ANDA Product infringes one or more claims of the '479 Patent.

ANSWER:

Denied.

86. Amneal has infringed one or more claims of the '479 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '479 Patent.

ANSWER:

Denied.

87. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '479 Patent would infringe one or more claims of the '479 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '479 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

88. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 200 ppm benzalkonium chloride," as required by Claim 1 of the '479 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 200 ppm benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '479 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's

ANDA Product meets every limitation of at least Claim 1 of the '479 Patent.

ANSWER:

Denied.

89. Amneal had actual and constructive notice of the '479 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '479 Patent would constitute an act of infringement of the '479 Patent.

ANSWER:

To the extent Paragraph 89 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '479 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 89.

90. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '479 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT VI:
[ALLEGED] INFRINGEMENT OF THE '777 PATENT BY AMNEAL"

91. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

92. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain

approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 92.

93. On information and belief, Amneal's ANDA Product infringes one or more claims of the '777 Patent.

ANSWER:

Denied.

94. Amneal has infringed one or more claims of the '777 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '777 Patent.

ANSWER:

Denied.

95. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '777 Patent would infringe one or more claims of the '777 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '777 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

96. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 0.02% w/v benzalkonium chloride," as required by Claim 1 of the '777 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 0.02% w/v benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '777 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '777 Patent.

ANSWER:

Denied.

97. Amneal had actual and constructive notice of the '777 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '777 Patent would constitute an act of infringement of the '777 Patent.

ANSWER:

To the extent Paragraph 97 calls for a legal conclusion, no response is required. Insofar as

any response is required, Amneal admits that it was aware of the '777 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 97.

98. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '777 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT VII:
[ALLEGED] INFRINGEMENT OF THE '630 PATENT BY AMNEAL"

99. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

100. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 100.

101. On information and belief, Amneal's ANDA Product infringes one or more claims of the '630 Patent.

ANSWER:

Denied.

102. Amneal has infringed one or more claims of the '630 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA

approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '630 Patent.

ANSWER:

Denied.

103. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '630 Patent would infringe one or more claims of the '630 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '630 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

104. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 200 ppm benzalkonium chloride," as required by Claim 1 of the '630 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 200 ppm benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '630 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '630 Patent.

ANSWER:

Denied.

105. Amneal had actual and constructive notice of the '630 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '630 Patent would constitute an act of infringement of the '630 Patent.

ANSWER:

To the extent Paragraph 105 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '630 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 105.

106. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '630 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT VIII:
[ALLEGED] INFRINGEMENT OF THE '338 PATENT BY AMNEAL"

107. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

108. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 108.

109. On information and belief, Amneal's ANDA Product infringes one or more claims of the '338 Patent.

ANSWER:

Denied.

110. Amneal has infringed one or more claims of the '338 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '338 Patent.

ANSWER:

Denied.

111. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '338 Patent would infringe one or more claims of the '338 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '338 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

112. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 0.02% w/v benzalkonium chloride," as required by Claim 1 of the '338 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 0.02% w/v benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '338 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '338 Patent.

ANSWER:

Denied.

113. Amneal had actual and constructive notice of the '338 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '338 Patent would constitute an act of infringement of the '338 Patent.

ANSWER:

To the extent Paragraph 113 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '338 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 113.

114. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '338 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT IX:
[ALLEGED] INFRINGEMENT OF THE '120 PATENT BY AMNEAL"

115. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

116. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 116.

117. On information and belief, Amneal's ANDA Product infringes one or more claims of the '120 Patent.

ANSWER:

Denied.

118. Amneal has infringed one or more claims of the '120 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '120 Patent.

ANSWER:

Denied.

119. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '120 Patent would infringe one or more claims of the '120 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '120 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

120. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 0.02% w/v benzalkonium chloride," as required by Claim 1 of the '120 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 0.02% w/v benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '120 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '120 Patent.

ANSWER:

Denied.

121. Amneal had actual and constructive notice of the '120 Patent prior to filing Amneal's

ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '120 Patent would constitute an act of infringement of the '120 Patent.

ANSWER:

To the extent Paragraph 121 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '120 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 121.

122. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '120 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT X:
[ALLEGED] INFRINGEMENT OF THE '127 PATENT BY AMNEAL"

123. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

124. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 124.

125. On information and belief, Amneal's ANDA Product infringes one or more claims of the '127 Patent.

ANSWER:

Denied.

126. Amneal has infringed one or more claims of the '127 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '127 Patent.

ANSWER:

Denied

127. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '127 Patent would infringe one or more claims of the '127 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '127 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

128. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 0.02% w/v benzalkonium chloride," as required by Claim 5 of the '127 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 0.02% w/v benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 5 of the '127 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 5 of the '127 Patent.

ANSWER:

Denied.

129. Amneal had actual and constructive notice of the '127 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '127 Patent would constitute an act of infringement of the '127 Patent.

ANSWER:

To the extent Paragraph 129 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '127 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 129.

130. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '127 Patent. Plaintiffs do not have an

adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT XI:
[ALLEGED] INFRINGEMENT OF THE '716 PATENT BY AMNEAL"

131. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

132. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 132.

133. On information and belief, Amneal's ANDA Product infringes one or more claims of the '716 Patent.

ANSWER:

Denied.

134. Amneal has infringed one or more claims of the '716 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '716 Patent.

ANSWER:

Denied.

135. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '716 Patent would infringe one or more claims of the '716 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '716 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

136. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 0.02% w/v benzalkonium chloride," as required by Claim 1 of the '716 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 0.02% w/v benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '716 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's ANDA Product meets every limitation of at least Claim 1 of the '716 Patent.

ANSWER:

Denied.

137. Amneal had actual and constructive notice of the '716 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '716 Patent would constitute an act of infringement of the '716 Patent.

ANSWER:

To the extent Paragraph 137 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '716 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 137.

138. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '716 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "COUNT XII: [ALLEGED] INFRINGEMENT OF THE '918 PATENT BY AMNEAL"

139. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER:

Amneal incorporates its responses to the preceding paragraphs as if fully set forth herein.

140. On information and belief, Amneal submitted Amneal's ANDA to the FDA, and thereby seeks FDA approval of Amneal's ANDA Product.

ANSWER:

This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Amneal admits that it sent Plaintiffs a letter pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) stating that Amneal had submitted ANDA No. 217289 to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of proposed bimatoprost products before the expiration of the patents-in-suit. Amneal denies the remaining allegations in Paragraph 140.

141. On information and belief, Amneal's ANDA Product infringes one or more claims of the '918 Patent.

ANSWER:

Denied.

142. Amneal has infringed one or more claims of the '918 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Amneal's ANDA with a Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '918 Patent.

ANSWER:

Denied.

143. On information and belief, the importation, manufacture, sale, offer for sale, or use of Amneal's ANDA Product prior to the expiration of the '918 Patent would infringe one or more claims of the '918 Patent under 35 U.S.C. § 271(a), and/or Amneal would induce or contribute to the infringement of one or more claims of the '918 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER:

Denied.

144. For example, Amneal's Notice Letter disputes that Amneal's ANDA Product contains "about 200 ppm benzalkonium chloride," as required by Claim 1 of the '918 Patent. However, Amneal's ANDA seeks approval to market a product that contains "about 200 ppm benzalkonium chloride." Amneal does not dispute that the other limitations of Claim 1 of the '918 Patent are met by Amneal's ANDA Product. Accordingly, upon information and belief, Amneal's

ANDA Product meets every limitation of at least Claim 1 of the '918 Patent.

ANSWER:

Denied.

145. Amneal had actual and constructive notice of the '918 Patent prior to filing Amneal's ANDA and was aware that the filing of Amneal's ANDA with the request for FDA approval prior to the expiration of the '918 Patent would constitute an act of infringement of the '918 Patent.

ANSWER:

To the extent Paragraph 145 calls for a legal conclusion, no response is required. Insofar as any response is required, Amneal admits that it was aware of the '918 Patent when it submitted its ANDA. Amneal otherwise denies the allegations of Paragraph 145.

146. Plaintiffs will be irreparably harmed if Amneal is not enjoined from infringing and from actively inducing or contributing to the infringement of the '918 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER:

Denied.

RESPONSE TO "PRAYER FOR RELIEF"

The remainder of the Complaint for Infringement (Dkt. 1) is a prayer for relief and does not require a response. To the extent any response is required, Amneal denies that Plaintiffs are entitled to any relief whatsoever against Amneal in this action, either as prayed for in the Complaint for Infringement or otherwise.

AFFIRMATIVE DEFENSES

Amneal asserts the following defenses to the Complaint for Infringement, without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint for Infringement not otherwise admitted. Amneal reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery. Assertion of a defense is not a concession that Amneal

has the burden of proving the matter asserted.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs' claims are barred in whole or in part because Plaintiffs have not stated a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement of the '504 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '504 Patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '504 Patent)

The claims of the '504 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

For example, recent case law, including a case involving Allergan, confirms that claims 1, 2, and 3 of the '504 Patent are invalid for obviousness-type double patenting. *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023) (obviousness-type double patenting is a question of law) and *Allergan U.S., Inc. v. MSN Labs. Private Ltd.*, 2023 U.S. Dist. LEXIS 172641 (D. Del. Sept. 27, 2023) (holding that "the first-filed, first-issued" distinction is immaterial) (Ex. 1). Here, later filed and later issued claims that expire earlier render claims 1, 2, and 3 of the '504 Patent invalid. By way of example, the '504 Patent claims (which allegedly expire on June 13, 2027) are not patentably distinct from at least claims 9 and 14 of the '479 Patent (which allegedly expire on March 16, 2025). *Compare* Ex. 2 ('504 patent) at AMNEAL_000025 *with* Ex. 3 ('479 patent) at, *e.g.*, AMNEAL_000034.

FOURTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '353 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '353 Patent.

FIFTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '353 Patent)

The claims of the '353 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '118 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '118 Patent.

SEVENTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '118 Patent)

The claims of the '118 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

EIGHTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '605 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '605 Patent.

NINTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '605 Patent)

The claims of the ’605 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TENTH AFFIRMATIVE DEFENSE
(Non-Infringement of the ’479 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’479 Patent.

ELEVENTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the ’479 Patent)

The claims of the ’479 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWELFTH AFFIRMATIVE DEFENSE
(Non-Infringement of the ’777 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’777 Patent.

THIRTEENTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the ’777 Patent)

The claims of the ’777 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

FOURTEENTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '630 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '630 Patent.

FIFTEENTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '630 Patent)

The claims of the '630 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

SIXTEENTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '338 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '338 Patent.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '338 Patent)

The claims of the '338 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

EIGHTEENTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '120 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '120 Patent.

NINETEENTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '120 Patent)

The claims of the '120 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWENTIETH AFFIRMATIVE DEFENSE
(Non-Infringement of the '127 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '127 Patent.

TWENTY FIRST AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '127 Patent)

The claims of the '127 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWENTY SECOND AFFIRMATIVE DEFENSE
(Non-Infringement of the '716 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '716 Patent.

TWENTY THIRD AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '716 Patent)

The claims of the '716 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWENTY FOURTH AFFIRMATIVE DEFENSE
(Non-Infringement of the '918 Patent)

Amneal has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '918 Patent.

TWENTY FIFTH AFFIRMATIVE DEFENSE
(Invalidity and/or Unenforceability of the '918 Patent)

The claims of the '918 Patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWENTY SIXTH AFFIRMATIVE DEFENSE
(Invalid Extension of Patent Term)

Plaintiffs' alleged infringement claims based on the '504 Patent are barred in whole or in part because the '504 Patent has an incorrect patent term due to an improperly calculated patent term adjustment ("PTA"). The Patent Office incorrectly applied 35 U.S.C. § 154(b)(1)(C)(iii) in determining the PTA awarded to the '504 Patent. As recently confirmed by the Federal Circuit, the 35 U.S.C. § 154(b)(1)(C)(iii) only permits a PTA when a patent "issued under a decision in the review." *Sawstop Holding LLC v. Vidal*, 48 F.4th 1355, 1360 (Fed. Cir. 2022). A side-by-side comparison of the claims allowed during appeal to the Board of Patent Appeals and Interferences ("Board") (i.e., claims 4, 10, and 11) and those that ultimately issued in the '504 Patent confirms that the claims at issue in the appeal are substantively different than the claims that issued in the '504 Patent.

Claims at Issue in Appeal to the Board	The '504 Patent Issued Claims
1. (Rejected) A composition comprising from 0.005% to 0.02% bimatoprost by weight and from about 125 ppm to about 250 ppm benzalkonium chloride, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration. 2. (Rejected) The composition of claim 1 which further comprises an effective amount of EDTA. 3. (Rejected) The composition of claim 2 wherein the concentration of benzalkonium chloride is from about 150 ppm to about 200 ppm. 4. (Rejected) The composition of claim 3 having a pH of about 7.4 which consists essentially of about 0.015% bimatoprost, about 200 ppm benzalkonium chloride, from about 0 to about 0.03% EDTA, a phosphate buffer, NaCl, and water. 5. (Rejected) The composition of claim 1 wherein the concentration of bimatoprost is from about 0.01% to about 0.02%. 6. (Rejected) The composition of claim 5 wherein the concentration of bimatoprost is from about 0.015% to about 0.02%. 7. (Rejected) The composition of claim 6 wherein the concentration of benzalkonium chloride is from about 150 ppm to about 200 ppm. 8. (Rejected) The composition of claim 7 wherein the concentration of benzalkonium chloride is about 200 ppm. 9. (Rejected) The composition of claim 6 which further comprises an effective amount of EDTA. 10. (Rejected) The composition of claim 9 having a pH of about 7.4 which comprises about 0.015% bimatoprost, about 200 ppm benzalkonium chloride, from about 0 to about 0.03% EDTA, a phosphate buffer, and NaCl. 11. (Rejected) The composition of claim 10 having a pH of about 7.4 which consists of about 0.015% bimatoprost, about 200 ppm benzalkonium chloride, from about 0 to about 0.03% EDTA, a phosphate buffer, NaCl, and water.	1. A composition having a pH of about 7.3 which consists essentially of about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, a phosphate buffer, NaCl, and water, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration. 2. A composition having a pH of about 7.3 which comprises about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, citric acid monohydrate, a phosphate buffer, and NaCl wherein said composition is an aqueous liquid which is formulated for ophthalmic administration. 3. A composition having a pH of about 7.3 which comprises about 0.01% bimatoprost, 200 ppm benzalkonium chloride, about 0.014 citric acid monohydrate, a phosphate buffer, NaCl, and water wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

(Ex. 4, 2/19/2008 Appeal Brief (Claims Appendix) (prosecution of the application that issued as the '504 Patent) (annotations added) at AMNEAL_000047-48; Ex. 2, the '504 Patent (issued claims)) at AMNEAL_000025 (underlining added).

For example, dependent claims 4, 10, and 11 presented to the Board in the appeal each require an "effective amount of EDTA." The Board reversed the rejection as to only claims 4, 10, and 11. (Ex. 5, 5/10/2010 Decision on Appeal) at, *e.g.*, AMNEAL_000059. The patentee then amended claims 4, 10, and 11 so that none of the issued claims in the '504 Patent require an effective amount of EDTA. (Ex. 6, 6/16/2010, Claim Amendment) at AMNEAL_000062-64. The claims on appeal were also amended so that the claims that issued in the '504 Patent contain a different amount of bimatoprost (about 0.01%) and pH (about 7.3) compared to claims 4, 10, and 11 in the appeal (which

contain about 0.015% and about 7.4, respectively). (*Id.*). Accordingly, the '504 Patent claims did not issue under a decision in the review as required by the PTA statute and Federal Circuit precedence. Thus, the improperly calculated PTA for the '504 Patent renders it invalid and/or unenforceable during at least the extended term.

TWENTY SEVENTH AFFIRMATIVE DEFENSE
(Costs)

Upon information and belief, Plaintiffs are barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

TWENTY EIGHTH AFFIRMATIVE DEFENSE
(Adequate Remedy at Law, No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief at least because any alleged injury to Plaintiffs is not immediate or irreparable, Plaintiffs have an adequate remedy at law, and/or public policy concerns weigh against any injunctive relief.

TWENTY NINTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Amneal's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

THIRTIETH AFFIRMATIVE DEFENSE
(Additional Defenses)

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiffs Allergan, Inc. ("Allergan") and AbbVie Inc. ("AbbVie" and collectively with Allergan, "Plaintiffs") other than those expressly admitted herein, and without prejudice to the right of Defendants Amneal Pharmaceuticals of New York, LLC ("Amneal NY") and Amneal EU, Limited ("Amneal EU" and collectively with Amneal NY, "Amneal") to plead additional Counterclaims as the facts of the matter warrant, Amneal hereby

asserts the following Counterclaims against Plaintiffs:

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that ANDA No. 217289 does not infringe any valid and enforceable claim of United States Patent Nos. 9,851,504 ("'504 Patent"); 8,278,353 ("'353 Patent"); 8,299,118 ("'118 Patent"); 8,309,605 ("'605 Patent"); 8,338,479 ("'479 Patent"); 8,524,777 ("'777 Patent"); 8,586,630 ("'630 Patent"); 8,772,338 ("'338 Patent"); 8,933,120 ("'120 Patent"); 8,933,127 ("'127 Patent"); 9,155,716 ("'716 Patent"); and 9,241,918 ("'918 Patent") (collectively the "patents-in-suit") and that each and every claim of the patents-in-suit is invalid for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

THE PARTIES

2. Amneal Pharmaceuticals of New York, LLC, is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 50 Horseblock Road, Brookhaven, NY 11719.

3. Amneal EU is a limited liability company organized and existing under the laws of Ireland, having its principal place of business at Cahir Road, Cashel, Co. Tipperary, E25 ZD51, Ireland.

4. Upon information and belief and based on the allegations in the Complaint for Infringement, AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. Upon information and belief and based on the allegations in the Complaint for Infringement, Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

6. This Court has personal jurisdiction over AbbVie and Allergan because they have availed themselves of the legal protections of the State of New York by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff in this matter.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Plaintiffs have voluntarily submitted to the jurisdiction of the Court in this matter.

FACTUAL BACKGROUND

A. Bimatoprost Compositions

8. This case involves Amneal's ANDA for a generic version of ophthalmic formulations containing bimatoprost for the reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension. But bimatoprost has been disclosed and used for this purpose for several decades. Indeed, Plaintiff Allergan received approval and marketed similar bimatoprost compositions under the LUMIGAN® brand since at least 2001. Plaintiffs in this case are attempting to block or delay Amneal from entering the market with twelve related second-generation patents all requiring "about 200 ppm" benzalkonium chloride that Amneal's proposed bimatoprost products do not infringe, and a patent—the '504 Patent—which has an unlawful extension rendering it invalid and/or unenforceable beyond when it would otherwise expire without the unlawful patent term adjustment on March 16, 2025.

B. The Patents-In-Suit

9. The patents-in-suit are all related and share the same specification. While all the patents-in-suit generally describe the same bimatoprost formulations and methods of using those

formulations, the '504 Patent expires 819 days after the others because it received a patent term adjustment ("PTA").

Patent No	Patent Expiration
7851504	06/13/2027
8278353	03/16/2025
8299118	03/16/2025
8309605	03/16/2025
8338479	03/16/2025
8524777	03/16/2025
8586630	03/16/2025
8772338	03/16/2025
8933120	03/16/2025
8933127	03/16/2025
9155716	03/16/2025
9241918	03/16/2025

10. Claim 1 of the '504 Patent is exemplary of all the claimed formulations:

> Claim 1 of the '504: A composition having a pH of about 7.3 which consists essentially of about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, a phosphate buffer, NaCl, and water, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

11. The patents-in-suit thus claim a formulation and methods of using a formulation that has 0.01% bimatoprost and about 200 ppm (0.02% w/v) benzalkonium chloride. To that end, the specification discloses several "embodiments" of these claimed compositions:

> One embodiment comprises 0.01% Bimatoprost, 0.02% Benzalkonium Chloride, 0.268% Sodium Phosphate Dibasic, Heptahydrate, 0.014% Citric Acid, Monohydrate, 0.81% Sodium Chloride, and water, wherein the pH is 7.3.

Ex. 2, '504 Patent, col. 2, ll. 64-67 (annotated) (AMNEAL_000023).

> Another embodiment comprises 0.02% Bimatoprost, 0.02% Benzalkonium Chloride, 0.268% Sodium Phosphate Dibasic, Heptahydrate, 0.014% Citric Acid, Monohydrate, 0.81% Sodium Chloride, and water, wherein the pH is7.3.
>
> Another embodiment consists essentially of 0.01% Bimatoprost, 0.02% Benzalkonium Chloride, 0.268% Sodium Phosphate Dibasic, Heptahydrate, 0.014% Citric Acid, Monohydrate, 0.81% Sodium Chloride, and water, wherein the pH is 7.3.

Id. at col. 3, ll. 10-18 (annotated) (AMNEAL_000024).

> Another embodiment consists of 0.01% Bimatoprost, 0.02% Benzalkonium Chloride, 0.268% Sodium Phosphate Dibasic, Heptahydrate, 0.014% Citric Acid, Monohydrate, 0.81% Sodium Chloride, and water, wherein the pH is 7.3.

Id. at col. 3, ll. 34-37 (annotated) (AMNEAL_000024).

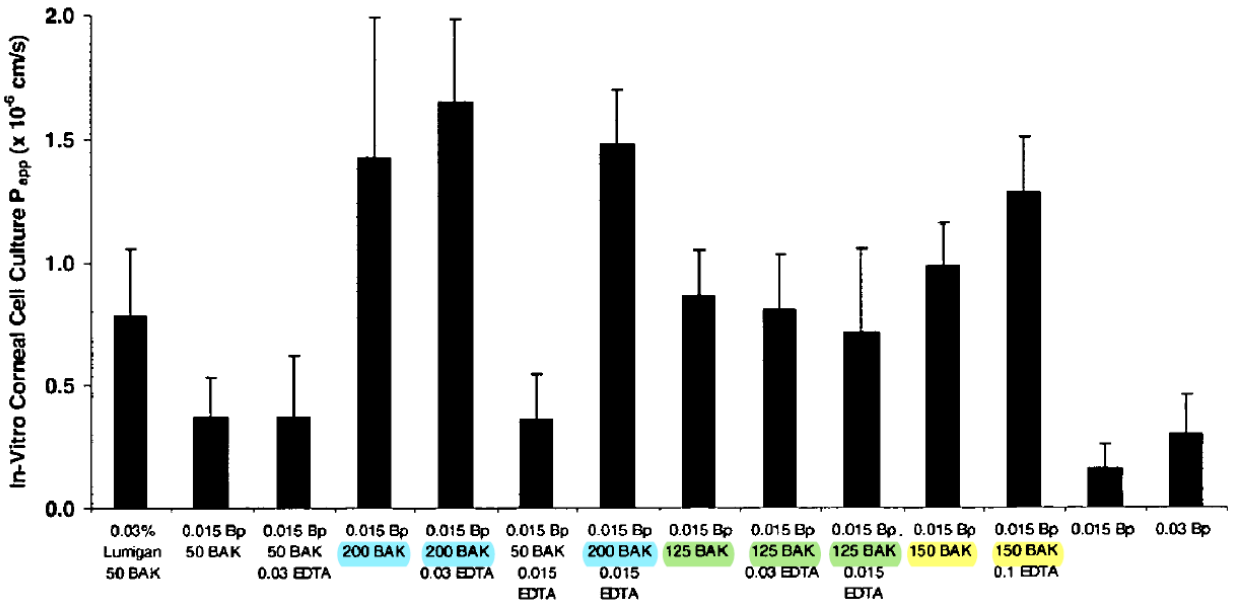
12. The common specification also discloses, but does not claim, several other bimatoprost "compositions." According to the specification, during the alleged discovery of the claimed invention, the inventors tested other bimatoprost compositions with, *inter alia*, varying amounts of benzalkonium chloride to determine what amount of benzalkonium chloride yielded formulations that achieved the highest bimatoprost permeability. As shown in the annotated excerpt below, these compositions included bimatoprost formulations containing 125 ppm benzalkonium chloride and 150 ppm benzalkonium chloride.

TABLE 3

Formulation
A. 0.03% Bimatoprost (50 ppm BAK) - Control
B. 0.015% Bimatoprost (50 ppm BAK)
C. 0.015% Bimatoprost (50 ppm BAK) 0.03% EDTA
D. 0.015% Bimatoprost (200 ppm BAK)
E. 0.015% Bimatoprost (200 ppm BAK) 0.03% EDTA
F. 0.015% Bimatoprost (50 ppm BAK) 0.015% EDTA
G. 0.015% Bimatoprost (200 ppm BAK) 0.015% EDTA
H. 0.015% Bimatoprost (125 ppm BAK)
I. 0.015% Bimatoprost (125 ppm BAK) 0.03% EDTA
J. 0.015% Bimatoprost (125 ppm BAK) 0.015% EDTA
K. 0.015% Bimatoprost (150 ppm BAK)
L. 0.015% Bimatoprost (150 ppm BAK) 0.1% EDTA
M. 0.015% Bimatoprost
N. 0.03% Bimatoprost

Id. at col. 5, ll. 2-17 (annotated).

13. The specification further discloses that formulations with 200 ppm exhibited the highest bimatoprost permeability:



Id. at Fig. 2 (annotated).

14. The specification also discloses, but does not claim, other bimatoprost compositions with several other ranges of benzalkonium chloride concentrations:

> A composition comprising from 0.005% to 0.02% bimatoprost by weight and from 100 ppm to 250 ppm benzalkonium chloride, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration is disclosed herein.

Id. at col. 1, ll. 61-65 (annotated).

> In certain compositions the concentration of BAK is from 150 ppm to 200 ppm. In other compositions the concentration of BAK is from 150 ppm to 200 ppm. In other compositions the concentration of BAK is from 150 ppm to 250 ppm.

Id. at col. 2, ll. 10-13 (annotated).

> Certain compositions comprise from 150 to 250 ppm BAK and an effective amount of EDTA.

Id. at col. 2, ll. 24-25 (annotated).

C. Relevant Prosecution History

15. Given the specification's disclosure of bimatoprost compositions with varying amounts of, *inter alia*, benzalkonium chloride, Plaintiffs initially tried to obtain claims to broad ranges of benzalkonium chloride, including "100 ppm to 250 ppm" and "150 ppm to 200 ppm."

> **CLAIMS**
>
> What is claimed is:
>
> 1. A composition comprising from 0.005% to 0.02% bimatoprost by weight and from 100 ppm to 250 ppm benzalkonium chloride, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.
>
> 2. The composition of claim 1 which further comprises an effective amount of EDTA.
>
> 3. The composition of claim 2 wherein the concentration of benzalkonium chloride is from 150 ppm to 200 ppm.

Ex. 7, 3/16/2005 Initial Claims filed with Application (annotated) (AMNEAL_000067-68).

16. The United States Patent Office repeatedly rejected these claims as obvious over Plaintiffs' earlier bimatoprost formulations, forcing Plaintiffs to narrow its claims and ultimately give up claims to those ranges. *See, e.g.*, Ex. 8, 6/20/2006 Office Action (AMNEAL_000069-73). For example, in response to Patent Office rejections Plaintiffs first narrowed the broadest claimed range from "100 ppm to 250 ppm" to "about 125 ppm to about 250 ppm":

> 1. (Currently Amended) A composition comprising from 0.005% to 0.02% bimatoprost by weight and from ~~100 ppm~~ about 125 ppm to about 250 ppm

Ex. 9, 8/25/2006 Response at, *e.g.*, AMNEAL_000075. The Patent Office rejected these claims as obvious too. Ex. 10, 11/13/2006 Final Office Action at, *e.g.*, AMNEAL_000081-85. Plaintiffs appealed this rejection to the Board of Patent Appeals and Interferences ("Board"). The pending claims subject to this appeal included several different benzalkonium chloride ranges, including "about 125 ppm to 250 ppm"; "about 150 ppm to about 200 ppm"; and "about 200 ppm":

1. (Rejected) A composition comprising from 0.005% to 0.02% bimatoprost by weight and from about 125 ppm to about 250 ppm benzalkonium chloride, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.
2. (Rejected) The composition of claim 1 which further comprises an effective amount of EDTA.
3. (Rejected) The composition of claim 2 wherein the concentration of benzalkonium chloride is from about 150 ppm to about 200 ppm.
4. (Rejected) The composition of claim 3 having a pH of about 7.4 which consists essentially of about 0.015% bimatoprost, about 200 ppm benzalkonium chloride, from about 0 to about 0.03% EDTA, a phosphate buffer, NaCl, and water.
5. (Rejected) The composition of claim 1 wherein the concentration of bimatoprost is from about 0.01% to about 0.02%.
6. (Rejected) The composition of claim 5 wherein the concentration of bimatoprost is from about 0.015% to about 0.02%.
7. (Rejected) The composition of claim 6 wherein the concentration of benzalkonium chloride is from about 150 ppm to about 200 ppm.
8. (Rejected) The composition of claim 7 wherein the concentration of benzalkonium chloride is about 200 ppm.
9. (Rejected) The composition of claim 6 which further comprises an effective amount of EDTA.
10. (Rejected) The composition of claim 9 having a pH of about 7.4 which comprises about 0.015% bimatoprost, about 200 ppm benzalkonium chloride, from about 0 to about 0.03% EDTA, a phosphate buffer, and NaCl.
11. (Rejected) The composition of claim 10 having a pH of about 7.4 which consists of about 0.015% bimatoprost, about 200 ppm benzalkonium chloride, from about 0 to about 0.03% EDTA, a phosphate buffer, NaCl, and water.

Ex. 4 (AMNEAL_000036-50). The Board upheld the rejection of claims to the broad ranges "about 125 ppm to 250 ppm" and "about 150 ppm to about 200 ppm" and found that three narrower claims (4, 10, and 11) to bimatoprost compositions with "about 0.015%" bimatoprost, "about 200 ppm"

BAK, and "about 0% to about 0.03% EDTA" were not obvious. *See* Ex. 5 at, *e.g.*, AMNEAL_000059.

17. In response to the Board's decision, Plaintiffs amended the claims to narrow the benzalkonium range to rejected claim 1:

> 1. (currently amended) A composition comprising from ~~0.005% to 0.02%~~ about 0.01 – 0.015% bimatoprost by weight and from about 125 ppm to about ~~250~~ 200 ppm benzalkonium chloride, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

See Ex. 6 at, *e.g.*, AMNEAL_000062. Plaintiffs also made significant changes to the claims that the Board found non-obvious, including removing the EDTA limitation and changing the recited pH and amount of bimatoprost:

> 4. (currently amended) The composition of claim ~~3~~ 1 having a pH of about ~~7.4~~ 7.3 which consists essentially of about 0.01~~5~~% bimatoprost, about 200 ppm benzalkonium chloride, ~~from about 0 to about 0.03% EDTA~~, a phosphate buffer, NaCl, and water.
>
> 10. (currently amended) The composition of claim ~~9~~ 1 having a pH of about ~~7.4~~ 7.3 which comprises about 0.01~~5~~% bimatoprost, about 200 ppm benzalkonium chloride, ~~from about 0 to about 0.03% EDTA~~ citric acid monohydrate, a phosphate buffer, and NaCl.
>
> 11. (currently amended) The composition of claim ~~10~~ 1 having a pH of about ~~7.4~~ 7.3 which ~~consists of~~ comprises about 0.01~~5~~% bimatoprost, 200 ppm benzalkonium chloride, ~~from about 0 to about 0.03% EDTA~~, 0.014 citric acid monohydrate, a phosphate buffer, NaCl, and water.

Id. at, *e.g.*, AMNEAL_000062-63.

18. According to Plaintiffs, these claims were no longer the same as those that the Board

considered on appeal; they were now "similar compositions." *Id.* at, *e.g.*, AMNEAL_000065.

19. The Patent Office again rejected all claims except for those narrowly reciting "about 200 ppm" because there was "no convincing evidence to establish the unexpected or unobvious nature of the claimed invention. Ex. 11, 07/07/2010 Office Action at, *e.g.*, AMNEAL_000075.

20. Plaintiffs then cancelled all pending claims except for these narrow claims, including those reciting "about 125 ppm to 250 ppm" and "about 150 ppm to about 200 ppm" benzalkonium chloride.

1. (cancelled).

2. (cancelled).

3. (cancelled).

4. (currently amended) ~~The~~ A composition ~~of claim 1~~ having a pH of about 7.3 which consists essentially of about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, a phosphate buffer, NaCl, and water, wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

5. (cancelled).

6. (cancelled).

7. (cancelled).

8. (cancelled).

9. (cancelled).

10. (currently amended) ~~The~~ A composition ~~of claim 1~~ having a pH of about 7.3 which comprises about 0.01% bimatoprost, about 200 ppm benzalkonium chloride, citric acid monohydrate, a phosphate buffer, and NaCl wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

11. (currently amended) ~~The~~ A composition ~~of claim 1~~ having a pH of about 7.3 which comprises about 0.01% bimatoprost, 200 ppm benzalkonium chloride, about 0.014 citric acid monohydrate, a phosphate buffer, NaCl, and water wherein said composition is an aqueous liquid which is formulated for ophthalmic administration.

12. (cancelled).

13. (cancelled).

Ex. 12, 8/18/2010 Response at, *e.g.*, AMNEAL_000093-94.

21. As such, Plaintiffs could only obtain narrowed claims reciting "about 200 ppm" or "about 0.02%" benzalkonium chloride. Plaintiffs cannot reclaim the subject matter they removed from the claims to obtain the patents-in-suit.

D. Amneal's ANDA and Proposed Bimatoprost Products

22. According to the United States Food & Drug Administration ("FDA") publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book"), AbbVie holds approved New Drug Application ("NDA") No. 22184 for an ophthalmic solution containing 0.1 mg/mL of bimatoprost, marketed under the trade name LUMIGAN® 0.1%.

23. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

24. Upon information and belief, Allergan is the assignee listed on the face of the patents-in-suit.

25. Upon information and belief, one or more of the Plaintiffs caused the patents-in-suit to be listed in the Orange Book as patents associated with LUMIGAN® 0.1%.

26. Amneal has submitted ANDA No. 217289, seeking approval to engage in the commercial manufacture, use or sale of proposed bimatoprost products, to the FDA prior to the expiration of the patents-in-suit.

27. ANDA No. 217289 contained Paragraph IV Certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Amneal's proposed bimatoprost products.

28. On or around July 5, 2023, Amneal sent Plaintiffs a notice letter providing notice of Amneal's submission of ANDA No. 217289 to the FDA.

29. On or around July 27, 2023, Plaintiffs were provided with a copy of ANDA No. 217289 ("Amneal's ANDA") subject to an Offer of Confidential Access negotiated by the parties.

30. Amneal's ANDA describes the unit composition of its proposed bimatoprost products

[redacted]

31. A true and correct copy of an excerpt from Amneal's ANDA showing the unit compositions of Amneal's proposed bimatoprost products is attached hereto as Exhibit 13.

32. According to the Finished Product Specifications, [redacted]

33. Amneal's proposed bimatoprost products thus [redacted] as required by the claims of the patents-in-suit.

34. Despite being on notice of Amneal's non-infringement positions and having access to Amneal's ANDA, Plaintiffs filed this lawsuit alleging that Amneal infringes the patents-in-suit on or around August 17, 2023.

COUNT 1
(Declaratory Judgment of Invalidity of U.S. Patent No. 7,851,504)

35. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-34 of these Counterclaims as if fully set forth herein.

36. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '504 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '504 Patent.

37. Each and every claim of the '504 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

38. The alleged invention of the ’504 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the ’504 Patent.

39. The alleged invention of the ’504 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’504 Patent in the United States.

40. The ’504 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

41. The alleged invention of the ’504 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’504 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’504 Patent and would have had a reasonable expectation of success in doing so.

42. The subject matter claimed in the ’504 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

43. The ’504 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

44. The ’504 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

45. The claims of the ’504 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

46. Amneal is entitled to a judicial declaration that all claims of the ’504 Patent are invalid.

47. Further, as discussed in Amneal’s Twenty Sixth Affirmative Defense, above and incorporated by reference herein, the ’504 Patent is not lawfully issued because the facial expiration date of the ’504 Patent is incorrect because of an improperly calculated patent term adjustment.

COUNT 2
(Declaratory Judgment of Unenforceability of U.S. Patent No. 7,851,504)

48. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-47 of these Counterclaims as if fully set forth herein.

49. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal’s submission of ANDA No. 217289 and/or Amneal’s manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal’s proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable

claim of the '504 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

50. As discussed in Amneal's Twenty Sixth Affirmative Defense, above and incorporated by reference herein, the facial expiration date of the '504 Patent is incorrect because of an improperly calculated patent term adjustment. The '504 Patent is thus unenforceable beyond March 16, 2025.

51. Amneal is entitled to a judicial declaration that all claims of the '504 Patent are unenforceable beyond March 16, 2025.

COUNT 3
(Declaratory Judgment of Noninfringement of U.S. Patent No. 7,851,504)

52. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-51 of these Counterclaims as if fully set forth herein.

53. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '504 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

54. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '504 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted].

55. Because every claim of the '504 Patent [redacted]

[redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '504 Patent.

56. Amneal's proposed bimatoprost products will not infringe the '504 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

57. Amneal's proposed bimatoprost products also will not infringe the '504 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

58. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '504 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '504 Patent.

COUNT 4
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,278,353)

59. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-58 of these Counterclaims as if fully set forth herein.

60. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '353 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '353 Patent.

61. Each and every claim of the '353 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

62. The alleged invention of the ’353 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the ’353 Patent.

63. The alleged invention of the ’353 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’353 Patent in the United States.

64. The ’353 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

65. The alleged invention of the ’353 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’353 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’353 Patent and would have had a reasonable expectation of success in doing so.

66. The subject matter claimed in the ’353 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

67. The ’353 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

68. The ’353 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

69. The claims of the ’353 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

70. Amneal is entitled to a judicial declaration that all claims of the ’353 Patent are invalid.

COUNT 5
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,278,353)

71. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-70 of these Counterclaims as if fully set forth herein.

72. There is an actual, substantial, continuing, and justiciable controversy between Teva and Takeda regarding whether Amneal’s submission of ANDA No. 217289 and/or Amneal’s manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal’s proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the ’353 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

73. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’353 Patent either literally or under the

doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted].

74. Because every claim of the '353 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '353 Patent.

75. Amneal's proposed bimatoprost products will not infringe the '353 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

76. Amneal's proposed bimatoprost products also will not infringe the '353 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

77. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '353 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '353 Patent.

COUNT 6
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,299,118)

78. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-77 of these Counterclaims as if fully set forth herein.

79. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '118 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '118 Patent.

80. Each and every claim of the '118 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

81. The alleged invention of the '118 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '118 Patent.

82. The alleged invention of the '118 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '118 Patent in the United States.

83. The '118 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

84. The alleged invention of the '118 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '118 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine

the teachings of the prior art to achieve the alleged invention of the '118 Patent and would have had a reasonable expectation of success in doing so.

85. The subject matter claimed in the '118 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

86. The '118 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

87. The '118 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

88. The claims of the '118 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

89. Amneal is entitled to a judicial declaration that all claims of the '118 Patent are invalid.

COUNT 7
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,299,118)

90. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-89 of these Counterclaims as if fully set forth herein.

91. There is an actual, substantial, continuing, and justiciable controversy between Teva and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '118 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

92. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '118 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

93. Because every claim of the '118 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '118 Patent.

94. Amneal's proposed bimatoprost products will not infringe the '118 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

95. Amneal's proposed bimatoprost products also will not infringe the '118 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

96. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '118 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '118 Patent.

COUNT 8
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,309,605)

97. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-96 of these Counterclaims as if fully set forth herein.

98. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '605 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '605 Patent.

99. Each and every claim of the '605 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

100. The alleged invention of the '605 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '605 Patent.

101. The alleged invention of the '605 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '605 Patent in the United States.

102. The '605 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

103. The alleged invention of the ’605 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’605 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’605 Patent and would have had a reasonable expectation of success in doing so.

104. The subject matter claimed in the ’605 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

105. The ’605 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

106. The ’605 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

107. The claims of the ’605 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

108. Amneal is entitled to a judicial declaration that all claims of the '605 Patent are invalid.

COUNT 9
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,309,605)

109. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-108 of these Counterclaims as if fully set forth herein.

110. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '605 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

111. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '605 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

112. Because every claim of the '605 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '605 Patent.

113. Amneal's proposed bimatoprost products will not infringe the '605 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

114. Amneal's proposed bimatoprost products also will not infringe the '605 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

115. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '605 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '605 Patent.

COUNT 10
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,338,479)

116. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-115 of these Counterclaims as if fully set forth herein.

117. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '479 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '479 Patent.

118. Each and every claim of the '479 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

119. The alleged invention of the '479 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '479 Patent.

120. The alleged invention of the ’479 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’479 Patent in the United States.

121. The ’479 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

122. The alleged invention of the ’479 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’479 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’479 Patent and would have had a reasonable expectation of success in doing so.

123. The subject matter claimed in the ’479 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

124. The ’479 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

125. The ’479 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

126. The claims of the '479 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

127. Amneal is entitled to a judicial declaration that all claims of the '479 Patent are invalid.

COUNT 11
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,338,479)

128. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-127 of these Counterclaims as if fully set forth herein.

129. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '479 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

130. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '479 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

131. Because every claim of the '479 Patent [redacted]

[redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '479 Patent.

132. Amneal's proposed bimatoprost products will not infringe the '479 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

133. Amneal's proposed bimatoprost products also will not infringe the '479 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

134. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '479 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '479 Patent.

COUNT 12
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,524,777)

135. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-134 of these Counterclaims as if fully set forth herein.

136. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '777 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '777 Patent.

137. Each and every claim of the '777 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

138. The alleged invention of the ’777 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the ’777 Patent.

139. The alleged invention of the ’777 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’777 Patent in the United States.

140. The ’777 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

141. The alleged invention of the ’777 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’777 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’777 Patent and would have had a reasonable expectation of success in doing so.

142. The subject matter claimed in the ’777 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

143. The ’777 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

144. The ’777 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

145. The claims of the ’777 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

146. Amneal is entitled to a judicial declaration that all claims of the ’777 Patent are invalid.

COUNT 13
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,524,777)

147. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-146 of these Counterclaims as if fully set forth herein.

148. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal’s submission of ANDA No. 217289 and/or Amneal’s manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal’s proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the ’777 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

149. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’777 Patent either literally or under the

doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

150. Because every claim of the '777 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '777 Patent.

151. Amneal's proposed bimatoprost products will not infringe the '777 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

152. Amneal's proposed bimatoprost products also will not infringe the '777 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

153. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '777 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '777 Patent.

COUNT 14
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,586,630)

154. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-153 of these Counterclaims as if fully set forth herein.

155. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '630 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '630 Patent.

156. Each and every claim of the '630 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

157. The alleged invention of the '630 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '630 Patent.

158. The alleged invention of the '630 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '630 Patent in the United States.

159. The '630 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

160. The alleged invention of the '630 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '630 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine

the teachings of the prior art to achieve the alleged invention of the ’630 Patent and would have had a reasonable expectation of success in doing so.

161. The subject matter claimed in the ’630 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

162. The ’630 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

163. The ’630 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

164. The claims of the ’630 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

165. Amneal is entitled to a judicial declaration that all claims of the ’630 Patent are invalid.

COUNT 15
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,586,630)

166. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-165 of these Counterclaims as if fully set forth herein.

167. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '630 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

168. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '630 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

169. Because every claim of the '630 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '630 Patent.

170. Amneal's proposed bimatoprost products will not infringe the '630 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

171. Amneal's proposed bimatoprost products also will not infringe the '630 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or

amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

172. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '630 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '630 Patent.

COUNT 16
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,772,338)

173. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-172 of these Counterclaims as if fully set forth herein.

174. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '338 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '338 Patent.

175. Each and every claim of the '338 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

176. The alleged invention of the '338 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '338 Patent.

177. The alleged invention of the '338 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '338 Patent in the United States.

178. The ’338 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

179. The alleged invention of the ’338 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’338 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’338 Patent and would have had a reasonable expectation of success in doing so.

180. The subject matter claimed in the ’338 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

181. The ’338 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

182. The ’338 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

183. The claims of the '338 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

184. Amneal is entitled to a judicial declaration that all claims of the '338 Patent are invalid.

COUNT 17
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,772,338)

185. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-184 of these Counterclaims as if fully set forth herein.

186. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '338 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

187. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '338 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

188. Because every claim of the '338 Patent [redacted], the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '338 Patent.

189. Amneal's proposed bimatoprost products will not infringe the '338 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

190. Amneal's proposed bimatoprost products also will not infringe the '338 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

191. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '338 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '338 Patent.

COUNT 18
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,933,120)

192. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-191 of these Counterclaims as if fully set forth herein.

193. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '120 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '120 Patent.

194. Each and every claim of the '120 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

195. The alleged invention of the ’120 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the ’120 Patent.

196. The alleged invention of the ’120 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’120 Patent in the United States.

197. The ’120 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

198. The alleged invention of the ’120 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’120 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’120 Patent and would have had a reasonable expectation of success in doing so.

199. The subject matter claimed in the ’120 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

200. The ’120 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

201. The ’120 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

202. The claims of the ’120 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

203. Amneal is entitled to a judicial declaration that all claims of the ’120 Patent are invalid.

COUNT 19
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,933,120)

204. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-203 of these Counterclaims as if fully set forth herein.

205. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal’s submission of ANDA No. 217289 and/or Amneal’s manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal’s proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the ’120 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

206. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’120 Patent either literally or under the

doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted].

207. Because every claim of the '120 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '120 Patent.

208. Amneal's proposed bimatoprost products will not infringe the '120 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

209. Amneal's proposed bimatoprost products also will not infringe the '120 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

210. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '120 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '120 Patent.

COUNT 20
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,933,127)

211. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-210 of these Counterclaims as if fully set forth herein.

212. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '127 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '127 Patent.

213. Each and every claim of the '127 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

214. The alleged invention of the '127 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '127 Patent.

215. The alleged invention of the '127 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '127 Patent in the United States.

216. The '127 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

217. The alleged invention of the '127 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '127 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine

the teachings of the prior art to achieve the alleged invention of the '127 Patent and would have had a reasonable expectation of success in doing so.

218. The subject matter claimed in the '127 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

219. The '127 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

220. The '127 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

221. The claims of the '127 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

222. Amneal is entitled to a judicial declaration that all claims of the '127 Patent are invalid.

COUNT 21
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,933,127)

223. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-222 of these Counterclaims as if fully set forth herein.

224. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '127 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

225. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '127 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

226. Because every claim of the '127 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '127 Patent.

227. Amneal's proposed bimatoprost products will not infringe the '127 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

228. Amneal's proposed bimatoprost products also will not infringe the '127 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or

amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

229. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '127 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '127 Patent.

COUNT 22
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,155,716)

230. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-229 of these Counterclaims as if fully set forth herein.

231. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '716 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '716 Patent.

232. Each and every claim of the '716 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

233. The alleged invention of the '716 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the '716 Patent.

234. The alleged invention of the '716 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the '716 Patent in the United States.

235. The ’716 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

236. The alleged invention of the ’716 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’716 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’716 Patent and would have had a reasonable expectation of success in doing so.

237. The subject matter claimed in the ’716 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

238. The ’716 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

239. The ’716 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

240. The claims of the '716 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

241. Amneal is entitled to a judicial declaration that all claims of the '716 Patent are invalid.

COUNT 23
(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,155,716)

242. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-241 of these Counterclaims as if fully set forth herein.

243. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal's submission of ANDA No. 217289 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal's proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the '716 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

244. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '716 Patent either literally or under the doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

245. Because every claim of the '716 Patent [redacted] the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '716 Patent.

246. Amneal's proposed bimatoprost products will not infringe the '716 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

247. Amneal's proposed bimatoprost products also will not infringe the '716 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

248. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '716 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '716 Patent.

COUNT 24
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,241,918)

249. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-248 of these Counterclaims as if fully set forth herein.

250. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding the invalidity of the '918 Patent, based on Plaintiffs' allegations in its Complaint for Infringement that Amneal has infringed or will infringe the '918 Patent.

251. Each and every claim of the '918 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

252. The alleged invention of the ’918 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the ’918 Patent.

253. The alleged invention of the ’918 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for the ’918 Patent in the United States.

254. The ’918 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

255. The alleged invention of the ’918 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’918 Patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’918 Patent and would have had a reasonable expectation of success in doing so.

256. The subject matter claimed in the ’918 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge or such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

257. The ’918 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

258. The ’918 Patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

259. The claims of the ’918 Patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the claimed invention, as required by 35 U.S.C. § 112.

260. Amneal is entitled to a judicial declaration that all claims of the ’918 Patent are invalid.

COUNT 25
(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,241,918)

261. Amneal realleges and incorporates by reference the allegations in Paragraphs 1-260 of these Counterclaims as if fully set forth herein.

262. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Plaintiffs regarding whether Amneal’s submission of ANDA No. 217289 and/or Amneal’s manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal’s proposed bimatoprost products, infringe, have infringed, or will infringe any valid and enforceable claim of the ’918 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

263. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’918 Patent either literally or under the

doctrine of equivalents and is not liable for such infringement. For example, Amneal's proposed bimatoprost products [redacted]

264. Because every claim of the '918 Patent [redacted], the manufacture, use, sale, or importation of Amneal's proposed bimatoprost products will not literally infringe the '918 Patent.

265. Amneal's proposed bimatoprost products will not infringe the '918 Patent under the doctrine of equivalents at least because the dedication-disclosure rule bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

266. Amneal's proposed bimatoprost products also will not infringe the '918 Patent under the doctrine of equivalents because argument-based prosecution history estoppel and/or amendment-based prosecution history estoppel bars the application of the doctrine of equivalents with respect to Amneal's proposed bimatoprost products.

267. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '918 Patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Amneal's proposed bimatoprost products, have not infringed, do not infringe, and will not infringe any valid and enforceable claims of the '918 Patent.

PRAYER FOR RELIEF

Wherefore, Amneal respectfully requests that this Court enter judgment against Plaintiffs and issue an order:

a. Dismissing Plaintiffs' Complaint for Infringement with prejudice and denying each request for relief made by Plaintiffs' therein;

b. Declaring all claims of the patents-in-suit invalid;

c. Declaring that the ’504 Patent was improperly granted a patent term adjustment and its claims cannot be enforced beyond March 16, 2025;

d. Declaring that the filing of the ANDA No. 217289 has not infringed and does not infringe any valid and enforceable claim, if any, of the patents-in-suit;

e. Declaring that Amneal has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, either directly or under the doctrine of equivalents, of the patents-in-suit;

f. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Amneal’s proposed bimatoprost products, do not, and would not, if marketed, directly or indirectly infringe any valid and enforceable claim, if any, of the patents-in-suit;

g. Declaring that this case is an exceptional case in favor of Amneal pursuant to 35 U.S.C. § 285;

h. Declaring Amneal the prevailing party and awarding costs and attorney fees to Amneal;

i. Awarding Amneal such other and further relief as the Court deems just and equitable.

Dated: November 6, 2023

GREENBERG TRAURIG, LLP

/s/ Jonathan R. Wise

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