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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CUBIST PHARMACEUTICALS LLC,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC,
AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, AMNEAL PHARMACEUTICALS
PVT. LTD., and AMNEAL EU, LIMITED,

Defendants.

Civil Action No. 3:19-cv-15439-BRM-ZNQ

**SECOND AMENDED COMPLAINT
FOR PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiff Cubist Pharmaceuticals LLC (“Cubist” or “Plaintiff”) by its attorneys, for their complaint against Amneal Pharmaceuticals LLC (“Amneal Pharma”), Amneal Pharmaceuticals of New York, LLC (“Amneal NY”), Amneal Pharmaceuticals Pvt. Ltd. (“Amneal Ltd.”), and Amneal EU, Limited (“Amneal EU”) (collectively, “Amneal” or “Defendants”), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 9,138,456 (the “’456 patent”) under the laws of the United States, 35 U.S.C. § 100, *et seq.*, and for a declaratory judgment of infringement of the ’456 patent and U.S. Patent No. 8,835,382 (“the ’382 patent”) (the ’456 and ’382 patents, collectively, “the Patents-In-Suit”). This action arises from Amneal NY’s filing of Abbreviated New Drug Application (“ANDA”) No. 212397 (“the Amneal ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Plaintiff’s CUBICIN RF[®] drug product (“Amneal’s Proposed ANDA Product”).

THE PARTIES

2. Cubist is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Weyrstrasse 20, 6000 Lucerne 6, Switzerland.

3. Upon information and belief, Amneal Pharma is a limited liability company organized and existing under the laws of the State of Delaware, and having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, Somerset County, New Jersey 08807. Amneal Pharma is in the business of, among other things, manufacturing and

marketing generic copies of branded pharmaceutical products throughout the United States including in this Judicial District.

4. Upon information and belief, Amneal NY is a limited liability company organized and existing under the laws of the State of Delaware. Upon information and belief, Amneal NY has a principal place of business at 50 Horseblock Road, Brookhaven, New York 11719, and, per Amneal's letter dated November 1, 2018 notifying Cubist that Amneal NY had submitted ANDA No. 212397 ("Amneal's Notice Letter"), a place of business at 400 Crossing Blvd., Third Floor, Bridgewater, Somerset Country, New Jersey 08807. Upon information and belief, Amneal NY is a wholly owned subsidiary, and agent of Amneal Pharma. Upon information and belief, Amneal NY is the U.S. agent of Amneal Pharma, Amneal Ltd., and Amneal EU, Limited. Upon information and belief, Amneal NY, in conjunction with Amneal Pharmaceuticals Company GmbH, originally submitted the Amneal ANDA to the FDA. Amneal NY is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including in this Judicial District.

5. Upon information and belief, Amneal Ltd. is a company organized and existing under the laws of India. Upon information and belief, Amneal Ltd. has a principal place of business at Plot No. 15, PHARMEZ Special Economic Zone, Sarkhej-Bavla N.H. No. 8A, Vil.: Matoda, Tal.: Sanada, Ahmedabad, Gujarat 382213, India. Upon information and belief, Amneal Ltd. is a direct or indirect wholly owned subsidiary of Amneal Pharma. Amneal Ltd. is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products that are marketed throughout the United States including in this Judicial District.

6. Upon information and belief, Amneal EU, Limited ("Amneal EU") is a company organized and existing under the laws of Ireland. Upon information and belief Amneal

EU has a principal place of business at Cahir Road, Cashel, Co. Tipperary, Ireland E25 XD5 1. Upon information and belief, Amneal EU is the current holder of the Amneal ANDA. Upon information and belief, Amneal EU is a direct or indirect wholly owned subsidiary of Amneal Pharma. Upon information and belief, Amneal EU has been transferred all rights to Amneal's ANDA, and is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products that are marketed throughout the United States including in this Judicial District.

THE PATENTS-IN-SUIT

7. On September 22, 2015, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’456 patent, which is owned by Cubist, entitled “Lipopetide Compositions And Related Methods.” A copy of the ’456 patent is attached as Exhibit A.

8. On September 16, 2014, the USPTO duly and lawfully issued the ’382 patent, which is owned by Cubist, entitled “Lipopetide Compositions And Related Methods.” A copy of the ’382 patent is attached as Exhibit B.

THE CUBICIN RF[®] DRUG PRODUCT

9. Cubist holds approved New Drug Application (“NDA”) No. 021572 for daptomycin for injection, which is prescribed and sold under the trademark CUBICIN RF[®]. CUBICIN RF[®] is indicated for the treatment of complicated skin and skin structure infections and *Staphylococcus aureus* bloodstream infections in adult and pediatric patients.

10. The claims of the ’456 patent cover, *inter alia*, solid pharmaceutical daptomycin compositions.

11. The claims of the '382 patent cover, *inter alia*, methods of manufacturing solid pharmaceutical daptomycin compositions.

12. Pursuant to 21 U.S.C. § 335(b)(1), and attendant FDA regulations, the '456 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to CUBICIN RF[®].

SUBJECT MATTER JURISDICTION

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. This Court further has subject matter jurisdiction over Cubist's request for a declaratory judgment under 28 U.S.C. §§ 2201 and 2202.

PERSONAL JURISDICTION AND VENUE OVER AMNEAL PHARMA

14. This Court has personal jurisdiction over Amneal Pharma because Amneal Pharma has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. Upon information and belief, Amneal Pharma regularly and continuously transacts business within New Jersey, including by establishing a principal place of business in New Jersey and by selling pharmaceutical products in New Jersey. Upon information and belief, Amneal Pharma derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

15. This Court also has personal jurisdiction over Amneal Pharma because, *inter alia*, this action arises from actions of Amneal Pharma directed toward New Jersey. For example, Amneal Pharma's counsel sent Amneal's Notice Letter directed to Cubist's offices in New Jersey stating that Amneal NY had submitted ANDA No. 212397 seeking approval to

commercially manufacture, use, import, offer for sale, and sell Amneal's Proposed ANDA Product prior to the expiration of the '456 patent. If Amneal Pharma succeeds in obtaining FDA approval, it would sell Amneal's Proposed ANDA Product in New Jersey and other states, causing injury to Plaintiff in New Jersey.

16. Upon information and belief, Amneal Pharma has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

17. Upon information and belief, Amneal Pharma plans to market such products and intends a future course of conduct that includes acts of patent infringement in New Jersey. Upon information and belief, Amneal Pharma's acts have led and will lead to foreseeable harm and injury to Plaintiff in New Jersey. Upon information and belief, following approval of the Amneal ANDA, Amneal Pharma will make, use, import, sell, and/or offer for sale the Amneal's Proposed ANDA Product in the United States, including in New Jersey. Upon information and belief, Amneal Pharma will conduct such acts from its regular and established place of business in Bridgewater, Somerset County, New Jersey.

18. Upon information and belief, Amneal Pharma has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

19. Amneal Pharma has previously been sued in this Judicial District and has availed itself of courts in New Jersey through the assertion of claims and counterclaims in suits brought in New Jersey, including *Amneal Pharmaceuticals LLC v. Reckitt Benckiser Pharmaceuticals, Inc. et al.*, No. 3:15-cv-08864-MAS-DEA (D.N.J.) (filing complaint asserting

claims); *Senju Pharmaceutical Co. et al. v. Amneal Pharmaceuticals LLC et al.*, No. 3:18-cv-05571 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims); *BTG International Limited et al. v. Actavis Laboratories FL, Inc. et al.*, No. 2:15-cv-05909-KM-JBC (D.N.J.) (same); *Shire Pharmaceutical Development Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, No. 1:15-cv-02865-RBK-JS (D.N.J.) (same); *Novo Nordisk Inc. et al. v. Amneal Pharmaceuticals, LLC, et al.*, No. 3:13-cv-04915-MAS-DEA (D.N.J.) (same); *Luitpold Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, No. 3:12-cv-05064-JAP-DEA (D.N.J.) (same), and has consented to the jurisdiction of this Court in these cases and others, including *Janssen Products, LP et al v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585 (D.N.J.) (not contesting personal jurisdiction or venue); *Symed Labs Limited et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-13628-CCC-MF (D.N.J.) (same).

20. On information and belief, Amneal Pharma, Amneal NY, Amneal Ltd., and Amneal EU operate and act in concert as an integrated, unitary business. On information and belief, Amneal Pharma, acting in concert with Amneal NY, Amneal Ltd., and Amneal EU has made and will continue to make substantial and meaningful preparations in this Judicial District towards infringement, including the preparation and submission of the Amneal ANDA seeking FDA approval to market Amneal's Proposed ANDA Product throughout the United States, including in this Judicial District, before expiration of the '456 patent. On information and belief, among other actions, Amneal Pharma signed Amneal's Notice Letter stating that Amneal NY had submitted the Amneal ANDA to the FDA seeking approval to market Amneal's Proposed ANDA Product before the expiration of the '456 patent.

21. Venue is proper for Amneal Pharma under 28 U.S.C. §§ 1391(c) and 1400(b) because Amneal Pharma has a regular and established place of business in Bridgewater,

Somerset Country, New Jersey, and has or will commit acts of infringement in New Jersey, as set forth in paragraphs 17 and 42-63.

PERSONAL JURISDICTION AND VENUE OVER AMNEAL NY

22. This Court has personal jurisdiction over Amneal NY because Amneal NY has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. Upon information and belief, Amneal NY regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Upon information and belief, Amneal NY derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

23. Upon information and belief, Amneal NY has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

24. The Amneal ANDA identifies Amneal NY as an entity that would market Amneal's Proposed ANDA Product in the United States. Upon information and belief, Amneal NY agreed to market such product and intends a future course of conduct that includes acts of patent infringement in New Jersey. Upon information and belief, Amneal NY's acts have led to and will lead to foreseeable harm and injury to Plaintiff in New Jersey. Upon information and belief, following approval of the Amneal ANDA, Amneal NY will make, use, import, sell, and/or offer for sale the Amneal's Proposed ANDA Product in the United States, including in New Jersey. Upon information and belief, Amneal NY has previously submitted to the

jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

25. On information and belief, Amneal NY acts as the agent of Amneal Pharma, Amneal Ltd., and Amneal EU with respect to the Amneal ANDA. On information and belief, one reflection of that is that Amneal's Notice Letter, which was signed by Amneal Pharma, identifies Amneal NY as the party that submitted the ANDA. On information and belief, Amneal NY submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Amneal Pharma, and Amneal Ltd., including the ANDA seeking FDA approval to market Amneal's Proposed ANDA Product before expiration of the '456 patent.

26. Amneal NY has previously been sued in this Judicial District and has availed itself of courts in New Jersey through the assertion of counterclaims in suits brought in New Jersey, including *BTG International Limited et al. v. Actavis Laboratories FL, Inc. et al.*, No. 2:15-cv-05909-KM-JBC (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims); *Shire Pharmaceutical Development Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, No. 1:15-cv-02865-RBK-JS (D.N.J.) (same); *Novo Nordisk Inc. et al. v. Amneal Pharmaceuticals, LLC, et al.*, No. 3:13-cv-04915-MAS-DEA (D.N.J.) (same); *Luitpold Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, No. 3:12-cv-05064-JAP-DEA (D.N.J.) (same), and has consented to the jurisdiction of this Court in these cases and others, including *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585 (D.N.J.) (not contesting personal jurisdiction or venue).

27. Venue is proper for Amneal NY under 28 U.S.C. §§ 1391(c) and 1400(b) because Amneal NY has a regular and established place of business in Bridgewater, Somerset

Country, New Jersey, and has or will commit acts of infringement in New Jersey, as set forth in paragraphs 24 and 42-63.

PERSONAL JURISDICTION AND VENUE OVER AMNEAL LTD.

28. This Court has personal jurisdiction over Amneal Ltd. because, *inter alia*, Amneal Ltd. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiff in New Jersey. For example, on information and belief, following approval of Amneal's Proposed ANDA Product, Amneal Ltd. will make, use, import, sell, and/or offer for sale Amneal's Proposed ANDA Product in the United States, including in New Jersey.

29. This Court also has personal jurisdiction over Amneal Ltd. because, *inter alia*, this action arises from actions of Amneal Ltd. directed toward New Jersey. ANDA No. 212397 seeks approval to commercially manufacture, use, import, offer for sale, and sell Amneal's Proposed ANDA Product, which upon information and belief will be manufactured by Amneal Ltd., prior to the expiration of the '456 patent. The sale of Amneal's Proposed ANDA Product in New Jersey and other states would cause injury to Plaintiff in New Jersey.

30. The Court also has personal jurisdiction over Amneal Ltd. because Amneal Ltd. has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Amneal Ltd. regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Amneal Ltd. derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

31. On information and belief, Amneal Ltd. has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

32. On information and belief, Amneal Ltd. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

33. On information and belief, Amneal Ltd. has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases. Amneal Ltd. has previously been sued in this Judicial District and has availed itself of courts in New Jersey through the assertion of claims and counterclaims in suits brought in New Jersey, including *Forest Laboratories, LLC et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:17-cv-11680 (D.N.J.) (not contesting personal jurisdiction or venue and asserting counterclaims), and has consented to the jurisdiction of this Court in these cases and others, including *Janssen Products, LP et al v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585 (D.N.J.) (not contesting personal jurisdiction or venue).

34. Venue is proper for Amneal Ltd. under 28 U.S.C. §§ 1391(c)-(d) and 1400(b). Amneal Ltd. is a foreign company and venue is proper in any judicial district having personal jurisdiction, including this Judicial District.

PERSONAL JURISDICTION AND VENUE OVER AMNEAL EU

35. This Court has personal jurisdiction over Amneal EU because, *inter alia*, Amneal EU has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) by virtue of becoming the holder of all ownership rights to the Amneal ANDA, and intends a future course

of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiff in New Jersey. For example, on information and belief, following approval of Amneal's Proposed ANDA Product, Amneal EU will make, use, import, sell, and/or offer for sale Amneal's Proposed ANDA Product in the United States, including in New Jersey.

36. This Court also has personal jurisdiction over Amneal EU because, *inter alia*, this action arises from actions of Amneal EU directed toward New Jersey. Upon information and belief, Amneal EU's acts have led to and will lead to foreseeable harm and injury to Plaintiff in New Jersey. Amneal EU is the holder of ANDA No. 212397 and seeks approval to commercially manufacture, use, import, offer for sale, and sell Amneal's Proposed ANDA Product prior to the expiration of the '456 patent. If Amneal EU succeeds in obtaining FDA approval, it will make, use, import, sell, and/or offer for sale the Amneal's Proposed ANDA Product in the United States, including in New Jersey, causing injury to Plaintiff in New Jersey. In addition, Amneal EU became the holder of ANDA No. 212397 after this lawsuit was filed and, upon information and belief, Amneal EU knew of the existence of this lawsuit and its pendency in New Jersey prior to becoming the holder ANDA No. 212397.

37. The Court also has personal jurisdiction over Amneal EU because Amneal EU has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Amneal EU regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Amneal EU derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

38. On information and belief, Amneal EU has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

39. On information and belief, Amneal EU derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

40. Venue is proper for Amneal EU under 28 U.S.C. §§ 1391(c)-(d) and 1400(b). Amneal EU is a foreign company and venue is proper in any judicial district having personal jurisdiction, including this Judicial District.

AMNEAL'S INFRINGING ANDA SUBMISSION

41. On or about November 1, 2018, Cubist received from Amneal Pharma's counsel Amneal's Notice Letter, stating that Amneal NY had submitted the Amneal ANDA to the FDA seeking approval to market Amneal's Proposed ANDA Product before the expiration of the '456 patent. Amneal's Proposed ANDA Product is intended to be a generic version of CUBICIN RF[®].

42. Amneal's Notice Letter notified Plaintiff that the Amneal ANDA includes a certification pursuant to § 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug and Cosmetic Act ("Amneal's Paragraph IV Certification"), and that in Amneal's opinion, the '456 patent is "unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug product for which ANDA No. 212397 has been submitted by AMNEAL."

43. Amneal's Paragraph IV Certification alleges that Amneal's Proposed ANDA Product does not infringe certain claims of the '456 patent. Notwithstanding these allegations, on information and belief, discovery and/or testing will show that Amneal's Proposed ANDA Product infringes the '456 patent.

44. On information and belief, Amneal's Proposed ANDA Product will be manufactured outside the United States. On information and belief, upon FDA approval, Amneal's Proposed ANDA Product will be imported into the United States by Amneal Pharma, Amneal NY, and/or Amneal Ltd. On information and belief, discovery and/or testing will show that Amneal's Proposed ANDA Product and/or the method by which it is manufactured infringes at least claims 1-3, 5-15, and 17-18 of the '382 patent.

45. Upon information and belief, the Amneal ANDA seeks FDA approval to market Amneal's Proposed ANDA Product before the expiration of the '382 patent.

46. Upon information and belief, Amneal intends to market Amneal's Proposed ANDA Product in the United States.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,138,456 BY DEFENDANTS

47. Plaintiff repeats and realleges paragraphs 1-46 above as if fully set forth herein.

48. By filing the Amneal ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Amneal's Proposed ANDA Product before the expiration of the '456 patent, Amneal committed an act of infringement under 35 U.S.C. § 271(e)(2).

49. Upon information and belief, discovery and/or testing will show that if Amneal commercially makes, uses, offers to sell, or sells Amneal's Proposed ANDA Product

within the United States, including in New Jersey, or imports Amneal's Proposed ANDA Product into the United States, including in New Jersey, or induces or contributes to any such conduct during the term of the '456 patent, it would further infringe at least claims 1-2, 7-11 and 15 of the '456 patent under 35 U.S.C. § 271(a), (b), and/or (c). In addition, Amneal's Paragraph IV Certification does not dispute that it infringes at least one claim of the '456 patent.

50. Amneal has had knowledge of the '456 patent since at least the date it submitted the Amneal ANDA.

51. Plaintiff will be irreparably harmed if Amneal is not enjoined from infringing the '456 patent. Plaintiff does not have an adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,138,456 BY DEFENDANTS

52. Plaintiff repeats and realleges paragraphs 1-51 above as if fully set forth herein.

53. On information and belief, Amneal has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Products prior to the expiration of the '456 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Amneal's planned manufacture, use, offer to sell, or sale of Amneal's Proposed ANDA Product within the United States, including in New Jersey, or importation of Amneal's Proposed ANDA Product into the United States, including in New Jersey, or inducement or contribution to any such conduct during the term of the '456 patent, infringes any valid claim of the '456 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

54. Plaintiff seeks a declaratory judgment that Amneal's manufacture, use, offer to sell, or sale of Amneal's Proposed ANDA Product within the United States or importation of Amneal's Proposed ANDA Product into the United States will infringe any valid claim of the '456 patent under 35 U.S.C. § 271(a), (b), and/or (c). In addition, Amneal's Paragraph IV Certification does not dispute that it infringes at least one claim of the '456 patent.

COUNT III: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,835,382 BY DEFENDANTS

55. Plaintiff repeats and realleges paragraphs 1-54 above as if fully set forth herein.

56. On information and belief, Amneal has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by the methods patented by the '382 patent prior to its expiration. An actual and substantial controversy has arisen and now exists between the parties concerning whether Amneal's planned use, offer to sell, or sale of Amneal's Proposed ANDA Product within the United States, including in New Jersey, or importation of Amneal's Proposed ANDA Product into the United States, including in New Jersey, or inducement or contribution to any such conduct during the term of the '382 patent, infringes any valid claim of the '382 patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

57. On information and belief, Amneal has made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States a product which is made by the methods patented by the '382 patent prior to its expiration, including by developing a method that infringes claims of the '382 patent, actually using that method to prepare batches of Amneal's Proposed ANDA Product,

filing the Amneal ANDA, and systematically attempting to meet the applicable regulatory requirements for approval of the Amneal ANDA in order to secure FDA approval to commercially market product made by its infringing method in the United States, as well as by engaging in litigation to manufacture, offer to sell, sell, use, and/or import Amneal's Proposed ANDA Product prior to the expiration of the '382 patent, including the assertion of counterclaims.

58. Amneal's actions, including, but not limited to developing a method that infringes claims of the '382 patent, actually using that method to prepare batches of Amneal's Proposed ANDA Product, filing the Amneal ANDA, and systematically attempting to meet the applicable regulatory requirements for approval of the Amneal ANDA in order to secure FDA approval to commercially market product made by its infringing method in the United States, as well as engaging in litigation to manufacture, offer to sell, sell, use, and/or import Amneal's Proposed ANDA Product prior to the expiration of the '382 patent, including the assertion of counterclaims, indicate a refusal to change its course of action.

59. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Amneal's Proposed ANDA Product will constitute infringement of, and/or induce or contribute to infringement of, at least claims 1-3, 5-15, and 17-18 of the '382 patent.

60. Plaintiff seeks a declaratory judgment that Amneal's manufacture of Amneal's Proposed ANDA Product in India, and subsequent importation of Amneal's Proposed ANDA Product into the United States and/or use, offer to sell, and/or sale within the United States will infringe a valid claim of the '382 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g).

61. Amneal has had knowledge of the '382 patent since at least November 1, 2018, the date of Amneal's Notice Letter.

62. Plaintiff will be irreparably harmed if Amneal is not enjoined from infringing the '382 patent. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment that Amneal has infringed one or more claims of the '456 patent by filing ANDA No. 212397;

B. A Judgment that Amneal has infringed, and that Amneal's making, using, selling, offering to sell, or importing Amneal's Proposed ANDA Product would constitute infringement of one or more claims of the '456 patent, and/or induces or contributes to the infringement of, one or more claims of the '456 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

C. A Declaration that Amneal has infringed, and that Amneal's making, using, selling, offering to sell, or importing Amneal's Proposed ANDA Product infringes of one or more claims of the '456 patent, and/or induces or contributes to the infringement of, one or more claims of the '456 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

D. A Declaration that Amneal's making, using, selling, offering to sell, or importing Amneal's Proposed ANDA Product infringes of one or more claims of the '382 patent, and/or induces or contributes to the infringement of, one or more claims of the '382 patent pursuant to 35 U.S.C. § 271(a), (b), (c) and/or (g);

E. A permanent injunction restraining and enjoining Amneal, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from

engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Amneal's Proposed ANDA Product until after the expiration of the Patents-In-Suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

F. An Order that the effective date of any approval of ANDA No. 212397 relating to Amneal's Proposed ANDA Product be a date that is not earlier than the expiration date of the Patents-In-Suit plus any other regulatory exclusivity to which Plaintiff is or becomes entitled.

G. Such other and further relief as the Court may deem just and proper.

Dated: April 6, 2020

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1(d)

Pursuant to Local Civil Rule 201.1, I hereby certify the above-captioned matter is not subject to compulsory arbitration in that, *inter alia*, the Plaintiff seeks non-monetary injunctive relief and the amount in controversy exceeds the \$150,000 threshold exclusive of interest and costs and any claim for punitive damages.

Dated: April 6, 2020

By: s/ John E. Flaherty
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