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

CUBIST PHARMACEUTICALS LLC, Plaintiff, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN N.V. AND MYLAN LABORATORIES LIMITED, Defendants.	Civil Action No. 1:20-cv-00052-IMK **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** (Filed Electronically)

Plaintiff Cubist Pharmaceuticals LLC ("Cubist" or "Plaintiff") by its attorneys, for their complaint against Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals"), Mylan Inc., Mylan N.V., and Mylan Laboratories Limited ("Mylan Labs") (collectively, "Mylan" 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") under the laws of United States, 35 U.S.C. § 100, et seq. and 28 U.S.C. §§ 2201 and 2202. This action arises from Mylan's submission of Abbreviated New Drug Application ("ANDA") No. 213966 ("Mylan's 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 ("Mylan'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 Weystrasse 20, 6000 Lucerne 6, Switzerland.

3. Upon information and belief, Defendant Mylan N.V. is a corporation organized and existing under the laws of Netherlands, having a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. On information and belief, the Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania.

4. Upon information and belief, Defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

5. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is a wholly owned subsidiary of Mylan N.V.

6. Upon information and belief, Defendant Mylan Labs is a company organized and existing under the laws of India, having a principal place of business at Plot No.

564/A/22, Road No. 92, Jubilee Hills, Hyderabad, Telangana 500034, India. Mylan Labs is a wholly owned subsidiary of Mylan Inc.

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. Pursuant to 21 U.S.C. § 355(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

12. 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 MYLAN

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. This Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with the State of West Virginia. On information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business in this Judicial District. On information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. By virtue of its physical presence in West Virginia, this Court has personal jurisdiction over Mylan Pharmaceuticals.

15. On information and belief, Mylan Pharmaceuticals is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Mylan's ANDA. On information and belief, Mylan Pharmaceuticals also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

16. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of West Virginia. On information and belief, Mylan Inc. purposefully has conducted and continues to conduct business in this Judicial District.

17. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Mylan's ANDA. On information and belief, Mylan Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

18. This Court has personal jurisdiction over Mylan N.V. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in West Virginia, including directly or indirectly through its subsidiaries, agents, and/or alter egos, including Mylan Pharmaceuticals and Mylan Inc., companies registered with the West Virginia Secretary of State, and (2) maintains extensive and systematic contacts with the State of West Virginia, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in West Virginia including through, directly or indirectly, Mylan Pharmaceuticals and Mylan Inc.

19. This Court has personal jurisdiction over Mylan Labs because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in West Virginia, including directly or indirectly through its subsidiaries, agents, and/or alter egos, including Mylan Pharmaceuticals and Mylan Inc., companies registered with the West Virginia Secretary of State, and (2) maintains extensive and systematic contacts with the State of West Virginia,

including the marketing, distribution, and/or sale of generic pharmaceutical drugs in West Virginia including through, directly or indirectly, Mylan Pharmaceuticals and Mylan Inc.

20. This Court has personal jurisdiction over Mylan Pharmaceuticals and Mylan Inc. because, *inter alia*, they: (1) have purposefully availed themselves of the privilege of doing business in West Virginia, including directly or indirectly through their subsidiaries, agents, and/or alter egos, including companies registered with the West Virginia Secretary of State; and (2) maintain extensive and systematic contacts with the State of West Virginia, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in West Virginia including through, directly or indirectly, their subsidiaries, agents, and/or alter egos.

21. This Court has personal jurisdiction over Mylan because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Mylan intends a future course of conduct that includes acts of patent infringement in West Virginia. These acts have led and will continue to lead to foreseeable harm and injury to Cubist in West Virginia and in this Judicial District.

22. Mylan N.V.'s website (https://www.mylan.com/en/about-mylan/leadership) states that "[t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania."

23. Mylan N.V.'s Form 10-K Annual Report for the Period Ending 12/31/2016 ("Mylan Annual Report") states that on February 27, 2015, "Mylan Inc. became an indirect wholly owned subsidiary of Mylan N.V., and Mylan Inc.'s common stock ceased trading on the NASDAQ." See Mylan Annual Report at 53. The Mylan Annual Report further states that "Mylan N.V. is the successor to Mylan Inc." *Id.* at 55.

24. On information and belief, Mylan Pharmaceuticals, Mylan Inc., Mylan N.V., and Mylan Labs work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

25. On information and belief, Mylan Pharmaceuticals and Mylan Labs act at the direction, and for the benefit, of Mylan N.V. and Mylan Inc., and are controlled and/or dominated by Mylan N.V. and Mylan Inc.

26. On information and belief, members of the Mylan corporate family have locations in or are incorporated in the State of West Virginia. On information and belief, these entities are controlled and/or dominated by Mylan Pharmaceuticals, Mylan Inc., Mylan N.V. and/or Mylan Labs, and/or are alter egos of Mylan Pharmaceuticals, Mylan Inc., Mylan N.V., and /or Mylan Labs.

27. On information and belief, Mylan Pharmaceuticals, Mylan Inc., Mylan N.V. and Mylan Labs, directly or indirectly or through each other or other entities, maintain regular and established places of business in West Virginia.

28. On information and belief, Mylan Pharmaceuticals, Mylan Inc., Mylan N.V., and Mylan Labs have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g.*, *Almirall, LLC v. Mylan Pharms. Inc.*, No. 20-cv-00006 (N.D.W. Va.) (Mylan Pharmaceuticals consented to personal jurisdiction and venue and raised counterclaims); *Novartis Pharms. Corp. v. Mylan Pharms. Inc.*, No. 19-cv-00201 (N.D.W. Va.) (Mylan Pharmaceuticals consented to personal jurisdiction and venue and raised counterclaims); *Merck Sharp & Dohme Corp. v. Mylan Pharms. Inc. et al.*, No. 19-cv-00101 (N.D.W. Va.) (Mylan Pharmaceuticals and Mylan Inc. consented to personal jurisdiction and

venue and raised counterclaims); *Pfizer Inc. et al. v. Mylan Pharms. Inc. et al.*, No. 19-cv-00097 (N.D.W. Va.) (Mylan Pharmaceuticals and Mylan Inc. consented to personal jurisdiction and venue and raised counterclaims); *Anacor Pharms., Inc. et al. v. Mylan Pharms. Inc. et al.*, No. 18-cv-00202 (N.D.W. Va.) (Mylan Pharmaceuticals and Mylan Inc. consented to personal jurisdiction and venue and raised counterclaims); *AstraZeneca AB et al. v. Mylan Pharms. Inc. et al.*, No. 18-cv-00193 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan Inc., Mylan N.V., and Mylan Labs consented to personal jurisdiction and venue and raised counterclaims); *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.*, No. 17-cv-00181 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan Inc., Mylan N.V., and Mylan GmbH consented to personal jurisdiction and venue); *Sanofi-Aventis U.S. LLC et al. v. Mylan Pharms. Inc. et al.*, No. 17-cv-00005 (N.D.W. Va.) (Mylan Pharmaceuticals and Mylan Inc. consented to personal jurisdiction and venue and raised counterclaims); *Noven Pharma., Inc. v. Mylan Techs. Inc. et al.*, No. 15-cv-00194 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan Inc., Mylan N.V., and Mylan Technologies Inc. consented to personal jurisdiction and venue and raised counterclaims); *Indivior Inc. et al. v. Mylan Techs. Inc. et al.*, No. 15-cv-00209 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan N.V., and Mylan Technologies Inc. consented to personal jurisdiction and venue); *Boehringer Ingelheim Pharms. Inc. et al v. Mylan Pharms. Inc. et al*, 1-20-cv-00019 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan Inc. and Mylan Labs consented to personal jurisdiction and venue); *Pfizer Inc. et al. v. Mylan Inc. et al.*, 15-cv-00188 (N.D.W. Va.) (Mylan Pharmaceuticals and Mylan Labs consented to personal jurisdiction and venue and Mylan Labs raised counterclaims); *Fresenius Kabi USA, LLC et al. v. Mylan Labs. Ltd. et al.*, 15-cv-00185 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan Inc., and Mylan Labs consented to personal jurisdiction and venue and Mylan Labs raised counterclaims); *AstraZeneca Pharms. LP et al. v. Mylan Pharms. Inc.*, 15-cv-

00183 (N.D.W. Va.) (Mylan Pharmaceuticals, Mylan Inc., and Mylan Labs consented to personal jurisdiction and venue and raised counterclaims).

29. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business in Morgantown, West Virginia, Mylan Pharmaceuticals, Mylan Inc., and Mylan N.V. have a place of business in West Virginia, and Mylan Pharmaceuticals, Mylan Inc., and Mylan N.V. have or will commit acts of infringement in this judicial district, as set forth in Paragraphs 31-52.

30. Venue is proper for Mylan N.V. and Mylan Labs under 28 U.S.C. §§ 1391 and/or 1400(b). Mylan N.V. and Mylan Labs are foreign corporations and venue is proper in any judicial district having personal jurisdiction, including this judicial district. Additionally, Mylan N.V. operates in the United States through its subsidiary, Mylan Pharmaceuticals, which has a regular and established place of business in this district and Mylan N.V. has or will commit acts of infringement in this judicial district, as set forth in Paragraphs 31-52.

MYLAN'S INFRINGING ANDA SUBMISSION

31. On or about February 19, 2020, Cubist received from Mylan's counsel a Notice Letter, stating that Mylan had submitted its ANDA to the FDA seeking approval to market Mylan's Proposed ANDA Product before the expiration of the '456 patent. Mylan's Proposed ANDA Product is intended to be a generic version of CUBICIN RF®.

32. Mylan's Notice Letter notified Plaintiff that Mylan's ANDA includes a certification pursuant to § 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug and Cosmetic Act ("Mylan's Paragraph IV Certification"), and that in Mylan's opinion, the '456 patent is "invalid,

unenforceable and/or will not be infringed by the manufacture, use, or sale of the drug product described in Mylan's ANDA."

33. Mylan's Paragraph IV Certification alleges that Mylan'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 Mylan's Proposed ANDA Product infringes the '456 patent.

34. On information and belief, following FDA approval of Mylan's ANDA, Defendants Mylan Pharmaceuticals, Mylan N.V., Mylan Inc., and Mylan Labs will work in concert with one another to make, use, sell, or offer to sell Mylan's Proposed ANDA Product throughout the United States, or import such generic products into the United States.

35. On information and belief, Mylan's Proposed ANDA Product will be manufactured in India. On information and belief, upon FDA approval, Mylan's Proposed ANDA Product will be imported into the United States by Mylan Labs. On information and belief, discovery and/or testing will show that Mylan'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.

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

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

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

38. Plaintiff repeats and realleges paragraphs 1-37 above as if fully set forth herein.

39. By submitting its 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 Mylan's Proposed ANDA Product before the expiration of the '456 patent, Mylan committed an act of infringement under 35 U.S.C. § 271(e)(2).

40. Upon information and belief, discovery and/or testing will show that if Mylan commercially makes, uses, offers to sell, or sells Mylan's Proposed ANDA Product within the United States, including in this Judicial District, or imports Mylan's Proposed ANDA Product into the United States, including in this Judicial District, 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, Mylan's Paragraph IV Certification does not dispute that it infringes at least one claim of the '456 patent.

41. Mylan has had knowledge of the '456 patent since at least the date it submitted Mylan's ANDA.

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

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

43. Plaintiff repeats and realleges paragraphs 1-42 above as if fully set forth herein.

44. On information and belief, Mylan has made and will continue to make substantial and meaningful preparations to manufacture, use, offer to sell, or sell its Proposed ANDA Product prior to the expiration of the '456 patent. An actual and substantial controversy has arisen and now exists between the parties concerning whether Mylan's planned manufacture, use, offer to sell, or sale of Mylan's Proposed ANDA Product within the United States, including

in West Virginia, or importation of Mylan's Proposed ANDA Product into the United States, including in West Virginia, 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.

45. Plaintiff seeks a declaratory judgment that Mylan's manufacture, use, offer to sell, or sale of Mylan's Proposed ANDA Product within the United States or importation of Mylan's Proposed ANDA Product into the United States will infringe one or more claims, including but not limited to claims 1-2, 7-11 and 15, of the '456 patent under 35 U.S.C. § 271(a), (b), and/or (c). of the '456 patent under 35 U.S.C. § 271(a), (b), and/or (c). In addition, Mylan's Paragraph IV Certification does not dispute that it infringes at least one claim of the '456 patent.

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

46. Plaintiff repeats and realleges paragraphs 1-45 above as if fully set forth herein.

47. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiff and Mylan regarding the infringement of the '382 patent.

48. On information and belief, Mylan 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 Mylan's Proposed ANDA Product, and filing ANDA No. 213966 and systematically attempting to meet the applicable regulatory requirements for approval of that 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 Mylan's Proposed ANDA Product prior to the expiration of the '382 patent, including the assertion of counterclaims.

49. Mylan'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 Mylan's Proposed ANDA Product, and filing ANDA No. 213966 and systematically attempting to meet the applicable regulatory requirements for approval of that 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 Mylan'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.

50. Any importation into the United States and/or use, offer for sale, and/or sale in the United States of Mylan'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.

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

52. Mylan has had knowledge of the '382 patent since at least the date it sent the February 19, 2020 letter from Mylan's counsel.

53. Plaintiff will be irreparably harmed if Mylan 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 Mylan has infringed one or more claims of the ’456 patent by submitting ANDA No. 213966;

B. A Judgment that Mylan’s making, using, selling, offering to sell, or importing Mylan’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 Mylan’s importing, selling, offering to sell, or using Mylan’s Proposed ANDA Product as described in ANDA No. 213966 would constitute infringement of one or more claims of the ’382 patent, and/or induce or contribute 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);

D. A Declaration that Mylan has infringed, and that Mylan’s making, using, selling, offering to sell, or importing Mylan’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);

E. A permanent injunction restraining and enjoining Mylan, 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 Mylan’s Proposed ANDA Product until after the expiration

of the Patent-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. 213966 relating to Mylan's Proposed ANDA Product be a date that is not earlier than the expiration date of the Patent-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: July 13, 2020

By: s/ *Sandra K. Law*

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CERTIFICATE OF SERVICE

I certify that on the 13th day of July 2020, I electronically filed the foregoing "**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**" with the Clerk of the Court using the CM/ECF system, which will send notice of the same to the following counsel of record:

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