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

CUBIST PHARMACEUTICALS LLC,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC., MYLAN
INC., AND MYLAN N.V.,

Defendants.

Civil Action No. _____

**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., and Mylan N.V. (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.* 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.

THE PATENT-IN-SUIT

6. 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.

THE CUBICIN RF® DRUG PRODUCT

7. 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.

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

9. 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

10. 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

11. This Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Mylan Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100214277. On information and belief, Mylan Pharmaceuticals is registered with the State of New Jersey's Department of Health as a wholesaler and manufacturer under Registration No. 5003762. On information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals has a place of business at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Pharmaceuticals publicly touts its New Jersey presence at <https://mylanbetterhealth.com/en/us/new-jersey>.

12. 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 product 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.

13. This Court has personal jurisdiction over Mylan Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Mylan Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100971292. On information and belief, Mylan Inc. purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. has a place of business at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Inc. publicly touts its New Jersey presence at <https://mylanbetterhealth.com/en/us/new-jersey>.

14. 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 product 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.

15. This Court has personal jurisdiction over Mylan N.V. because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Mylan Pharmaceuticals and Mylan Inc., companies registered with the State of New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution,

and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Mylan Pharmaceuticals and Mylan Inc.

16. 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 has sent notice of that infringement to Cubist in the State of New Jersey. On information and belief, Mylan intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Cubist in New Jersey and in this Judicial District.

17. 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.”

18. Mylan N.V.’s Form 10-K Annual Report for the Period Ending 12/13/2016 (“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.

19. On information and belief, Mylan Pharmaceuticals, Mylan Inc., and Mylan N.V. 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.

20. On information and belief, Mylan Pharmaceuticals acts at the direction, and for the benefit, of Mylan N.V. and Mylan Inc., and is controlled and/or dominated by Mylan N.V. and Mylan Inc.

21. On information and belief, Mylan Inc., Mylan Pharmaceuticals, and Mylan N.V. have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g., Baxter Healthcare Corp., et al. v. Agila Specialties Private Ltd., et al.*, Civil Action No. 14-7094 (JBS)(JS) (D.N.J.) (Mylan Pharmaceuticals); *Astrazeneca AB, et al. v. Mylan Pharms. Inc., et al.*, Civil Action No. 13-4022 (MLC)(DEA) (D.N.J.) (Mylan Pharmaceuticals and Mylan Inc.); *Janssen Prods., L.P., et al. v. Lupin Ltd., et al.*, Civil Action No. 10-5954 (WHW)(CLW) (D.N.J.) (Mylan Pharmaceuticals and Mylan Inc.).

22. Mylan Inc. and Mylan Pharmaceuticals have further availed themselves of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g., Mylan Pharms. Inc. v. Celgene Corp.*, Civil Action No. 14-2094 (ES)(MAH) (D.N.J.); *Mylan Inc., et al. v. Apotex Inc., et al.*, Civil Action No. 14-4560 (MAS)(LHG) (D.N.J.).

23. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because Mylan has regular and established place of business in Basking Ridge, Somerset Country, New Jersey, and has or will commit acts of infringement in New Jersey, as set forth in paragraphs 12, 14 and 19-20 and 24-32.

MYLAN'S INFRINGING ANDA SUBMISSION

24. 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®. Mylan's Notice Letter was addressed, *inter alia*, to Plaintiff's parent, Merck & Co., in Kenilworth, New Jersey.

25. 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."

26. 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.

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

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

28. Plaintiff repeats and realleges paragraphs 1-27 above as if fully set forth herein.

29. 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).

30. 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.

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

32. 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

33. Plaintiff repeats and realleges paragraphs 1-32 above as if fully set forth herein.

34. 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 New Jersey, or importation of Mylan'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.

35. 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). In addition, Mylan's Paragraph IV Certification does not dispute that it infringes at least one claim of the '456 patent.

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 has infringed, and that Mylan's making, using, selling, offering to sell, or importing Mylan's Proposed ANDA Product infringes 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 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;

E. 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.

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

Dated: March 23, 2020

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action alleges infringement of the same patients at issue in the following matters:

- *Cubist Pharmaceuticals LLC v. Cipla USA, Inc., et al.*,
Civil Action No. 3:19-cv-12920 (BRM) (ZNQ).
- *Cubist Pharmaceuticals LLC v. Amneal Pharmaceuticals LLC, et al.*,
Civil Action No. 3:19-cv-15439 (BRM) (ZNQ).

Dated: March 23, 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: March 23, 2020

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