IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Cubist Pharmaceuticals LLC, by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL" or "Defendants") of Abbreviated New Drug Application ("ANDA") No. 208375 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CUBICIN® prior to the expiration of U.S. Patent Nos. 6,468,967; 6,852,689; 8,058,238; and 8,129,342.

PARTIES

2. Plaintiff Cubist Pharmaceuticals LLC ("Cubist" or "Plaintiff") is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 65 Hayden Avenue, Lexington, Massachusetts.

3. Upon information and belief, Defendant DRL Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India. Upon information and belief, DRL Ltd.,

itself and through its subsidiaries and agents, including DRL Inc., manufactures, distributes and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of New Jersey, with its registered office at 107 College Road East, Princeton, NJ 08540. Upon information and belief, DRL Inc. manufactures and/or distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the direct benefit of DRL Ltd.

5. Upon information and belief, DRL Ltd. and DRL Inc. acted collaboratively in the preparation and submission of ANDA No. 208375. Upon information and belief, DRL's preparation and submission of ANDA No. 208375 was done at the direction, under the control, and for the direct benefit of DRL Ltd.

6. Upon information and belief, following any FDA approval of ANDA No. 208375, DRL Ltd., itself and through its subsidiaries and agents, including DRL Inc., will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 208375 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

9. The court has personal jurisdiction over each of the Defendants because, among other things, they have each committed, or aided, abetted, contributed to and/or participated in

the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Cubist, a Delaware corporation, which sells CUBICIN® throughout the United States, including the State of Delaware. This Court also has personal jurisdiction over the Defendants by virtue of, among other things, their systematic and continuous contacts with Delaware as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

10. Upon information and belief, DRL Ltd., itself and through its subsidiaries and agents, including DRL Inc., currently manufactures and distributes for sale dozens of drug products throughout the United States, including in this judicial district.

11. Upon information and belief, DRL Ltd. directs the operations, management and activities of DRL Inc. in the United States.

12. Upon information and belief, DRL Ltd., directly or through DRL Inc., routinely files ANDAs seeking FDA approval to market its drug products in the United States.

13. Upon information and belief, DRL Ltd. and DRL Inc. collaborate in the manufacture, marketing, and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in this judicial district.

14. Upon information and belief, DRL Inc. sells generic drug products in the United States, including in this judicial district, that are manufactured by DRL Ltd.

15. DRL has taken advantage of the jurisdiction of this Court by affirmatively filing counterclaims and requesting entry of judgment in other actions before this Court, including *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 15-cv-306-GMS (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 15-cv-179 (GMS)

(D. Del.); and *Allos Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, No. 14-778-RGA (D. Del.).

16. This Court has personal jurisdiction over DRL Inc. by virtue of, among other things, its systematic and continuous contacts with Delaware.

17. This Court has personal jurisdiction over DRL Ltd. by virtue of, among other things, its systematic and continuous contacts with Delaware.

18. In the alternative, this Court may exercise personal jurisdiction over DRL Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) DRL Ltd. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) DRL Ltd. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over DRL Ltd. satisfies due process.

BACKGROUND

19. CUBICIN® (daptomycin for injection) is an intravenous bactericidal antibiotic approved by the FDA for the treatment of complicated skin and skin structure infections caused by certain Gram-positive microorganisms, such as *Staphylococcus aureus*, including methicillin-resistant strains, also known as MRSA. CUBICIN® is also approved for the treatment of *S. aureus* bloodstream infections (bacteremia), including right-sided infective endocarditis caused by MRSA.

20. Cubist sells CUBICIN® in the United States pursuant to a New Drug Application that has been approved by the FDA.

21. United States Patent No. 6,468,967 ("the '967 patent"), entitled "Methods for Administration of Antibiotics" (Exhibit A hereto), was duly and legally issued on October 22, 2002. The '967 patent, which is owned by Cubist, will expire on September 24, 2019.

22. United States Patent No. 6,852,689 ("the '689 patent"), entitled "Methods for Administration of Antibiotics" (Exhibit B hereto), was duly and legally issued on February 8, 2005. The '689 patent, which is owned by Cubist, will expire on September 24, 2019.

23. United States Patent No. 8,058,238 ("the '238 patent"), entitled "High Purity Lipopeptides" (Exhibit C hereto), was duly and legally issued on November 15, 2011. The '238 patent, which is owned by Cubist, will expire on November 28, 2020.

24. United States Patent No. 8,129,342 ("the '342 patent"), entitled "High Purity Lipopeptides" (Exhibit D hereto), was duly and legally issued on March 6, 2012. The '342 patent, which is owned by Cubist, will expire on November 28, 2020.

25. CUBICIN®, or its use, is covered by one or more claims of the '967, '689, '238, and '342 patents, which have been listed in connection with CUBICIN® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

26. By letter dated December 9, 2015 (the "Notice Letter"), DRL notified Cubist that it had submitted to the FDA ANDA No. 208375 for daptomycin for injection, for intravenous use, a generic version of CUBICIN® ("DRL's ANDA Product").

27. In the Notice Letter, DRL stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '967, '689, '238, and '342 patents and alleged that the '967, '689, '238, and '342 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of DRL's ANDA Product.

28. On December 8, 2014, the United States District Court for the District of Delaware entered an order in *Cubist Pharmaceuticals, Inc. v. Hospira, Inc.*, C.A. No. 12-367-GMS (consolidated), which, in relevant part, held certain claims of the '967, '689, '238, and '342 patents invalid.

29. On November 12, 2015, the United States Court of Appeals for the Federal Circuit issued an opinion in *Cubist Pharmaceuticals, Inc. v. Hospira, Inc.*, Nos. 2015-1197, 2015-1204, and 2015-1259, affirming the District Court's decision.

30. Because Cubist believes the judgment of invalidity is incorrect, on December 14, 2015, Cubist filed a combined petition for panel rehearing and rehearing en banc in the United States Court of Appeals for the Federal Circuit, in which it requested reconsideration of certain issues in the appeal. No mandate in the appeal has issued.

31. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I
Infringement of U.S. Patent No. 6,468,967

32. Plaintiff incorporates each of the preceding paragraphs 1 – 31 as if fully set forth herein.

33. The use of DRL's ANDA Product is covered by one or more claims of the '967 patent.

34. DRL had knowledge of the '967 patent when it submitted its ANDA to the FDA.

35. DRL's submission of ANDA No. 208375 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA Product before the expiration of the '967 patent was an act of infringement of the '967 patent.

36. The commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product would infringe one or more claims of the '967 patent.

37. Upon information and belief, use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '967 patent.

38. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208375.

39. Upon information and belief, DRL will actively induce infringement of the '967 patent when its ANDA is approved, and plan and intends to, and will do so, immediately and imminently upon approval.

40. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '967 patent, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to the infringement of the '967 patent immediately and imminently upon approval of ANDA No. 208375.

41. The foregoing actions by DRL constitute and/or would constitute infringement of the '967 patent, active inducement of infringement of the '967 patent, and/or contribution to the infringement by others of the '967 patent.

42. Upon information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the '967 patent, actively inducing infringement of the '967 patent, and/or contributing to the infringement by others of the '967 patent.

43. Unless DRL is enjoined from infringing the ’967 patent, actively inducing infringement of the ’967 patent, and/or contributing to the infringement by others of the ’967 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT II
Infringement of U.S. Patent No. 6,852,689

44. Plaintiff incorporates each of the preceding paragraphs 1 – 43 as if fully set forth herein.

45. The use of DRL’s ANDA Product is covered by one or more claims of the ’689 patent.

46. DRL had knowledge of the ’689 patent when it submitted its ANDA to the FDA.

47. DRL’s submission of ANDA No. 208375 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL’s ANDA Product before the expiration of the ’689 patent was an act of infringement of the ’689 patent.

48. The commercial manufacture, use, offer for sale, sale and/or importation of DRL’s ANDA Product would infringe one or more claims of the ’689 patent.

49. Upon information and belief, use of DRL’s ANDA Product in accordance with and as directed by DRL’s proposed labeling for that product would infringe one or more claims of the ’689 patent.

50. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208375.

51. Upon information and belief, DRL will actively induce infringement of the ’689 patent when its ANDA is approved, and plans and intends to, and will do so, immediately and imminently upon approval.

52. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '689 patent, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to the infringement of the '689 patent immediately and imminently upon approval of ANDA No. 208375.

53. The foregoing actions by DRL constitute and/or would constitute infringement of the '689 patent, active inducement of infringement of the '689 patent, and/or contribution to the infringement by others of the '689 patent.

54. Upon information and belief, DRL acted without a reasonable basis for believing that it would not be liable for infringing the '689 patent, actively inducing infringement of the '689 patent, and/or contributing to the infringement by others of the '689 patent.

55. Unless DRL is enjoined from infringing the '689 patent, actively inducing infringement of the '689 patent, and/or contributing to the infringement by others of the '689 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT III
Infringement of U.S. Patent No. 8,058,238

56. Plaintiff incorporates each of the preceding paragraphs 1 – 55 as if fully set forth herein.

57. DRL's ANDA Product is covered by one or more claims of the '238 patent.

58. DRL's submission of ANDA No. 208375 for the purpose of the obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA Product before the expiration of the '238 patent was an act of infringement of the '238 patent.

59. The commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product would infringe one or more claims of the '238 patent.

60. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product immediately and imminently upon approval of ANDA No. 208375.

61. The foregoing actions by DRL constitute and/or would constitute infringement of the '238 patent.

62. Unless DRL is enjoined from infringing the '238 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT IV
Infringement of U.S. Patent No. 8,129,342

63. Plaintiff incorporates each of the preceding paragraphs 1 – 62 as if fully set forth herein.

64. DRL's ANDA Product is covered by one or more claims of the '342 patent.

65. DRL's submission of ANDA No. 208375 for the purpose of the obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA Product before the expiration of the '342 patent was an act of infringement of the '342 patent.

66. The commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product would infringe one or more claims of the '342 patent.

67. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product immediately and imminently upon approval of ANDA No. 208375.

68. The foregoing actions by DRL constitute and/or would constitute infringement of the ’342 patent.

69. Unless DRL is enjoined from infringing the ’342 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court grant the following relief:

(a) A judgment that DRL’s submission of ANDA No. 208375 was an act of infringement of the ’967, ’689, ’238, and ’342 patents, and that DRL’s manufacture, use, offer to sell, sale, or importation of DRL’s ANDA Product prior to the expiration of the ’967, ’689, ’238, and ’342 patents, will infringe, actively induce infringement, and/or contribute to the infringement of the ’967, ’689, ’238, and ’342 patents;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of DRL’s ANDA No. 208375, or any product or compound that infringes the ’967, ’689, ’238, and ’342 patents, shall not be earlier than the expiration of the ’967, ’689, ’238 and ’342 patents;

(c) An Order permanently enjoining DRL, and its affiliates and subsidiaries, and each of its officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing DRL’s ANDA Product, or any product or compound that infringes the ’967, ’689, ’238, and ’342 patents, or inducing or contributing to the infringement of the ’967, ’689, ’238, and ’342 patents until after the expiration of the ’967, ’689, ’238, and ’342 patents;

(d) A declaration that this is an exceptional case and an award of attorneys’ fees to plaintiff pursuant to 35 U.S.C. § 285;

(e) Plaintiff’s reasonable costs of suit incurred; and

(f) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff Cubist Pharmaceuticals LLC

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
Emily Whelan
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

January 21, 2016