

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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|----------------------------------|---|----------------|
| CUBIST PHARMACEUTICALS, INC., |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | C.A. No. _____ |
| |) | |
| TEVA PARENTERAL MEDICINES, INC., |) | |
| TEVA PHARMACEUTICALS USA, INC., |) | |
| and TEVA PHARMACEUTICAL |) | |
| INDUSTRIES LTD., |) | |
| |) | |
| Defendants. |) | |

COMPLAINT

Plaintiff Cubist Pharmaceuticals, Inc., 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 defendant Teva Parenteral Medicines, Inc. of Abbreviated New Drug Application (“ANDA”) No. 91-039 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 and 6,852,689, which expire on September 24, 2019, and U.S. Patent No. RE39,071, which expires on June 15, 2016.

PARTIES

2. Plaintiff Cubist Pharmaceuticals, Inc. (“Cubist”) is a corporation 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 Teva Parenteral Medicines, Inc. (“TPM”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 19 Hughes, Irvine, California. Upon information and belief, TPM is a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc. TPM acts as an agent of Teva Pharmaceuticals USA, Inc.

4. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

5. Upon information and belief, Defendant Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petah Tikva, Israel.

6. Upon information and belief, TPM’s preparation and submission of ANDA No. 91-039 was done collaboratively with, and at least in part for the benefit of, Teva USA and Teva Ltd.

7. TPM, Teva USA, and Teva Ltd. are collectively referred to hereafter as “Teva.”

8. Teva manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

9. 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.

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

11. TPM and Teva USA are subject to personal jurisdiction in Delaware because, among other things, they are residents and citizens of the State of Delaware and have submitted themselves to the jurisdiction of courts in Delaware by virtue of their incorporation under Delaware law. Teva Ltd. is also subject to personal jurisdiction in Delaware because, among other things, Teva Ltd. directly and/or through its wholly-owned subsidiaries, manufactures, markets, and sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware.

BACKGROUND

12. 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.

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

14. 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.

15. 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.

16. United States Patent No. RE39,071 (“the RE’071 patent”), entitled “Anhydro-and Isomer-A-21978C Cyclic Peptides” (Exhibit C hereto), was duly and legally issued on April 18, 2006. The RE’071 patent, which is owned by Cubist, will expire on June 15, 2016.

17. CUBICIN[®], or its use, is covered by one or more claims of the ‘967, ‘689 and RE’071 patents, and the ‘967, ‘689 and RE’071 patents have been listed in connection with CUBICIN[®] in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

18. By letter dated February 6, 2009 (the “Notice Letter”), Teva notified Cubist that it had submitted to the FDA ANDA No. 91-039 for Daptomycin for Injection, 500mg/vial, a drug product that is a generic version of CUBICIN[®] (“Teva’s ANDA Product”). The purpose of the submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva’s ANDA Product prior to the expiration of the ‘967, ‘689 and RE’071 patents.

19. In the Notice Letter, Teva also notified Cubist that, as a part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA,

21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '967, '689 and RE'071 patents. Upon information and belief, Teva submitted ANDA No. 91-039 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '967, '689 and RE'071 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Teva's ANDA Product.

20. 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

21. Plaintiff incorporates each of the proceeding paragraphs 1 – 20 as if fully set forth herein.

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

23. Teva had knowledge of the '967 patent when it submitted its ANDA to the FDA.

24. Teva's submission of ANDA No. 91-039 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '967 patent is an act of infringement of the '967 patent.

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

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

27. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-039.

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

29. Upon information and belief, Teva knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '967 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to the infringement of the '967 patent immediately and imminently upon approval of ANDA No. 91-039.

30. The foregoing actions by Teva 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.

31. Upon information and belief, Teva 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.

32. Unless Teva 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

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

34. The use of Teva's ANDA Product is covered by one or more claims of the '689 patent.

35. Teva had knowledge of the '689 patent when it submitted its ANDA to the FDA.

36. Teva's submission of ANDA No. 91-039 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '689 patent is an act of infringement of the '689 patent.

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

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

39. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-039.

40. Upon information and belief, Teva plans and intends to, and 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.

41. Upon information and belief, Teva knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '689 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Teva plans and intends to, and will, contribute to the infringement of the '689 patent immediately and imminently upon approval of ANDA No. 91-039.

42. The foregoing actions by Teva constitute and/or will 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.

43. Upon information and belief, Teva 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.

44. Unless Teva 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. RE39,071

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

46. Teva's ANDA Product and its use are covered by one or more claims of the RE'071 patent.

47. Teva had knowledge of the RE'071 patent when it submitted its ANDA to the FDA.

48. Teva's submission of ANDA No. 91-039 for the purpose of the obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the RE'071 patent is an act of infringement of the RE'071 patent.

49. The commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Product would infringe one or more claims of the RE'071 patent.

50. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product immediately and imminently upon approval of ANDA No. 91-039.

51. The foregoing actions by Teva constitute and/or would constitute infringement of the RE'071 patent.

52. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringing the RE'071 patent.

53. Unless Teva is enjoined from infringing the RE'071 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 Teva's submission of ANDA No. 91-039 was an act of infringement of the '967, '689 and RE'071 patents, and that Teva's making, using, offering to sell, selling, or importing Teva's ANDA Product prior to the expiration of the '967, '689 and RE'071 patents, will infringe, actively induces infringement, and/or contributes to the infringement of the '967, '689 and RE'071 patents;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Teva's ANDA No. 91-039, or any product or compound that infringes the '967, '689 and RE'071 patents, shall be a date that is not earlier than the expiration of the '967, '689 and RE'071 patents;

(c) An Order permanently enjoining Teva, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Teva's ANDA Product, or any product or compound that infringes the '967, '689 and RE'071 patents, or inducing or contributing to the infringement of the '967, '689 and RE'071 patents until after the expiration of the '967, '689 and RE'071 patents;

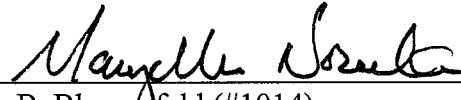
(d) Damages or other monetary relief if Teva engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Teva's ANDA Product, or any product or compound that infringes the '967, '689 and RE'071 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '967, '689 and RE'071 patents;

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

(f) Plaintiff's reasonable costs of suit incurred; and

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

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