IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 09-189-GMS
	)	
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., And TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
Defendants.	)	

ANSWER OF DEFENDANT
TEVA PHARMACEUTICAL INDUSTRIES LTD.

Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") hereby answers the Complaint filed by plaintiff Cubist Pharmaceuticals, Inc. ("Cubist"), as follows:

1. Teva Ltd. admits that the Complaint purports to state an action under the patent laws of the United States, Title 35, United States Code. Teva Ltd. further admits that Teva Parenteral Medicines, Inc. ("TPM") filed an Abbreviated New Drug Application No. 91-039 ("ANDA No. 91-039") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell Daptomycin for Injection, 500 mg /vial ("the TPM ANDA Product"), a generic version of CUBICIN®, prior to the expiration of U.S. Patent Nos. 6,468,967 ("the '967 patent") and 6,852,689 ("the '689 patent"), both of which are listed in the FDA Orange Book as expiring on September 24, 2019, and U.S. Patent No. RE39,071 ("the RE'071 patent"), which is listed in the FDA Orange Book as expiring on June 15, 2016. Teva Ltd. denies the remaining allegations in paragraph 1 of the Complaint.

PARTIES

2. On information and belief, Teva Ltd. admits the allegations in paragraph 2 of the Complaint.

3. Because paragraph 3 makes allegations directed only to TPM and Teva USA, no response is required from Teva Ltd.

4. Teva Ltd. admits that Teva USA is a Delaware corporation with it principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Teva Ltd. further states that Teva USA is indirectly a wholly-owned subsidiary of Teva Ltd. Teva Ltd. denies the remaining allegations in paragraph 4 of the Complaint.

5. Teva Ltd. admits that it is an Israel corporation with its principal place of business at 5 Basel Street, Petah Tikva, Israel.

6. Teva Ltd. admits that TPM is indirectly a wholly owned subsidiary of Teva USA, which is indirectly a wholly owned subsidiary of Teva Ltd. Teva Ltd. otherwise denies the allegations of paragraph 6 of the Complaint. To the extent that paragraph 6 makes allegations directed to TPM and Teva USA., no response is required from Teva Ltd.

7. Teva Ltd. understands that Plaintiff is using the term "Teva" in its Complaint to refer to TPM, Teva USA and Teva Ltd. collectively, but denies that it is appropriate to do so. Teva Ltd. will respond to such allegations as if they were directed to it separately.

8. Teva Ltd. denies the allegations of paragraph 8 directed to Teva Ltd. To the extent that paragraph 8 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

JURISDICTION AND VENUE

9. Teva Ltd. admits that subject matter jurisdiction in this Court is proper as to TPM pursuant to 28 U.S.C. §§ 1331 and 1338(a). Teva Ltd. denies the remaining allegations in paragraph 9 of the Complaint.

10. Teva Ltd. denies the allegations of paragraph 10 directed to Teva Ltd. To the extent that paragraph 10 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

11. Teva Ltd. denies the allegations of paragraph 11 directed to Teva Ltd. To the extent that paragraph 11 makes allegations directed to TPM and Teva USA., no response is required from Teva Ltd.

BACKGROUND

12. Upon information and belief, Teva Ltd. admits that CUBICIN® is indicated for certain complicated skin and skin structure infections, including ones caused by susceptible isolates of certain Gram-positive microorganisms including *Staphylococcus aureus*, including methicillin-resistant isolates. Upon information and belief, CUBICIN® is also indicated for the treatment of *S. aureus* bloodstream infections (bacteremia), including right-sided infective endocarditis caused by methicillin-susceptible and methicillin-resistant isolates. Teva Ltd. denies the remaining allegations in paragraph 12 of the Complaint.

13. Upon information and belief, Teva Ltd. admits the allegations in paragraph 13 of the Complaint.

14. Upon information and belief, Teva Ltd. admits that United States Patent No. 6,468,967 ("the '967 patent") states on its face that it is entitled "Methods for Administration of Antibiotics" and further states that it was issued on October 22, 2002 and is assigned on its

face to Cubist. Upon information and belief, Teva USA admits that the '967 patent is listed in the FDA Orange Book as expiring on September 24, 2019. Teva Ltd. further admits that what appears to be a true and correct copy of the '967 patent was attached to the Complaint as Exhibit A. Teva Ltd. denies the remaining allegations of paragraph 14.

15. Upon information and belief, Teva Ltd. admits that United States Patent No. 6,852,689 ("the '689 patent") states on its face that it is entitled "Methods for Administration of Antibiotics" and further states that it was issued on February 8, 2002 and is assigned on its face to Cubist. Upon information and belief, Teva Ltd. admits that the '689 patent is listed in the FDA Orange Book as expiring on September 24, 2019. Teva Ltd. further admits that what appears to be a true and correct copy of the '689 patent was attached to the Complaint as Exhibit B. Teva Ltd. denies the remaining allegations of paragraph 15.

16. Upon information and belief, Teva Ltd. admits that United States Patent No. RE39,071 ("the RE'071 patent") states on its face that it is entitled "Anhydro-and Isomer-A-21978C Cyclic Peptides" and further states that it was issued on April 18, 2006 and that an assignment was recorded in the PTO on April 23, 2007 assigning the RE'071 patent to Cubist. Upon information and belief, Teva Ltd. admits that the RE'071 patent is listed in the FDA Orange Book as expiring on September 24, 2019. Teva Ltd. denies that the copy of the RE'071 patent attached to the Complaint as Exhibit C is a true and accurate copy of the RE'071 patent as corrected. Teva Ltd. denies the remaining allegations of paragraph 16.

17. Teva Ltd. admits that the '967, '689 and RE'071 patents have been listed in the FDA Orange Book in connection with CUBICIN®. Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 of the Complaint and therefore denies the same.

18. Teva Ltd. denies the allegations of paragraph 18 of the Complaint with respect to Teva Ltd. To the extent that paragraph 18 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

19. Teva Ltd. denies the allegations of paragraph 19 of the Complaint with respect to Teva Ltd. To the extent that paragraph 19 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

20. Teva Ltd. admits the allegations of paragraph 20.

COUNT I
U.S. PATENT NO. 6,468,967

21. In response to the allegations contained in paragraph 21 of the Complaint, Teva Ltd. realleges its responses to paragraphs 1-20 as if fully set forth herein.

22. Teva Ltd. denies as to Teva Ltd. that all future uses of the TPM ANDA Product in accord with its proposed labeling would necessarily be covered by at least one claim of the '967 patent, given that the claims have not yet been construed, and further denies that any claims that might cover such future uses are valid and enforceable. To the extent that paragraph 22 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

23. Teva Ltd. admits that it had knowledge of the '967 patent when TPM submitted the TPM ANDA to the FDA. To the extent that paragraph 23 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

24. Teva Ltd. denies the allegations of paragraph 24 of the Complaint with respect to Teva Ltd. To the extent that paragraph 24 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

25. Teva Ltd. denies the allegations of paragraph 25 of the Complaint with respect to Teva Ltd. To the extent that paragraph 25 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

26. Teva Ltd. denies that the use of the TPM ANDA Product in accordance with and as directed by TPM's proposed labeling would infringe any valid and enforceable claim of the '967 patent. To the extent that paragraph 26 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

27. Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 27 with respect to Teva Ltd. and therefore denies the same. To the extent that paragraph 27 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

28. Teva Ltd. denies that it plans and intends to, and will, actively induce infringement of any valid and enforceable claim of the '967 patent and, because Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the allegation that it will take such action immediately and imminently upon approval of ANDA No. 91-039, Teva Ltd. further denies the same. To the extent that paragraph 28 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

29. Teva USA denies knowledge that the TPM ANDA Product and its proposed labeling are especially made or adapted for use in infringing any valid and enforceable claim of the '967 patent and accordingly further denies that the TPM ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Teva USA further denies that Teva USA plans and intends to, and will, contribute to infringement of any valid and enforceable claim of the '689 patent and, because Teva USA is without information or knowledge sufficient

to form a belief as to the truth of the allegation that it will take such action immediately and imminently upon approval of ANDA No. 91-039, Teva USA further denies the same. To the extent that paragraph 29 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

30. Teva Ltd. denies with respect to Teva Ltd. To the extent that paragraph 30 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

31. Teva Ltd. denies with respect to Teva Ltd. To the extent that paragraph 31 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

32. Teva Ltd. denies the allegations in paragraph 32 of the Complaint.

COUNT II
U.S. PATENT NO. 6,852,689

33. In response to the allegations contained in paragraph 33 of the Complaint, Teva Ltd. realleges its responses to paragraphs 1-32 as if fully set forth herein.

34. Teva Ltd. denies as to Teva Ltd. that all future uses of the TPM ANDA Product in accord with its proposed labeling would necessarily be covered by at least one claim of the '689 patent, given that the claims have not yet been construed, and further denies that any claims that might cover such future uses are valid and enforceable. To the extent that paragraph 34 makes allegations directed to TPM and Teva USA., no response is required from Teva Ltd.

35. Teva Ltd. admits that it had knowledge of the '689 patent when TPM submitted the TPM ANDA to the FDA. To the extent that paragraph 35 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

36. Teva Ltd. denies the allegations of paragraph 36 of the Complaint with respect to Teva Ltd.. To the extent that paragraph 36 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

37. Teva Ltd. denies the allegations of paragraph 37 of the Complaint with respect to Teva Ltd. To the extent that paragraph 37 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

38. Teva Ltd. denies that the use of the TPM ANDA Product in accordance with and as directed by TPM's proposed labeling would infringe any valid and enforceable claim of the '689 patent. To the extent that paragraph 38 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

39. Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 39 with respect to Teva Ltd. and therefore denies the same. To the extent that paragraph 39 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

40. Teva Ltd. denies that it plans and intends to, and will, actively induce infringement of any valid and enforceable claim of the '689 patent and, because Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the allegation that it will take such action immediately and imminently upon approval of ANDA No. 91-039, Teva Ltd. further denies the same. To the extent that paragraph 40 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

41. Teva Ltd. denies knowledge that the TPM ANDA Product and its proposed labeling are especially made or adapted for use in infringing any valid and enforceable claim of the '689 patent. Teva Ltd. further denies that the TPM ANDA Product and its proposed labeling are not suitable for substantial noninfringing use with respect to one or more of the claims of the '689 patent. Teva Ltd. further denies that Teva Ltd. plans and intends to, and will, contribute to infringement of any valid and enforceable claim of the '689 patent and, because

Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the allegation that it will take such action immediately and imminently upon approval of ANDA No. 91-039, Teva Ltd. further denies the same. To the extent that paragraph 41 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

42. Teva Ltd. denies with respect to Teva Ltd. To the extent that paragraph 42 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

43. Teva Ltd. denies with respect to Teva Ltd. To the extent that paragraph 43 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

44. Teva Ltd. denies the allegations in paragraph 44 of the Complaint.

COUNT III
U.S. PATENT NO. RE 39,071

45. In response to the allegations contained in paragraph 46 of the Complaint, Teva Ltd. realleges its responses to paragraphs 1-44 as if fully set forth herein.

46. Teva Ltd. denies as to Teva Ltd. that all TPM ANDA Products and all future uses of the TPM ANDA Product in accord with its proposed labeling would necessarily be covered by at least one claim of the RE'071 patent, given that the claims have not yet been construed, and further denies that any claims that might cover such future product and future uses are valid and enforceable. To the extent that paragraph 46 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

47. Teva Ltd. admits that it had knowledge of the '689 patent when TPM submitted ANDA No. 91-039 to the FDA. To the extent that paragraph 47 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

48. Teva Ltd. denies the allegations of paragraph 48 of the Complaint with respect to Teva Ltd. To the extent that paragraph 48 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

49. Teva Ltd. denies the allegations of paragraph 49 of the Complaint with respect to Teva Ltd. To the extent that paragraph 49 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

50. Teva Ltd. is without information or knowledge sufficient to form a belief as to the truth of the allegations of paragraph 50 with respect to Teva Ltd. and therefore denies the same. To the extent that paragraph 50 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

51. Teva Ltd. denies with respect to Teva Ltd. To the extent that paragraph 51 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

52. Teva Ltd. denies with respect to Teva Ltd. To the extent that paragraph 52 makes allegations directed to TPM and Teva USA, no response is required from Teva Ltd.

53. Teva Ltd. denies the allegations in paragraph 53 of the Complaint.

Teva Ltd. further answers that any allegations in the Complaint requiring a response from Teva Ltd. not specifically admitted are denied.

ANSWER TO PRAYER FOR RELIEF

Teva Ltd. denies that Plaintiff is entitled to the judgment and relief prayed for in paragraphs (a) through (g) of the Complaint.

FIRST DEFENSE

The manufacture, use, offer for sale, sale or importation of the TPM ANDA Product that is the subject of ANDA No. 91-039 does not and will not infringe, either literally or under the doctrine of equivalents, one or more claims of each of the '967, '689 and RE'071 patents.

SECOND DEFENSE

The claims of each of the '967, '689 and RE'071 patents are either (1) not infringed, either literally or under the doctrine of equivalents, by the TPM ANDA Product or its use in accord with the labeled instructions and/or (2) are invalid under one or more of 35 U.S.C. § 102, § 103, § 112 and/or the doctrine of obviousness-type double patenting over U.S. Patent No. 4,537,717.

THIRD DEFENSE

The claims of the RE'071 patent are also invalid for failure to meet the requirements of 35 U.S.C. § 251 and the certificate of correction issued for the RE'071 patent is invalid for failure to meet the requirements of 35 U.S.C. § 255.

FOURTH DEFENSE

The Complaint fails to allege that Teva Ltd. has taken any action constituting an act of infringement under the patent laws of the United States of America and therefore fails to state a cause of action against Teva Ltd.

FIFTH DEFENSE

The Complaint fails to state a cause of action against Teva Ltd. for a declaratory judgment under 28 U.S.C. § 2201.

RELIEF REQUESTED

Wherefore, Teva Ltd. respectfully requests that this Court:

A. Enter judgment that TPM's proposed Daptomycin for Injection (500 mg/vial) product and its use in accord with the labeled instructions do not infringe any valid and enforceable claim of U.S. Patent Nos. 6,468,967, 6,852,689 and RE39,071;

B. Enter an order dismissing the Complaint, with prejudice, and denying Cubist the relief requested in its Complaint and any relief whatsoever;

C. Declare this case exceptional and award Teva Ltd. its reasonable attorney's fees and costs incurred in this litigation; and

D. Grant such other and further relief as the nature of the case may require and as the Court may deem just, proper and equitable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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Dated: May 6, 2009
914965/34185

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on May 6, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on May 6, 2009, the attached document was Electronically Mailed to the following person(s):

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