IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC., and SCHERING CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Millennium Pharmaceuticals, Inc. and Schering Corporation, by their attorneys, hereby allege 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. 90-854 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of INTEGRILIN® prior to the expiration of U.S. Patent No. 5,747,447 and U.S. Patent No. 5,968,902.

PARTIES

2. Plaintiff Millennium Pharmaceuticals, Inc. ("Millennium") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 40 Landsdowne Street, Cambridge, Massachusetts.

3. Plaintiff Schering Corporation ("Schering") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey.

4. 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. Upon information and belief, Teva Ltd. is in the business of developing, manufacturing, marketing, and selling generic drugs. Upon information and belief, Teva Ltd. established Defendant Teva Pharmaceuticals USA, Inc. and Defendant Teva Parenteral Medicines, Inc., for the purpose of distributing, marketing, and selling its generic drug products throughout the United States.

5. 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 Ltd. and is controlled and/or dominated by Teva Ltd. Upon information and belief, Teva USA, itself and through its wholly-owned subsidiary and agent Defendant Teva Parenteral Medicines, Inc., manufactures and/or distributes numerous generic drugs for sale and use throughout the United States at the direction, under the control, and for the direct benefit of Teva Ltd.

6. 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. Upon information and belief, TPM is controlled and/or dominated by Teva Ltd. and Teva USA. Upon information and belief,

TPM is the United States agent for Teva Ltd. and Teva USA for purposes including, but not limited to, making regulatory submissions to the FDA relating to generic injectable products. Upon information and belief, TPM also is the United States marketing and sales agent for Teva Ltd. and Teva USA relating to generic injectable products, wherein, following FDA approval of an ANDA, TPM manufacturers and supplies the approved generic injectable drug product to Teva USA, which then markets and sells the product throughout the United States at the direction, under the control, and for the direct benefit of Teva Ltd.

7. Upon information and belief, TPM's preparation and submission of ANDA No. 90-854 was done at the direction, under the control, and for the direct benefit of Teva USA and Teva Ltd. Upon information and belief, Teva Ltd. and Teva USA directed TPM to submit ANDA No. 90-854, in whole or in part, to shield Teva Ltd. and Teva USA from liability for patent infringement based upon that act.

8. Teva USA maintains a website at URL www.tevausa.com at which it represents that it is dedicated to market generic injectables in the United States. Specifically, Teva USA's website states: "Teva markets over 125 injectable products . . . ." Upon information and belief, based in part on representations on their website, Teva USA and TPM hold themselves out as a unitary entity by representing to the public that the activities of TPM are directed, controlled, and carried out by Teva USA.

9. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 90-854, Teva Ltd. itself and through its wholly-owned subsidiary Teva USA will sell its generic product throughout the United States.

10. TPM, Teva USA, and Teva Ltd. are collectively referred to hereafter as "Teva."

11. 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

12. 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.

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

14. 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. In addition, this Court has personal jurisdiction over each of the Defendants because each has consented to jurisdiction in this district in previous litigations by affirmatively filing claims.

BACKGROUND

15. INTEGRILIN® is an antithrombotic agent that reversibly inhibits platelet aggregation by preventing binding of fibrinogen to the glycoprotein IIb-IIIa receptor.

INTEGRILIN® is indicated for the treatment of patients with acute coronary syndrome, including patients who are to be managed medically and those undergoing percutaneous coronary intervention, including intracoronary stenting.

16. Schering sells INTEGRILIN® in the United States pursuant to a New Drug Application that has been approved by the FDA.

17. United States Patent No. 5,747,447 ("the '447 patent"), entitled "Stable Polypeptide Composition" (Exhibit A hereto), was duly and legally issued on May 5, 1998. The '447 patent is owned by Millennium and exclusively licensed to Schering.

18. United States Patent No. 5,968,902 ("the '902 patent"), entitled "Platelet Aggregation Inhibitors" (Exhibit B hereto), was duly and legally issued on October 19, 1999. The '902 patent is owned by Millennium and exclusively licensed to Schering.

19. INTEGRILIN® and the use of INTEGRILIN® is covered by one or more claims of the '447 and '902 patents and the '447 and '902 patents have been listed in connection with INTEGRILIN® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

20. By letter dated February 13, 2009 (the "Notice Letter"), Teva notified Millennium and Schering that it had submitted to the FDA ANDA No. 90-854, for Teva's Eptifibatide, Injection, 2 mg/mL, 10 mL Vial and 100 mL Vial, a drug product that is a generic version of INTEGRILIN® ("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 '447 and '902 patents.

21. In the Notice Letter, Teva also notified Millennium and Schering 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 '447 and '902 patents. Upon information and belief, Teva submitted ANDA No. 90-854 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '447 and '902 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Teva's ANDA Product.

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

COUNT I:
INFRINGEMENT OF U.S. PATENT NO. 5,747,447

23. Plaintiffs incorporate each of the proceeding paragraphs 1 – 22 as if fully set forth herein.

24. The use of Teva's ANDA Product is covered by one or more claims of the '447 patent.

25. Teva had knowledge of the '447 patent when it submitted its ANDA.

26. Teva's filing of the ANDA No. 90-854 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 '447 patent is an act of infringement of the '447 patent.

27. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product would infringe one or more claims of the '447 patent.

28. 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 '447 patent.

29. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-854.

30. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '447 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

31. Upon information and belief, Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '447 patent, and that Teva's 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 '447 patent immediately and imminently upon approval of ANDA No. 90-854.

32. The foregoing actions by Teva constitute and/or will constitute infringement of the '447 patent, active inducement of infringement of the '447 patent, and/or contribution to the infringement by others of the '447 patent.

33. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringing the '447 patent, actively inducing infringement of the '447 patent, and/or contributing to the infringement by others of the '447 patent.

34. Unless Teva is enjoined from infringing the '447 patent, actively inducing infringement of the '447 patent, and/or contributing to the infringement by others of the '447

patent, Millennium and Schering will suffer irreparable injury. Millennium and Schering have no adequate remedy at law.

COUNT II:
INFRINGEMENT OF U.S. PATENT NO. 5,968,902

35. Plaintiffs incorporate each of the proceeding paragraphs 1 – 34 as if fully set forth herein.

36. The use of Teva's ANDA Product is covered by one or more claims of the '902 patent.

37. Teva had knowledge of the '902 patent when it submitted its ANDA.

38. Teva's filing of the ANDA No. 90-854 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 '902 patent is an act of infringement of the '902 patent.

39. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product would infringe one or more claims of the '902 patent.

40. 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 '902 patent.

41. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-854.

42. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the '902 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

43. Upon information and belief, Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '902 patent, and that Teva's 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 '902 patent immediately and imminently upon approval of ANDA No. 90-854.

44. The foregoing actions by Teva constitute and/or will constitute infringement of the '902 patent, active inducement of infringement of the '902 patent, and/or contribution to the infringement by others of the '902 patent.

45. Upon information and belief, Teva acted without a reasonable basis for believing that it would not be liable for infringing the '902 patent, actively inducing infringement of the '902 patent, and/or contributing to the infringement by others of the '902 patent.

46. Unless Teva is enjoined from infringing the '902 patent, actively inducing infringement of the '902 patent, and/or contributing to the infringement by others of the '902 patent, Millennium and Schering will suffer irreparable injury. Millennium and Schering have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

(a) A judgment that the '447 and '902 patents are infringed by Teva's ANDA Product, that Teva's submission of ANDA No. 90-854 is an act of infringement of the '447 and

'902 patents, and that Teva's making, using, offering to sell, selling, marketing, distributing, or importing Teva's ANDA Product, or any product or compound that infringes the '447 and '902 patents, prior to the expiration of the '447 and '902 patents, will infringe, actively induces infringement, and contributes to the infringement of the '447 and '902 patents.

(b) A declaration that the '447 and '902 patents are valid and enforceable;

(c) 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. 90-854, or any product or compound that infringes the '447 and '902 patents, shall be a date which is not earlier than the expiration of the '447 and '902 patents;

(d) 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 '447 and '902 patents, or inducing or contributing to the infringement of the '447 and '902 patents until after the expiration of the '447 and '902 patents;

(e) 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 '447 and '902 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '447 and '902 patents.

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

(g) Plaintiffs' reasonable costs of suit incurred; and

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

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