IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

ABBOTT LABORATORIES, an Illinois Corporation, Plaintiff, v. MATRIX LABORATORIES INC. MATRIX LABORATORIES LTD. MYLAN INC. Defendants.	)	Civil Action No. FILED: MARCH 13, 2009 09CV1586 JUDGE DOW MAGISTRATE JUDGE COLE CH

COMPLAINT

Plaintiff Abbott Laboratories ("Abbott"), by way of Complaint against Matrix Laboratories Inc., Matrix Laboratories Limited, and Mylan Inc. (collectively "Defendants"), states as follows:

THE PARTIES

1. Plaintiff Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of Illinois with its corporate headquarters at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Defendant Matrix Laboratories Inc. ("Matrix Inc.") is a corporation organized and existing under the laws of Delaware, having its principal place of business located at 76 South Orange Ave., Suite 301, South Orange, NJ 07079. Matrix Inc. is a wholly-owned subsidiary of, and U.S. agent for, Defendant Matrix Laboratories Limited ("Matrix Ltd.").

3. Matrix Ltd. is a corporation organized under the laws of India, having principal place of business located at 1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad, 500 003, India.

4. Defendant Mylan Inc. (formerly known as Mylan Laboratories Inc.) is a corporation organized under the laws of the Commonwealth of Pennsylvania, with a principal place of business located at 1500 Corporate Drive, Canonsburg, PA 15317. Mylan Inc., directly or through its wholly owned subsidiary (Mylan Pharmaceuticals Inc.), is in the business of manufacturing, marketing and selling generic pharmaceutical drugs for U.S. consumers. Defendant Mylan Inc. is the majority owner of, and has a controlling interest in, Matrix Ltd.

5. On information and belief, the acts of Matrix Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Matrix Ltd. and/or Mylan Inc.

6. On information and belief, the acts of Matrix Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Matrix Inc. and/or Mylan Inc.

7. On information and belief, the acts of Mylan Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Matrix Inc. and/or Matrix Ltd.

NATURE OF THE ACTION

8. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 ("the '359 patent") and United States Patent Number 7,364,752 B1 ("the '752 patent"), arising under the United States Patent Laws, Title 35, United States Code, §100, *et seq.*,

and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 91-202, which Mylan Inc., Matrix Ltd., and Matrix Inc. filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of Abbott's successful Kaletra® tablets that are sold in the United States.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over each of the Defendants.

11. Matrix Ltd. formulates, develops, manufactures, and sells active pharmaceutical ingredients (API), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Matrix's products"). Matrix Ltd. routinely files ANDAs and seeks FDA approval to market Matrix's products in the United States. Most of Matrix Ltd.'s manufacturing facilities are FDA-approved and it focuses its marketing efforts on regulated markets such as the U.S.

12. On information and belief, Matrix Ltd., either directly or through one or more of its wholly owned subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of Matrix's products in this judicial district. On information and belief, Matrix Ltd. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

13. Matrix Inc., a wholly owned subsidiary of Matrix Ltd., directly and/or through Matrix Ltd. and/or Mylan Inc., seeks FDA approval for, markets and/or sells generic drugs throughout the United States, including Illinois and this judicial district. On information and

belief, a substantial volume of pharmaceutical products for which Matrix Inc. has sought FDA approval for are marketed or sold in this judicial district. On information and belief, Matrix Inc. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived substantial revenue.

14. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Matrix Inc.'s ANDA No. 91-202, which is the subject of this lawsuit. On information and belief, Matrix Inc.'s actions relating to ANDA No. 91-202 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and at least in part for the benefit of, its parent companies Matrix Ltd. and/or Mylan Inc.

15. Mylan Inc. is in the business of formulating, developing, manufacturing, and selling generic drugs. Mylan Inc.'s U.S. product portfolio includes approximately 180 products. Mylan Inc., either directly or through one or more of its wholly owned subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in this judicial district. Mylan Inc. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived substantial revenue.

16. Mylan Pharmaceuticals Inc., a wholly owned subsidiary of Mylan Inc., currently maintains a drug distributor license issued by the State of Illinois, for the purpose of, *inter alia,* distributing Mylan Inc.'s and/or Matrix Ltd.'s products in Illinois, and in this judicial district. Mylan Inc., either directly or through one or more of its subsidiaries, owns and maintains a facility in this judicial district.

17. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. operate as a an integrated business ultimately controlled by Mylan Inc. For example, Mylan Inc.'s website,

http://www.mylan.com/our_businesses/matrix.aspx lists "Matrix" as one of "Our Businesses." Based on Mylan Inc.'s 10-Q SEC form for the period ending June 30, 2008 for the six months ended June 30, 2008, the Matrix division of Mylan Inc. reported total revenues of $222.3 million.

18. On information and belief, Matrix Inc., Matrix Ltd. and/or Mylan Inc. have on more than one occasion collaborated to develop, seek FDA approval for, manufacture, import, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) in the United States, and Illinois, including this judicial district.

19. On information and belief, Matrix Inc., Matrix Ltd., and Mylan Inc. acted in concert to seek approval from the FDA to market generic copies of Abbott's Kaletra® tablets that are the subject of ANDA No. 91-202 throughout the United States and in this judicial district.

20. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided or 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 Abbott, an Illinois corporation residing in this judicial district.

21. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their marketing and sales activities in this judicial district, including but not limited to the substantial, continuous and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

BACKGROUND

23. Abbott is the holder of approved New Drug Application ("NDA") No. 21-906 for lopinavir/ritonavir tablets, which Abbott markets and sells under the trademark Kaletra®. Abbott manufactures and sells various dosage strengths of Kaletra® tablets in the United States under NDA No. 21-906.

24. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file with the FDA ANDA No. 91-202 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market two dosage strengths of lopinavir/ritonavir tablets (collectively "Matrix's generic lopinavir/ritonavir tablets"), which are generic copies of Abbott's Kaletra® tablets.

25. ANDA No. 91-202 seeks FDA approval of a pharmaceutical composition comprising ritonavir and lopinavir in 100 mg/25 mg and 200 mg/50 mg dosage strengths.

26. On January 30, 2009, Abbott received a letter on behalf of Matrix Inc., dated January 29, 2009, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 91-202 ("Matrix's Notice letter") pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Matrix's Notice Letter notified Abbott that Matrix Inc. had filed ANDA No. 91-202, seeking approval to market Matrix's generic lopinavir/ritonavir tablets.

THE PATENTS-IN-SUIT

27. The '359 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on December 12, 2006. Abbott is the owner by assignment of the '359 patent and has the right to sue for infringement thereof. A true and correct copy of the '359 patent is attached as Exhibit A.

28. The '752 patent was duly and legally issued by the PTO on April 29, 2008. Abbott is the owner by assignment of the '752 patent and has the right to sue for infringement thereof. A true and correct copy of the '752 patent is attached as Exhibit B.

FIRST COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 7,148,359 B2

29. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file ANDA No. 91-202 in order to obtain approval to market Matrix's generic lopinavir/ritonavir tablets in the United States before the expiration of the '359 patent. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 patent are purportedly invalid, unenforceable, or not infringed.

30. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial marketing of Matrix's generic lopinavir/ritonavir tablets before the expiration date of the '359 patent constitutes infringement of one or more claims of the '359 patent, either literally or under the doctrine of equivalents.

31. Upon FDA approval of ANDA No. 91-202, Mylan Inc., Matrix Ltd., and Matrix Inc. will infringe one or more claims of the '359 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Matrix's generic lopinavir/ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity.

32. The offering to sell, sale, and/or importation of Matrix's generic lopinavir/ritonavir tablets would actively induce infringement of at least one of the claims of the '359 patent, either literally or under the doctrine of equivalents.

33. Abbott will be irreparably harmed if Mylan Inc., Matrix Ltd., and Matrix Inc. are not enjoined from infringing or actively inducing infringement of at least one claim of the '359 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 7,364,752 B1

34. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file ANDA No. 91-202 in order to obtain approval to market Matrix's generic lopinavir/ritonavir tablets in the United States before the expiration of the '752 patent. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 patent are purportedly invalid, unenforceable, or not infringed.

35. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial marketing of Matrix's generic lopinavir/ritonavir tablets before the expiration date of the '752 patent constitutes infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

36. Upon FDA approval of ANDA No. 91-202, Mylan Inc., Matrix Ltd., and Matrix Inc. will infringe one or more claims of the '752 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Matrix's generic

lopinavir/ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

37. On information and belief, Matrix Inc., Matrix Ltd., and/or Mylan Inc. know and intend that physicians will prescribe and patients will take Matrix's generic lopinavir/ritonavir tablets for which approval is sought in ANDA No. 91-202 to treat HIV infection, and therefore will infringe at least one claim in the '752 patent.

38. On information and belief, Mylan Inc., Matrix Ltd., and Matrix Inc. had knowledge of the '752 patent and, by their promotional activities and package insert for Matrix's generic lopinavir/ritonavir tablets, know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

39. The offering to sell, sale, and/or importation of Matrix's generic lopinavir/ritonavir tablets would actively induce infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

40. Abbott will be irreparably harmed if Mylan Inc., Matrix Ltd., and Matrix Inc. are not enjoined from infringing or actively inducing or contributing to infringement of at least one claim of the '752 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

THIRD COUNT FOR INFRINGEMENT
UNITED STATES PATENT NOs. 7,148,359 B2 AND 7,364,752 B1

41. On information and belief, Mylan Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA

No. 91-202 to the FDA. On information and belief, Mylan Inc. was aware of the '359 and '752 patents when it engaged in these knowing and purposeful activities referred to above.

42. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Mylan Inc. induced the infringement of the '359 and '752 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 91-202. The filing of the ANDA by Mylan Inc., Matrix Ltd., and Matrix Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Mylan Inc.'s active and knowing aiding and abetting Matrix Ltd. and Matrix Inc. in the filing of ANDA No. 91-202 constitutes induced infringement.

43. Abbott will be substantially and irreparably harmed by Mylan Inc.'s infringing activities unless those activities are enjoined by this Court. Abbott has no adequate remedy at law.

FOURTH COUNT FOR INFRINGEMENT
UNITED STATES PATENT NOs. 7,148,359 B2 AND 7,364,752 B1

44. On information and belief, Matrix Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 91-202 to the FDA. On information and belief, Matrix Ltd. was aware of the '359 and '752 patents when it engaged in these knowing and purposeful activities referred to above.

45. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Matrix Ltd. induced the infringement of the '359 and '752 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 91-202. The filing of the ANDA by Mylan Inc., Matrix Ltd., and Matrix Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Matrix Ltd.'s active and knowing aiding and abetting Mylan Inc. and Matrix Inc. in the filing of ANDA No. 91-202 constitutes induced infringement.

46. Abbott will be substantially and irreparably harmed by Matrix Inc.'s infringing activities unless those activities are enjoined by this Court. Abbott has no adequate remedy at law.

FIFTH COUNT FOR INFRINGEMENT
UNITED STATES PATENT NOs. 7,148,359 B2 AND 7,364,752 B1

47. Matrix Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 91-202 to the FDA. Matrix Inc. was aware of the '359 and '752 patents when it engaged in these knowing and purposeful activities referred to above.

48. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Matrix Inc. induced the infringement of the '359 and '752 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 91-202. The filing of the ANDA by Mylan Inc., Matrix Ltd., and Matrix Inc. constitutes direct infringement under 35 U.S.C. § 271(e). Matrix Inc.'s active and knowing aiding and abetting Matrix Ltd. and Mylan Inc. in the filing of ANDA No. 91-202 constitutes induced infringement.

49. Abbott will be substantially and irreparably harmed by Matrix Inc.'s infringing activities unless those activities are enjoined by this Court. Abbott has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Abbott respectfully requests that this Court enter judgment in its favor as follows:

1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for

sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '359 patent was an act of infringement of the '359 patent;

2) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Matrix Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '359 patent was an act of induced infringement of the '359 patent;

3) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Matrix Ltd.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '359 patent was an act of induced infringement of the '359 patent;

4) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Mylan Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '359 patent was an act of induced infringement of the '359 patent;

5) declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets would constitute infringement of the '359 patent;

6) declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for

sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '752 patent was an act of infringement of the '752 patent;

7) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Matrix Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '752 patent was an act of induced infringement of the '752 patent;

8) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Matrix Ltd.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '752 patent was an act of induced infringement of the '752 patent;

9) declaring that, under 35 U.S.C. §§ 271(e)(2)(A) and 271(b), Mylan Inc.'s active and knowing aiding and abetting of the submission to the FDA of ANDA No. 91-202 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets before the expiration of the '752 patent was an act of induced infringement of the '752 patent;

10) declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Matrix's generic lopinavir/ritonavir tablets would constitute infringement of the '752 patent;

11) ordering that the effective date of any FDA approval of Defendants' generic lopinavir/ritonavir tablets shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

12) ordering that the effective date of any FDA approval of Defendants' generic lopinavir/ritonavir tablets shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

13) enjoining Defendants and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Matrix's generic lopinavir/ritonavir tablets within the United States or importing into the United States Matrix's generic lopinavir/ritonavir tablets, until the expiration of the '359 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

14) enjoining Defendants and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Matrix's generic lopinavir/ritonavir tablets within the United States or importing into the United States Matrix's generic lopinavir/ritonavir tablets, until the expiration of the '752 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

15) enjoining Defendants and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining approval of ANDA No. 91-202 until the expiration of the '359 patent, and any additional periods of exclusivity;

16) enjoining Defendants and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining approval of ANDA No. 91-202 until the expiration of the '752 patent, and any additional periods of exclusivity;

17) declaring this to be an exceptional case and awarding Abbott its attorney fees under 35 U.S.C. § 285;

18) awarding Abbott its costs and expenses in this action; and

19) awarding Abbott any further and additional relief as this Court deems just and proper.

Dated: March 13, 2009

ABBOTT LABORATORIES

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