IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES,	)	
Plaintiff,	)	
v.	)	
	)	C.A. No. _____
ROXANE LABORATORIES, INC.	)	
Defendant.	)	

COMPLAINT

Plaintiff Abbott Laboratories, by way of Complaint against Roxane Laboratories, Inc., 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. Abbott is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Defendant Roxane Laboratories, Inc. ("Roxane") is a corporation organized and existing under the laws of Nevada, having its principal place of business located at 1809 Wilson Road, Columbus, Ohio 43216.

NATURE OF THE ACTION

3. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 ("the '359 patent"), United States Patent Number 7,364,752 B1 ("the '752 patent"), and United States Patent No. 5,648,497 ("the '497 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. This action relates to Abbreviated New Drug Application ("ANDA") No. 202573, which Roxane 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 Norvir® tablets that are sold in the United States, and which Roxane subsequently amended.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Roxane.

6. On information and belief, Roxane formulates, develops, markets, and sells active pharmaceutical ingredients (API), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Roxane's products"). Roxane routinely files ANDAs and seeks FDA approval to market its products in the United States.

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

8. 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 Roxane's ANDA No. 202573, which is the subject of this lawsuit.

9. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, its 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.

10. Roxane has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Roxane has filed counterclaims for declaratory judgment in *Abbott Laboratories v. Roxane Laboratories, Inc.*, No. 10-998 and *GlaxoSmithKline LLC v. Roxane Laboratories, Inc.*, No. 11-542.

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

BACKGROUND

12. Abbott is the holder of approved New Drug Application ("NDA") No. 22-417 for ritonavir tablets, which Abbott markets and sells under the trademark Norvir®. Abbott manufactures and sells Norvir® 100 mg tablets in the United States under NDA No. 22-417.

13. Roxane filed with the FDA ANDA No. 202573 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market ritonavir tablets 100 mg ("Roxane's generic ritonavir tablets"), which are generic copies of Abbott's Norvir® tablets.

14. Upon information and belief, ANDA No. 202573 seeks FDA approval of a pharmaceutical composition comprising ritonavir in a 100 mg dosage strength.

15. Upon information and belief, ANDA No. 202573 seeks FDA approval to market Roxane's generic ritonavir tablets in the United States.

16. On March 24, 2011, Abbott received a letter on behalf of Roxane, dated March 21, 2011, purporting to be a "Patent Notice Pursuant to § 505(b)(3)(B) [21 USC § 355(b)(4)(B)]" for ANDA No. 202573 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Roxane's March 24, 2011 Notice Letter notified Abbott that Roxane had filed ANDA No. 202573, seeking approval to market Roxane's generic ritonavir tablets prior to the expiration of the '359 and '752 patents.

17. On April 6, 2012, Abbott received a letter on behalf of Roxane, dated March 29, 2012, purporting to be a "Patent Notice Pursuant to § 505(j)(2)(B)(ii) [21 USC § 355(j)(2)(B)(ii)]" for ANDA No. 202573 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Roxane's April 6, 2012 Notice Letter notified Abbott that Roxane had amended ANDA No. 202573, seeking approval to market Roxane's generic ritonavir tablets prior to, *inter alia*, the expiration of the '497 patent.

THE PATENTS-IN-SUIT

18. 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. Abbott lists the '359 patent in the Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417. The '359 patent is currently the subject of a reexamination proceeding pending at the United States Patent and Trademark Office. A true and correct copy of the '359 patent is attached as Exhibit A.

19. 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. Abbott lists the ’752 patent in the Orange Book for NDA No. 22-417. The ’752 patent is currently the subject of a reexamination proceeding pending at the United States Patent and Trademark Office. A true and correct copy of the ’752 patent is attached as Exhibit B.

20. The ’497 patent was duly and legally issued by the PTO on July 15, 1997. Abbott is the owner by assignment of the ’497 patent and has the right to sue for infringement thereof. Abbott lists the ’497 patent in the Orange Book for NDA No. 22-417. The ’497 patent is currently the subject of a reexamination proceeding pending at the United States Patent and Trademark Office. A true and correct copy of the ’497 patent is attached as Exhibit C.

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

21. Paragraphs 1-20 are incorporated herein by reference.

22. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane’s generic ritonavir tablets in the United States before the expiration of the ’359 patent. On information and belief, Roxane filed 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 and/or not infringed.

23. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane’s generic 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.

24. Upon FDA approval of ANDA No. 202573, Roxane 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 Roxane's generic 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. 202573 shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity.

25. The offering to sell, sale, making, and/or importation of Roxane's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '359 patent, either literally or under the doctrine of equivalence. Roxane's has knowledge and is aware of Abbott's '359 patent, as evidenced by Roxane's March 24, 2011 Notice Letter.

26. Abbott will be irreparably harmed if Roxane is 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

27. Paragraphs 1-26 are incorporated herein by reference.

28. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane's generic ritonavir tablets in the United States before the expiration of the '752 patent. On information and belief, Roxane filed 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 and/or not infringed.

29. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic 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.

30. Upon FDA approval of ANDA No. 202573, Roxane 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 Roxane's generic ritonavir tablets, and by actively inducing infringement by others under § 271(b) and contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 202573 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

31. On information and belief, Roxane knows and intends that physicians will prescribe and patients will take Roxane's generic ritonavir tablets for which approval is sought in ANDA No. 202573 to treat HIV infection, and therefore will infringe at least one claim in the '752 patent.

32. On information and belief, Roxane had knowledge of the '752 patent and, by its promotional activities and package insert for Roxane's generic ritonavir tablets, knows or should know that it 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.

33. The offering to sell, sale, and/or importation of Roxane's generic ritonavir tablets would actively induce or contribute to infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents. Roxane's has knowledge and is aware of Abbott's '752 patent, as evidenced by Roxane's March 24, 2011 Notice Letter.

34. Abbott will be irreparably harmed if Roxane is not enjoined from infringing and actively inducing and 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 PATENT INFRINGEMENT
UNITED STATES PATENT NO. 5,648,497

35. Paragraphs 1-34 are incorporated herein by reference.

36. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane's generic ritonavir tablets in the United States before the expiration of the '497 patent. On information and belief, Roxane filed 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 '497 patent are purportedly invalid and/or not infringed.

37. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic ritonavir tablets before the expiration date of the '497 patent constitutes infringement of one or more claims of the '497 patent, either literally or under the doctrine of equivalents.

38. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the '497 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Roxane's generic 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. 202573 shall be no earlier than the expiration date of the '497 patent and any additional periods of exclusivity.

39. The offering to sell, sale, making, and/or importation of Roxane's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '497 patent, either literally or under the doctrine of equivalence. Roxane's has knowledge and is aware of Abbott's '497 patent, as evidenced by Roxane's April 6, 2012 Notice Letter.

40. Abbott will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the '497 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.

FOURTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '359 PATENT

41. Paragraphs 1-40 are incorporated herein by reference.

42. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage and methods of use as the Norvir® product sold by Abbott.

43. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

44. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '359 patent.

45. Roxane's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '359 patent.

46. Abbott will be substantially and irreparably damaged and harmed if Roxane's threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

FIFTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '752 PATENT

47. Paragraphs 1-46 are incorporated herein by reference.

48. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage and methods of use as the Norvir® product sold by Abbott.

49. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

50. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '752 patent.

51. Roxane's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '752 patent.

52. Abbott will be substantially and irreparably damaged and harmed if Roxane's threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

SIXTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '497 PATENT

53. Paragraphs 1-52 are incorporated herein by reference.

54. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage as the Norvir® product sold by Abbott.

55. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

56. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '497 patent.

57. Roxane's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '497 patent.

58. Abbott will be substantially and irreparably damaged and harmed if Roxane's threatened infringement is not enjoined. Abbott does not have an 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), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '359 patent was an act of infringement of the '359 patent;

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

3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '752 patent was an act of infringement of the '752 patent;

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

5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '359 patent was an act of infringement of the '497 patent;

6) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets would constitute infringement of the '497 patent;

7) ordering that the effective date of any FDA approval of Roxane's generic 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);

8) ordering that the effective date of any FDA approval of Roxane's generic 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);

9) ordering that the effective date of any FDA approval of Roxane's generic ritonavir tablets shall be no earlier than the expiration date of the '497 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

10) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic 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);

11) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic 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);

12) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic ritonavir tablets, until the expiration of the '497 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

13) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the '359 patent, and any additional periods of exclusivity;

14) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the '752 patent, and any additional periods of exclusivity;

15) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the '497 patent, and any additional periods of exclusivity;

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

17) declaring the '359 patent valid and enforceable;

18) declaring the ’752 patent valid and enforceable;

19) declaring the ’497 patent valid and enforceable;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Mary B. Graham (#2256)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
mnoreika@mnat.com
Attorneys for Abbott Laboratories

OF COUNSEL:

Barbara R. Rudolph
Jennifer A. Johnson
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
Tel: (202) 408-4000
Fax: (202) 408-4400

April 10, 2012
5860791