IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

ABBVIE INC. 1 North Waukegan Road North Chicago, IL 60064, Plaintiff, v. ROXANE LABORATORIES, INC. 1809 Wilson Road Columbus, OH 43228 c/o CT Corporation System 1300 East 9th Street Cleveland, OH 44114, Defendant.	)	Civil Action No. 13-708

COMPLAINT

Plaintiff AbbVie Inc., by way of Complaint against Roxane Laboratories, Inc., states as follows:

THE PARTIES

1. Plaintiff AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global biopharmaceutical company 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 43228.

NATURE OF THE ACTION

3. This is a civil action for patent infringement of United States Patent Number 8,268,349 B2 ("the '349 patent") and United States Patent Number 8,399,015 B2 ("the '015 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 AbbVie'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 as evidenced by, *inter alia*, having conducted business in Ohio including but not limited to the substantial, continuous and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district, having availed itself of the rights and benefits of Ohio law, previously admitting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Ohio.

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

BACKGROUND

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

8. 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 AbbVie's Norvir® tablets.

9. ANDA No. 202573 seeks FDA approval of a pharmaceutical composition comprising ritonavir in a 100 mg dosage strength.

10. ANDA No. 202573 seeks FDA approval to market Roxane's generic ritonavir tablets in the United States.

11. On March 24, 2011, Abbott Laboratories ("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 United States Patent Number 7,148,359 B2 ("the '359 patent") and United States Patent Number 7,364,752 B1 ("the '752 patent"). The '359 patent and the '752 patent are the subject of *Roxane Laboratories, Inc. v. Abbott Laboratories and AbbVie Inc.*, C.A. No. 2:12-cv-312-MHW-NMK, which is currently pending in this District.

12. 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 United States Patent Number 5,648,497 ("the '497 patent"), United States Patent Number 6,037,157 C1 ("the '157 patent"), and United States Patent Number 6,703,403 B2 ("the '403 patent"). The '497 patent, the '157 patent, and the '403 patent, as well as the '359 patent and the '752 patent, are the subject of *AbbVie Inc. v. Roxane Laboratories, Inc.*, C.A. No. 2:13-cv-00645-MHW-NMK, which is currently pending in this District.

13. On July 8, 2013, AbbVie received a letter on behalf of Roxane, dated June 28, 2013, 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 June 28, 2013, notice letter notified AbbVie that Roxane had amended ANDA No. 202573, seeking approval to market Roxane's generic ritonavir tablets prior to, *inter alia*, the expiration of the '349 patent and the '015 patent.

THE PATENTS-IN-SUIT

14. The '349 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on September 18, 2012. AbbVie is the owner by assignment of the '349 patent and has the right to sue for infringement thereof. AbbVie lists the '349 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417. A true and correct copy of the '349 patent is attached as Exhibit A. The '349 patent expires on February 25, 2025, inclusive of pediatric exclusivity.

15. The ’015 patent was duly and legally issued by the PTO on March 19, 2013. AbbVie is listed as the assignee on the face of the ’015 patent. AbbVie is the owner by assignment of the ’015 patent and has the right to sue for infringement thereof. AbbVie lists the ’015 patent in the Orange Book for NDA No. 22-417. A true and correct copy of the ’015 patent is attached as Exhibit B. The ’015 patent expires on February 25, 2025, inclusive of pediatric exclusivity.

FIRST COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 7,148,349 B2

16. Paragraphs 1-15 are incorporated herein by reference.

17. 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 ’349 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 ’349 patent are purportedly invalid and/or not infringed.

18. 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 ’349 patent constitutes infringement of one or more claims of the ’349 patent, either literally or under the doctrine of equivalents.

19. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the ’349 patent, either literally or under the doctrine of equivalents, under § 271(a) 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 '349 patent and any additional periods of exclusivity.

20. On information and belief, Roxane is aware and/or has knowledge that healthcare professionals and/or patients will use Roxane's generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the '349 patent.

21. 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 '349 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of AbbVie's '349 patent, as evidenced by Roxane's June 28, 2013, notice letter.

22. AbbVie will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the '349 patent. Pursuant to 35 U.S.C. § 283, AbbVie entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 8,399,015 B2

23. Paragraphs 1-22 are incorporated herein by reference.

24. 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 '015 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 '015 patent are purportedly invalid and/or not infringed.

25. 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 ’015 patent constitutes infringement of one or more claims of the ’015 patent, either literally or under the doctrine of equivalents.

26. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the ’015 patent, either literally or under the doctrine of equivalents, under § 271(a) 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 ’015 patent and any additional periods of exclusivity.

27. On information and belief, Roxane is aware and/or has knowledge that healthcare professionals and/or patients will use Roxane’s generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the ’015 patent.

28. 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 ’015 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of AbbVie’s ’015 patent, as evidenced by Roxane’s June 28, 2013, notice letter.

29. AbbVie will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the ’015 patent. Pursuant to 35 U.S.C. § 283, AbbVie entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT FOR DECLARATORY JUDGMENT AS TO THE ’349 PATENT

30. Paragraphs 1-29 are incorporated herein by reference.

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

32. The manufacture, importation, sale, and offer for sale of Roxane's generic ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '349 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

33. If the FDA approves ANDA No. 202573, the manufacture, importation, sale, and offer for sale in the United States before the expiration of the '349 patent will actively induce infringement by others under 35 U.S.C. § 271(b) by Roxane of one or more claims of the '349 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b).

34. Roxane's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '349 patent.

35. A case or controversy exists between AbbVie and Roxane regarding the infringement and validity of the '349 patent.

36. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Roxane having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Roxane's threatened infringement of the '349 patent.

37. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

FOURTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '015 PATENT

38. Paragraphs 1-37 are incorporated herein by reference.

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

40. The manufacture, importation, sale, and offer for sale of Roxane's generic ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '015 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

41. If the FDA approves ANDA No. 202573, the manufacture, importation, sale, and offer for sale in the United States before the expiration of the '015 patent will actively induce infringement by others under 35 U.S.C. § 271(b) by Roxane of one or more claims of the '015 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b).

42. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '015 patent.

43. Roxane's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '015 patent.

44. A case or controversy exists between AbbVie and Roxane regarding the infringement and validity of the '015 patent.

45. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Roxane having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Roxane's threatened infringement of the '015 patent.

46. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AbbVie 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 '349 patent was an act of infringement of the '349 patent;

2) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the '349 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 '015 patent was an act of infringement of the '015 patent;

4) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the '015 patent;

5) 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 '349 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

6) 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 '015 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

7) 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 '349 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

8) 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 '015 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

9) 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 '349 patent, and any additional periods of exclusivity;

10) 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 '015 patent, and any additional periods of exclusivity;

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

12) declaring the '349 patent valid and enforceable;

13) declaring the '015 patent valid and enforceable;

14) awarding AbbVie its costs and expenses in this action; and

15) awarding AbbVie any further and additional relief as this Court deems just and proper.

Dated: July 18, 2013

Respectfully submitted,

/s/ Alycia N. Broz

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