

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

ROXANE LABORATORIES, INC.,  
1809 Wilson Road,  
Columbus, Ohio 43228

Plaintiff,

v.

ABBOTT LABORATORIES,  
100 Abbott Park Road,  
Abbott Park, Illinois 60064

and

ABBOTT LABORATORIES  
c/o CT Corporation System  
Statutory Agent  
1300 East 9<sup>th</sup> Street  
Cleveland, Ohio 44114

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiff Roxane Laboratories, Inc. (“Roxane”), for its Complaint against Abbott Laboratories (“Abbott”), alleges as follows:

**NATURE OF ACTION**

1. Roxane seeks declaratory judgment of invalidity and noninfringement of U.S. Patent Nos. 7,148,359 and 7,364,752 pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

## **PARTIES**

2. Roxane is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

3. Upon information and belief, Abbott is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

## **JURISDICTION AND VENUE**

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a); 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

5. The Court has personal jurisdiction over Abbott due to Abbott's systematic, purposeful, and continuous contacts in this judicial district. Upon information and belief, Abbott is registered with the Ohio Secretary of State to do business in the State of Ohio and in this judicial district. Upon information and belief, Abbott operates at least two facilities in this judicial district, including facilities located at 625 Cleveland Avenue, Columbus, Ohio; 1033 Kingsmill Parkway, Columbus, Ohio; 3300 Stelzer Road, Columbus, Ohio; and 6480 Busch Boulevard, Columbus, Ohio. Upon information and belief, Abbott has purposefully availed itself of this forum by commercializing pharmaceutical products in the State of Ohio and this judicial district, and deriving substantial revenues from such activities.

6. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c) and 21 U.S.C. § 355(j)(5)(C)(i)(II), as Abbott resides in and has a regular and established place of business in this judicial district.

### FACTUAL BACKGROUND

7. United States Patent No. 7,148,359 (“the ’359 patent”), entitled “Polymorph of a Pharmaceutical,” issued on December 12, 2006. A copy of the ’359 patent is attached hereto as Exhibit A.

8. United States Patent No. 7,364,752 (“the ’752 patent”), entitled “Solid Dispersion Pharmaceutical Formulations,” issued on April 29, 2008. A copy of the ’752 patent is attached hereto as Exhibit B.

9. Abbott is the named assignee of the ’359 and ’752 patents.

10. Upon information and belief, Abbott holds New Drug Application No. 022417 (“NDA 022417”) for oral ritonavir tablets, 100 mg, marketed under the brand name Norvir®. In connection with NDA 022417, Abbott caused the Food and Drug Administration (“FDA”) to list the ’359 and ’752 patents (collectively, the “Listed Patents”) in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”). By doing so, Abbott represented that a claim of patent infringement could reasonably be asserted against any unlicensed manufacture, use, or sale of oral ritonavir tablets, 100 mg. By causing the listing of the Listed Patents in the Orange Book, Abbott created a reasonable apprehension that it would file a patent infringement action against applicants seeking regulatory approval for generic oral ritonavir tablets, 100 mg.

11. Upon information and belief, Abbott sought and obtained the Listed Patents specifically for the purpose of limiting competition from generic oral ritonavir tablets.

12. Roxane has submitted Abbreviated New Drug Application No. 202573 (“ANDA 202573”) to the FDA in order to obtain regulatory approval to engage in the commercial manufacture, use, or sale of generic oral ritonavir tablets, 100 mg (the “Roxane ritonavir product”), before the expiration of the Listed Patents. The Roxane ritonavir product is

bioequivalent to Abbott's Norvir® product and has the same active ingredient, strength, dosage form, and route of administration. Roxane made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "paragraph IV certification") that the '359 and '752 patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the oral ritonavir tablets, 100 mg, that are the subject of ANDA 202573.

13. Roxane has made substantial preparations for the commercial manufacture, use, and sale of the Roxane ritonavir product.

14. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), by a letter sent to Abbott in 2011, Roxane provided notice to Abbott of the paragraph IV certification that it filed with ANDA 202573, together with an Offer of Confidential Access to ANDA 202573 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). This notice included a detailed statement of the factual and legal basis why the Listed Patents patent are invalid or will not be infringed.

15. Roxane's notification triggered a 45-day statutory period during which Abbott had the first opportunity to initiate patent infringement litigation. Abbott failed to bring an action for patent infringement during the 45-day statutory period. By listing the Listed Patents in the Orange Book but failing to bring an action for patent infringement, Abbott has injected uncertainty and insecurity into Roxane's pursuit of regulatory approval and subsequent commercialization of its generic oral ritonavir product.

16. Where no action for patent infringement is filed within the 45-day statutory period, 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5) provide for a civil action to obtain patent certainty and allow ANDA filers to obtain a declaratory judgment with respect to the Listed Patents. All of the conditions specified in 21 U.S.C. § 355(j)(5)(C)(i) for filing an action for declaratory judgment have been satisfied.

**COUNT ONE**

**(Declaratory Judgment Regarding U.S. Patent No. 7,148,359)**

17. Roxane reasserts and realleges paragraphs 1-16 above as if fully set forth herein.

18. The claims of the '359 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

19. The submission of ANDA 202573 does not infringe any valid claim of the '359 patent.

20. The commercial manufacture, use, offer for sale, sale, or importation of the Roxane ritonavir product would not infringe any valid claim of the '359 patent.

21. An actual and justiciable controversy exists between the parties with respect to the '359 patent. Roxane is entitled to a declaratory judgment that the '359 patent is invalid and/or not infringed.

**COUNT TWO**

**(Declaratory Judgment Regarding U.S. Patent No. 7,364,752)**

22. Roxane reasserts and realleges paragraphs 1-16 above as if fully set forth herein.

23. The claims of the '752 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

24. The submission of ANDA 202573 does not infringe any valid claim of the '752 patent.

25. The commercial manufacture, use, offer for sale, sale, or importation of the Roxane ritonavir product would not infringe any valid claim of the '752 patent.

26. An actual and justiciable controversy exists between the parties with respect to the '752 patent. Roxane is entitled to a declaratory judgment that the '752 patent is invalid and/or not infringed.

**PRAYER FOR RELIEF**

WHEREFORE, Roxane respectfully requests that this Court enter judgment in its favor and against Abbott and grant the following relief:

- A. Declare that the claims of the '359 patent are invalid;
- B. Declare that Roxane has not infringed the '359 patent;
- C. Declare that the manufacture, use, offer for sale, sale, or importation of the Roxane ritonavir product would not infringe any valid claim of the '359 patent;
- D. Declare that the claims of the '752 patent are invalid;
- E. Declare that Roxane has not infringed the '752 patent;
- F. Declare that the manufacture, use, offer for sale, sale, or importation of the Roxane ritonavir product would not infringe any valid claim of the '752 patent;
- G. Award Roxane its costs and reasonable attorneys' fees; and,
- H. Award Roxane such other and further relief as the Court deems just and proper.

Dated: April 10, 2012

Respectfully Submitted,

/s/ Drew H. Campbell

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