IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ROXANE LABORATORIES, INC., Plaintiff, v. LUPIN LIMITED, and LUPIN PHARMACEUTICALS, INC. Defendants.	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Roxane Laboratories, Inc. ("Roxane"), for its Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc., alleges as follows:

PARTIES

1. 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.

2. Upon information and belief, Lupin Limited is a corporation organized and existing under the laws of India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400 051, Maharastra, India.

3. Upon information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Virginia, has its principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202, and is a wholly-owned subsidiary of Lupin Limited.

4. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") manufacture, market, offer for sale, and/or sell generic drugs throughout the United States, including in the State of New Jersey.

NATURE OF ACTION

5. This is a civil action for declaratory and injunctive relief against Lupin for infringement of United States Patent No. 8,563,032 ("the '032 Patent"), arising from Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 20-2127 to the United States Food and Drug Administration ("FDA") for approval to market a generic calcium acetate capsule drug product ("the Accused Product") and Lupin's intent to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Accused Product in the United States imminently upon FDA approval to do so.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action because it arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals, Inc. because, upon information and belief, *inter alia*, Lupin Limited and Lupin Pharmaceuticals, Inc. each conduct business in New Jersey, have availed themselves of the rights and benefits of New Jersey Law, and have engaged in substantial and continuing contacts with New Jersey.

8. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. operate as a single entity with respect to regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in the state of New Jersey.

9. Upon information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. have each previously submitted to the jurisdiction of this Court in prior patent infringement cases

and have further previously availed themselves of the benefits of the laws of the state of New Jersey and this Court by asserting counterclaims in this district.

10. Upon information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in New Jersey.

11. Upon information and belief, Lupin Pharmaceuticals, Inc. has appointed National Registered Agents, Inc. of Princeton, New Jersey as its registered agent for the receipt of service of process.

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

THE PATENT-IN-SUIT

13. On October 22, 2013, the United States Patent and Trademark Office lawfully issued the '032 Patent, entitled "Formulation and Manufacturing Process for Calcium Acetate Capsules." A true and correct copy of the '032 Patent is attached hereto as Exhibit A. Roxane is the record owner of the '032 Patent by assignment.

14. The '032 Patent claims, *inter alia*, novel formulations of calcium acetate capsules. Calcium acetate capsules are used to control hyperphosphatemia in patients suffering from end stage renal failure.

ROXANE'S GENERIC CALCIUM ACETATE CAPSULE PRODUCT

15. Roxane submitted ANDA No. 77-728 to the FDA to market a generic form of calcium acetate capsules (the "Roxane Calcium Acetate Capsule Product") for the reduction of serum phosphorous in patients with end stage renal disease. The inventions disclosed in the '032 Patent arose out of Roxane's substantial and successful effort to develop the Roxane Calcium Acetate Capsule Product. Roxane's patented Calcium Acetate Capsule Product comprises flowable granules of calcium acetate within a capsule that is designated size 00.

16. The FDA approved Roxane's ANDA No. 77-728 in 2008, and thereafter, Roxane began marketing the Roxane Calcium Acetate Capsule Product.

DEFENDANT'S GENERIC CALCIUM ACETATE CAPSULE PRODUCT

17. Upon information and belief, Lupin filed ANDA No. 20-2127 seeking FDA approval for the Accused Product. Upon information and belief, Lupin Limited appointed Lupin Pharmaceuticals, Inc. as its authorized U.S. Agent for purposes of that submission, and Lupin Pharmaceuticals, Inc. has acted as such.

18. Upon information and belief, Lupin included within its ANDA a Paragraph IV certification stating that at least United States Patent No. 6,576,665, which is listed in the Orange Book as covering PhosLo®, the Reference Listed Drug for the Accused Product, is invalid or not infringed by the Accused Product.

19. Following its submission of its Paragraph IV certification, Lupin engaged in patent litigation with Fresenius Medical Care Holdings, Inc., the purported record owner of United States Patent No. 6,576,665 and holder of New Drug Application ("NDA") No. 21-160, upon which ANDA No. 20-2127 was based (hereinafter, the "Fresenius Litigation".)

20. Lupin resolved the Fresenius Litigation by settlement without the court entering judgment.

21. Upon information and belief, by filing ANDA No. 20-2127 and a Paragraph IV certification, and subsequently resolving the Fresenius Litigation by settlement, Lupin evidenced that it intends to, and will, engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Accused Product promptly upon receiving FDA approval to do so.

22. Upon information and belief, as of the date of this Complaint, FDA has not yet granted Lupin approval to market the Accused Product, and no samples of that Accused Product or related product specifications are publicly available.

23. Upon information and belief, Lupin took positions in the Fresenius Litigation that indicate the Accused Product likely falls within the scope of the '032 Patent.

24. Subsequent to resolving the Fresenius Litigation, Lupin filed a Citizen Petition with FDA seeking to have Roxane's Calcium Acetate Capsule Product, which is an embodiment of one or more claims of the '032 Patent, added as a second Reference Listed Drug in addition to PhosLo®, thus further indicating that the Accused Product likely falls within the scope of the '032 Patent.

25. Since at least January 2014, Roxane requested Lupin to provide samples of the Accused Product and other information sufficient to confirm that the Accused Product is within the scope of at least one claim of the '032 Patent. Roxane reiterated its request to Lupin in August 2014, further informing Lupin that its failure to respond would lead Roxane to assume that Lupin had no intention to cooperate with Roxane's investigation. As of the date of this Complaint, Lupin has not responded to any of Roxane's requests.

26. Based on the foregoing, Roxane is informed and believes, and based thereon alleges, that upon FDA approval of Lupin's ANDA No. 20-2127, Lupin will infringe one or more claims of the '032 Patent by making, offering to sell, selling, or importing the Accused Product in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

27. Lupin has been on constructive notice that its planned commercial launch of the Accused Product likely would infringe Roxane's '032 Patent since the '032 Patent issued on October 22, 2013.

28. Lupin received actual notice of the '032 Patent on or about January 30, 2014.

COUNT ONE
(Infringement of U.S. Patent No. 8,563,032)

29. Roxane reasserts and realleges Paragraphs 1-28 above as if fully set forth herein.

30. Upon information and belief, Lupin intends to, and will, engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accused Product promptly upon receiving FDA approval to do so.

31. Upon information and belief, Lupin intends to engage in such infringing conduct imminently.

32. On information and belief, the commercial manufacture, use, importation, offer for sale, and/or sale of the Accused Product likely would infringe one or more claims of the '032 Patent.

33. Lupin has had actual notice of the '032 Patent since on or about January 30, 2014, before the filing of this action, and has continued its efforts to bring the Accused Product to market in the United States despite an objectively high likelihood that such actions constitute infringement of a valid patent.

34. There is a justiciable controversy between the parties hereto as to infringement of the '032 Patent. By way of example, Lupin's submission of ANDA No. 20-2127 to the FDA constitutes activity directed toward infringement of a valid patent and a refusal to change course in the face of acts sufficient to create reasonable apprehension of forthcoming suit. Accordingly, there is a sufficient case or controversy under the Declaratory Judgment Act.

35. Upon information and belief, Lupin's infringement of the '032 Patent will be willful, deliberate, and intentional, and thus any manufacturing, sale, offer to sell, marketing, or importation of the Accused Product in the United States will demonstrate a reckless disregard of Roxane's patent rights.

36. Roxane will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Roxane does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Roxane respectfully requests the following relief:

A. A judgment that Lupin's making, using, selling, offering to sell, or importing of the Accused Product will infringe the '032 Patent;

B. A judgment providing that the effective date of any FDA approval for Lupin to make, use, offer for sale, and/or sell the Accused Product be no earlier than the expiration of the '032 Patent;

C. A preliminary and permanent injunction restraining and enjoining Lupin, its officers, agents, attorneys, servants, employees, and all persons in active concert or participation with them, from making, using, selling, offering to sell, or importing the Accused Product until after the expiration of the '032 Patent;

D. If Lupin engages in the commercial manufacture, use, offer to sell, sale, or importation of the Accused Product prior to the expiration of the '032 Patent, a judgment awarding Roxane damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

E. An order declaring that Lupin's infringement is and/or will be willful, warranting increased damages under 35 U.S.C. § 284;

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

G. An award of costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Dated: February 10, 2015

Respectfully Submitted,
/s/ Theodora McCormick

Theodora McCormick
Amy M. Handler
SILLS CUMMIS & GROSS P.C.
One Riverfront Plaza
Newark, New Jersey 07102
Telephone: (973) 643-7000
Facsimile: (973) 643-6500
tmccormick@sillscummis.com
ahandler@sillscummis.com

Attorneys for Plaintiff Roxane Laboratories, Inc.

Of Counsel:

LATHAM & WATKINS LLP

Kenneth G. Schuler
Marc N. Zubick
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
Telephone: (312) 876-7700
Facsimile: (312) 993-9767
kenneth.schuler@lw.com
marc.zubick@lw.com

Alexander E. Long
Brittany Merrill Yeng
12670 High Bluff Drive
San Diego, CA 92130
Telephone: (858) 523-5400
Facsimile: (858) 523-5450
alexander.long@lw.com
brittany.yeng@lw.com

Gregory K. Sobolski
505 Montgomery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 391-0600
Facsimile: (415) 395-8095
gregory.sobolski@lw.com