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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PROMETHEUS LABORATORIES INC., **Plaintiff,** **v.** **ROXANE LABORATORIES, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Prometheus Laboratories Inc. ("Prometheus"), by its undersigned attorneys, for its Complaint against defendant Roxane Laboratories, Inc. ("Roxane"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Roxane's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Prometheus' LOTRONEX® drug product prior to the expiration of United States Patent No. 6,284,770 (the "'770 patent") owned by Prometheus.

The Parties

2. Plaintiff Prometheus is a corporation organized and existing under the laws of the State of California, having a principal place of business at 9410 Carroll Park Drive, San Diego, California 92121.

3. On information and belief, defendant Roxane is a corporation organized under the laws of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

4. On information and belief, Roxane is registered to do business in the State of New Jersey, and maintains a registered agent for service of process in New Jersey. On information and belief, Roxane regularly transacts business within this judicial district. Further, on information and belief, Roxane develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Roxane has litigated patent cases in this district in the past without contesting personal jurisdiction, and, in at least some of those actions, Roxane has asserted counterclaims.

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Roxane has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, Roxane has customers in the State of New Jersey.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent In Suit

8. On September 4, 2001, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '770 patent, entitled "Medicaments for the treatment of non-constipated female irritable bowel syndrome" to inventors Allen Wayne Mangel and Allison Ruth Northcutt. The '770 patent was subsequently subject to reexamination proceedings before the USPTO that resulted in the cancellation or amendment of all of the original claims of that patent. On October 19, 2010, the USPTO duly and lawfully issued a reexamination certificate for the '770 patent. A copy of the '770 patent and its reexamination certificate are attached hereto as Exhibit A.

The LOTRONEX® Drug Product

9. Prometheus holds an approved New Drug Application ("NDA") under Section 505(a) of the FFDCA, 21 U.S.C. § 355(a), for alosetron hydrochloride tablets (NDA No. 21-107), which it sells under the trade name LOTRONEX®. The reexamined claims of the '770 patent cover, *inter alia*, methods of use and administration of alosetron or a pharmaceutically acceptable derivative thereof. Prometheus owns the '770 patent.

10. Following reexamination, the '770 patent was properly listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to LOTRONEX® pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations.

Acts Giving Rise to this Suit

11. Pursuant to Section 505 of the FFDCA, Roxane filed ANDA No. 200-652 ("Roxane's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 0.5 mg and 1.0 mg alosetron hydrochloride tablets ("Roxane's Proposed Products"), before the reexamined '770 patent expires.

12. In connection with the filing of its ANDA as described in the preceding paragraph, Roxane has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the reexamined '770 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA.

13. No earlier than January 28, 2011, Prometheus received written notice from Roxane concerning Roxane's ANDA certification ("Roxane's Notice Letter") relating to the reexamined '770 patent. Roxane's Notice Letter alleged that the claims of the reexamined '770 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA. Roxane's Notice Letter also informed Prometheus that Roxane seeks approval to market Roxane's Proposed Products before the reexamined '770 patent expires. This was the first, and only, notification sent by Roxane that addressed the reexamined claims of the '770 patent.

Count for Infringement of the '770 Patent

14. Plaintiff repeats and realleges the allegations of paragraphs 1-13 as though fully set forth herein.

15. Roxane's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of alosetron hydrochloride tablets, prior to the expiration of the reexamined '770 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

16. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Roxane has provided a written certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the reexamined '770 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA.

17. No earlier than January 28, 2011, Prometheus received written notice of Roxane's Paragraph IV Certification regarding the reexamined '770 patent. Roxane's Notice Letter alleged that the claims of the reexamined '770 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA. Roxane's Notice Letter also informed Prometheus that Roxane seeks approval to market Roxane's Proposed Products before the reexamined '770 patent expires. This was the first, and only, notification sent by Roxane that addressed the reexamined claims of the '770 patent.

18. There is a justiciable controversy between the parties hereto as to the infringement of the reexamined '770 patent.

19. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will infringe the reexamined '770 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Roxane's Proposed Products in the United States.

20. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will induce infringement of the reexamined '770 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Roxane's Proposed Products in the United States. On information and belief, upon FDA approval of Roxane's ANDA, Roxane will intentionally encourage acts of direct infringement with knowledge of the reexamined '770 patent and knowledge that its acts are encouraging infringement.

21. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will contributorily infringe the reexamined '770 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Roxane's Proposed Products in the United States. On information and belief, Roxane has had and continues to have knowledge that

Roxane's Proposed Products are especially adapted for a use that infringes the reexamined '770 patent and that there is no substantial non-infringing use for Roxane's Proposed Products.

22. Prometheus will be substantially and irreparably damaged and harmed if Roxane's infringement of the reexamined '770 patent is not enjoined.

23. Prometheus does not have an adequate remedy at law.

24. This case is an exceptional one, and Prometheus is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Prometheus respectfully requests the following relief:

(A) A Judgment be entered that Roxane has infringed the '770 patent by submitting ANDA No. 200-652;

(B) A Judgment be entered that Roxane has infringed, and that Roxane's making, using, selling, offering to sell, or importing Roxane's Proposed Products will infringe one or more claims of the '770 patent;

(C) An Order that the effective date of FDA approval of ANDA No. 200-652 be a date which is not earlier than the later of the expiration of the '770 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Roxane and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Roxane's Proposed Products until after the expiration of the '770 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Roxane, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the '770 patent, or

from actively inducing or contributing to the infringement of any claim of the '770 patent, until after the expiration of the '770 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Roxane's Proposed Products will directly infringe, induce and/or contribute to infringement of the '770 patent;

(G) To the extent that Roxane has committed any acts with respect to the methods claimed in the '770 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff Prometheus be awarded damages for such acts;

(H) If Roxane engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Roxane's Proposed Products prior to the expiration of the '770 patent, a Judgment awarding damages to Plaintiff Prometheus resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: March 4, 2011

By: s/ Charles M. Lizza

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