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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. In this action, Prometheus seeks to nullify Roxane's improper attempt to trigger the litigation process under the Federal Food, Drug and Cosmetics Act ("the FFDCA") for resolving patent disputes when a drug company seeks approval to market a generic version of a branded drug by filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA").

2. In addition, Roxane's proposed generic products would infringe United States Patent No. 6,284,770 ("the '770 patent") owned by Prometheus. Accordingly, in the alternative, if this Court finds that Roxane properly triggered the deadline for Prometheus to

sue Roxane under the FFDCA, Prometheus seeks all available relief under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, and other applicable laws for Roxane's infringement of the '770 patent.

The Parties

3. 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.

4. 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.

5. 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

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

7. 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.

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

The Patent In Suit

9. 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

10. 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.

11. 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

12. 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 '770 patent expires.

13. 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 original claims of the '770 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA ("Roxane's Paragraph IV Certification").

14. No earlier than December 6, 2010, Roxane sent an alleged written notice of its Paragraph IV Certification to Prometheus, a copy of which is attached hereto as Exhibit B. ("Roxane's Notice Letter"). Roxane's Notice Letter alleged that the claims of the '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 '770 patent expires. Roxane's Notice Letter, however, addressed the original '770 patent claims, rather than the claims allowed following reexamination.

15. Under the FFDCA, if the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice Letter from an ANDA filer, final approval of the ANDA is subject to a 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay protects innovator companies, such as Prometheus, from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. The innovator

company is thus provided up to a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market ("The ANDA patent litigation process").

16. In order to comply with the FFDCA, notification of a Paragraph IV patent certification must include a full and detailed explanation of the ANDA applicant's opinion that each claim of the patent is not valid, unenforceable, or will not be infringed. 21 U.S.C. § 355(j)(2)(B)(iv). Here, Roxane's Notice Letter failed to address the reexamined claims of the '770 patent. Due to this failure, Roxane did not provide Prometheus with the full and detailed explanation of the basis of Roxane's Paragraph IV Certification required by the FFDCA. Thus, Roxane's failure to provide a proper notification of patent certification to Prometheus did not trigger the 45-day period under 21 U.S.C. § 355(j)(5)(B)(iii). Further, because it is directed to non-existent claims of the '770 patent, Roxane's Paragraph IV Certification to the FDA is also defective.

17. In Response to Roxane's Notice Letter, Prometheus wrote to Roxane regarding its defective Notice Letter and Paragraph IV Certification. Prometheus asked Roxane to remedy these defects by amending its ANDA to contain a proper Paragraph IV Certification directed to the reexamined claims of the '770 patent and providing a proper Notice Letter to Prometheus addressing those claims. To date, Roxane has not done so.

Count I: Declaratory Judgment

18. Plaintiff repeats and realleges the allegations of paragraphs 1-17 as though fully set forth herein.

19. Roxane's Paragraph IV Certification and Notice Letter are defective because they do not address the reexamined claims of the '770 patent.

20. As a consequence, Roxane's Paragraph IV Certification and Notice Letter to Prometheus were defective, improper, null, void, and without legal effect.

21. Prometheus has asked Roxane to file a new Paragraph IV Certification and to provide a proper written notice of the certification, but, to date, Roxane has failed to do so.

22. An actual, substantial and justiciable controversy exists between Roxane and Prometheus regarding whether Roxane's Paragraph IV Certification and associated Notice Letter were defective, improper, null, void, and without legal effect and, as a consequence, whether Roxane improperly triggered the ANDA patent litigation process.

23. The controversy concerning the validity and effectiveness of Roxane's Paragraph IV Certification and associated Notice Letter will cause Prometheus to suffer substantial prejudice and unnecessary legal fees and costs unless the controversy is resolved by this Court.

24. Accordingly, Prometheus is entitled to a Judgment that: (1) Roxane's Paragraph IV Certification and associated Notice Letter are defective, improper, null, void, and without legal effect and that Roxane is not entitled to trigger the ANDA patent litigation process; (2) Roxane's Notice Letter did not commence the 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (3) if and when Roxane amends its ANDA to contain a Paragraph IV Certification directed to the reexamined claims of the '770 patent, it must provide notice of such certification to Prometheus that addresses those claims pursuant to 21 U.S.C. § 355(j)(2)(B)(iv); and (4) the 30-month stay will not begin until Prometheus has received a valid Paragraph IV Notice Letter from Roxane that addresses the reexamined claims of the '770 patent.

Count II: Infringement of the '770 Patent (In the Alternative to Count I)

25. Plaintiff repeats and realleges the allegations of paragraphs 1-24 as though fully set forth herein.

26. 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 '770 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. 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 '770 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA.

28. No earlier than December 6, 2010, Roxane sent written notice of its Paragraph IV Certification to Prometheus. Roxane's Notice Letter alleged that the claims of the '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 '770 patent expires.

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

30. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will infringe the '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.

31. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will induce infringement of the '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 '770 patent and knowledge that its acts are encouraging infringement.

32. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will contributorily infringe the '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 '770 patent and that there is no substantial non-infringing use for Roxane's Proposed Products.

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

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

35. 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 as to Count I:

(A) A Judgment that (1) Roxane's Paragraph IV Certification and associated Notice Letter are defective, improper, null, void, and without legal effect and that Roxane is not entitled to trigger the ANDA patent litigation process; (2) Roxane's Notice Letter did not commence the 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (3) if and when Roxane amends its ANDA to contain a Paragraph IV certification directed to the reexamined claims of the '770 patent, it must provide notice of such

certification to Prometheus that addresses those claims pursuant to 21 U.S.C. § 355(j)(2)(B)(iv); and (4) the 30-month stay will not begin until Prometheus has received a valid Paragraph IV Notice Letter from Roxane that addresses the reexamined claims of the '770 patent.

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

(C) Costs and expenses in this action; and

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

In the alternative to the above remedies, Plaintiff Prometheus respectfully requests the following relief as to Count II:

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

(F) A Judgment 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;

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

(H) Preliminary and permanent injunctions restraining and 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 Prometheus is or becomes entitled;

(I) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Roxane and 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 Prometheus is or becomes entitled;

(J) 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;

(K) A judgment awarding damages, together with interest, to Prometheus 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);

(L) A judgment awarding damages, together with interest, 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 patentt;

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

(N) Costs and expenses in this action; and

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

Dated: January 14, 2011

By: s/ Charles M. Lizza

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