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

MEDEVA PHARMA SUISSE A.G., and PROCTER & GAMBLE PHARMACEUTICALS, INC., Plaintiffs, v. ROXANE LABORATORIES, INC. Defendant.	Civ. Action No._____ **COMPLAINT FOR PATENT INFRINGEMENT** *Document filed electronically.*

Plaintiffs Medeva Pharma Suisse A.G. ("Medeva" and collectively "Plaintiffs") and Procter & Gamble Pharmaceuticals, Inc. ("Procter & Gamble" and collectively "Plaintiffs") by their attorneys, for their complaint against Roxane Laboratories, Inc. ("Roxane"), allege as follows:

THE PARTIES

1. Plaintiff Medeva, formerly Tillots Pharma AG, is a company organized and existing under the laws of Switzerland and has its principal place of business at Chemin de Croix Blanche, 10, Bulle 1630, Switzerland.

2. Plaintiff Procter & Gamble is a corporation organized and existing under the laws of Ohio and has its principal place of business at 8700 Mason-Montgomery Road, Mason, Ohio 45040.

3. Upon information and belief, Defendant Roxane is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228-9579. Roxane is registered to do business in New Jersey and the Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628, is its registered agent in New Jersey.

4. Upon information and belief, Roxane has availed itself of the legal protections of the State of New Jersey, having filed counterclaims seeking judicial relief from this Court in *Pharmaceutical Resources, Inc. et al v. Roxane Laboratories, Inc.*, Civil Action No. 2:03-3357. Roxane has also admitted to personal jurisdiction in this Court in the aforementioned action as well as in *Novartis Pharmaceuticals Corp. v. Roxane Laboratories, Inc.* 2:06-04126.

5. Upon information and belief, Roxane manufactures, markets, and sells many pharmaceutical products, including generic prescription drug products, that are marketed and sold to customers in the State of New Jersey.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,541,170 ("the '170 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Roxane is subject to personal jurisdiction in this judicial district because it is registered to do business in the State of New Jersey, has a registered agent in the State of New Jersey, and by virtue of, *inter alia*, its having conducted business in the State of New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

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

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

9. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

10. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the ANDA, the applicant

must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

11. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

12. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

13. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

PROCTER & GAMBLE'S APPROVED DRUG PRODUCT

14. Procter & Gamble is the holder of an approved new drug application, NDA No. 19-651, for a delayed-release oral tablet containing 400 mg of mesalamine. The NDA was first approved by FDA on January 31, 1992, and Procter & Gamble markets the approved drug product under the tradename ASACOL®. ASACOL® is approved for the treatment of mildly to moderately active ulcerative colitis and the maintenance of remission of ulcerative colitis.

15. FDA has listed the '170 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 19-651.

16. The '170 patent qualifies for listing in the Orange Book in connection with NDA No. 19-651 because it claims the approved drug product and an approved use of the drug product that is the subject of that NDA. Roxane has never challenged the listing of the patent in the Orange Book.

ROXANE'S ANDA

17. Roxane has represented that on or before September 14, 2007, it submitted to FDA an ANDA (ANDA No. 79-073) and paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for a 400 mg mesalamine delayed-release oral tablet purportedly bioequivalent to ASACOL® (the "Roxane generic mesalamine product"). The purpose of Roxane's ANDA and paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the Roxane generic mesalamine product.

18. Upon information and belief, the indications set forth in the proposed labeling submitted by Roxane in its ANDA No. 79-073 for the Roxane generic mesalamine product are the treatment of mildly to moderately active ulcerative colitis and the maintenance of remission of ulcerative colitis, the same indications as that set forth in the approved labeling for ASACOL®.

19. Upon information and belief, Roxane sent Procter & Gamble a "Patent Notice Pursuant to § 505(j)(2)(B)(ii) [21 U.S.C. § 355(j)(2)(B)(ii)]" dated September 14, 2007 (the "Notice Letter"). The Notice Letter represented that Roxane had submitted to FDA the Roxane ANDA and purported paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for a mesalamine delayed release tablet that is purportedly bioequivalent to Procter & Gamble's ASACOL® tablet.

20. Upon information and belief, the purpose of the Roxane ANDA and purported paragraph IV certifications was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its delayed release tablet containing mesalamine before the expiration of the patents listed in the Orange Book for NDA No. 19-651. Hence, Roxane's purpose in submitting the Roxane ANDA is to market its products described therein before expiration of the '170 patent.

21. The Roxane Notice Letter offered to grant Procter & Gamble access to certain confidential information in the Roxane ANDA. Procter & Gamble requested that Roxane provide certain product information on a confidential basis, which Roxane failed to provide before the expiration of the statutory period under 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(E)

22. Plaintiffs re-allege paragraphs 1 through 21 above as if fully set forth herein.

23. On July 30, 1996, the United States Patent and Trademark Office duly and legally issued the '170 patent, entitled "Orally Administrable Pharmaceutical Compositions."

The term of the '170 patent runs through July 30, 2013. A true and correct copy of the '170 patent is attached hereto as Exhibit A.

24. Medeva is the owner of the '170 patent, having acquired the '170 patent as successor in interest to Tillotts Pharma AG.

25. Procter & Gamble is the exclusive licensee of the '170 patent, pursuant to an exclusive license agreement between Tillotts Pharma AG and Procter & Gamble, giving Procter & Gamble the unlimited and unrestricted right to develop, make, have made, offer to sell, sell, import and/or dispose of delayed release mesalamine tablets in the United States and other territories. Pursuant to that exclusive license, Procter & Gamble currently markets ASACOL® in the United States. ASACOL® and its approved conditions of use fall within one or more of the claims of the '170 patent.

26. As exclusive licensee, Procter & Gamble is authorized to enforce the '170 patent.

27. The Roxane generic mesalamine product for which approval is sought in ANDA No. 79-073 falls within one or more of the claims of the '170 patent. If approved, the manufacture, use, importation or sale of the Roxane generic mesalamine product that is the subject of ANDA No. 79-073 would in infringe one or more of the claims of the '170 patent.

28. The conditions of use for the Roxane generic mesalamine product for which Roxane seeks approval in ANDA No. 79-073 fall within one or more of the claims of the '170 patent. If approved, use of the Roxane generic mesalamine product in accordance with the proposed labeling submitted in ANDA No. 79-073 would infringe one or more of the claims of the '170 patent.

29. Roxane is liable for infringement of the '170 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 79-073 with a paragraph IV certification seeking FDA approval of ANDA No. 79-073.

COUNT II: PATENT INFRINGEMENT UNDER 35 U.S.C. §§ 271(A), (B) & (C)

30. Plaintiffs re-allege paragraphs 1 through 29 above as if fully set forth herein.

31. Upon information and belief, if ANDA No. 79-073 is approved, Roxane intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the Roxane generic mesalamine product for which approval is sought in ANDA No. 79-073.

32. The manufacture, use, offer for sale, and sale in the United States, and importation into the United States, of the Roxane generic mesalamine product proposed and intended by Roxane would infringe one or more claims of the '170 patent, and Roxane would be liable for direct infringement under 35 U.S.C. § 271(a).

33. Upon information and belief, if approved, the Roxane generic mesalamine product for which approval is sought in Roxane's ANDA No. 79-073 will be administered to human patients for the treatment of mildly to moderately active ulcerative colitis and the maintenance of remission of ulcerative colitis, which administration would constitute direct infringement of one or more claims of the '170 patent. Upon information and belief, this infringement will occur at Roxane's behest, with its intent, knowledge, and encouragement, and Roxane will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Procter & Gamble's rights under the '170 patent.

34. Roxane's manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the Roxane generic mesalamine product for which approval is sought in ANDA No. 79-073 would actively induce and contribute to infringement of the '170 patent, and Roxane would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

35. Plaintiffs will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing or contributing to infringement of the '170 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Roxane has infringed the '170 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of the Roxane ANDA No. 79-073 for 400 mg mesalamine delayed release tablets be not earlier than the date of expiration of the '170 patent and any associated regulatory exclusivities extending that date;

C. A judgment declaring that Roxane's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Roxane generic mesalamine product for which approval is sought in ANDA No. 79-073 would constitute infringement of the '170 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction enjoining Roxane and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing

into the United States, the Roxane generic mesalamine product for which approval is sought in ANDA No. 79-073, or any mesalamine product that infringes or induces or contributes to the infringement of the '170 patent, until expiration of that patent and associated regulatory exclusivities extending that date;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

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

G. Such further and other relief as this Court determines to be just and proper.

___s/ David E. De Lorenzi_____
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Attorneys for Plaintiffs

DATED: October 26, 2007

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

I hereby certify that to my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

___s/ David E. De Lorenzi_____

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Dated: October 26, 2007