IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SOMAXON PHARMACEUTICALS, INC., and PROCOM ONE, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ACTAVIS ELIZABETH LLC, ACTAVIS, INC., MYLAN INC. and MYLAN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Somaxon Pharmaceuticals, Inc. ("Somaxon") and ProCom One, Inc. ("ProCom One") (collectively, "Plaintiffs") by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

This is an action for patent infringement of U.S. Patent No. 6,211,229 ("the '229 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Applications ("ANDAs") filed by Actavis Elizabeth LLC and Mylan Pharmaceuticals, Inc. with the U.S. Food and Drug Administration ("FDA") seeking FDA approval to market generic versions of the 3 mg and 6 mg forms of Somaxon's SILENOR® drug product.

PARTIES

1. Somaxon is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3570 Carmel Mountain Road, San Diego, CA 92130.

2. ProCom One is a corporation organized and existing under the laws of the State of Texas, with its principal place of business at P.O. Box 881117, Steamboat Springs, CO 80488.

3. Upon information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07207.

4. Upon information and belief, Actavis Elizabeth, LLC ("Actavis Elizabeth"), a wholly-owned subsidiary of Actavis, Inc., is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207.

5. Upon information and belief, Actavis Inc. and Actavis Elizabeth (collectively "Actavis") acted collaboratively in the preparation and submission of ANDA No. 201951. Upon information and belief, Actavis Elizabeth's preparation and submission of ANDA No. 201951 was done at the direction, under the control, and for the direct benefit of Actavis Inc.

6. Upon information and belief, following any FDA approval of ANDA No. 201951, Actavis Inc. and Actavis Elizabeth will work in concert with one another, and with other Actavis subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 201951 throughout the United States, and/or import such generic products into the United States.

7. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. is in the business of, among other things, developing, manufacturing, and selling generic copies of

branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including its wholly-owned subsidiary, Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals").

8. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. and is controlled and/or dominated by Mylan Inc. Upon information and belief, Mylan Pharmaceuticals manufacturers and/or distributes generic drugs for sale and use through the United States and in this judicial district at the direction, under the control, and for the benefit of Mylan Inc.

9. Upon information and belief, Mylan Inc. established Mylan Pharmaceuticals, its wholly-owned subsidiary, for the purposes of distributing, marketing, offering for sale and selling its generic drugs throughout the United States. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals work in concert with one another, and with other Mylan subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Mylan Inc. directs the operations, management and activities of Mylan Pharmaceuticals in the United States.

10. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals (collectively "Mylan") acted collaboratively in the preparation and submission of ANDA No. 202-337. Upon information and belief, Mylan Pharmaceuticals' preparation and submission of ANDA No. 202-337 was done at the direction, under the control, and for the direct benefit of Mylan Inc.

11. Upon information and belief, following any FDA approval of ANDA No. 202-337, Mylan Inc. and Mylan Pharmaceuticals will work in concert with one another, and with other Mylan subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 202-337 throughout the United States, including in this judicial district, and/or import such generic products into the United States.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

13. This Court has personal jurisdiction over Actavis Inc. and Actavis Elizabeth because both are Delaware entities and each has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 201951 that has led to foreseeable harm and injury to Somaxon, a Delaware corporation. This Court also has personal jurisdiction over Actavis Inc. and Actavis Elizabeth because they have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court in this district and have had persistent, systematic and continuous contacts with Delaware as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

14. Upon information and belief, Actavis Inc. and Actavis Elizabeth regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical

products in Delaware. Upon information and belief, Actavis Inc. and Actavis Elizabeth have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

15. Upon information and belief, Actavis Inc. and Actavis Elizabeth derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

16. This Court has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, *inter alia*, they each have committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 202-337 that has led to foreseeable harm and injury to Somaxon, a Delaware corporation. This Court also has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because they have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court in this district and have had persistent, systematic and continuous contacts with Delaware as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

17. Upon information and belief, Mylan Inc. maintains a website, www.mylan.com, advertising Mylan Inc.'s "global reach." According to Mylan Inc.'s website, Mylan Inc. is "one of the world's leading generics and specialty pharmaceutical companies, providing products to customers in more than 140 countries and territories," and "[t]he second largest generic pharmaceutical company in the U.S. by sales volume."

18. Upon information and belief, Mylan Pharmaceuticals distributes for sale hundreds of drug products through the United States, including in this judicial district. Upon information and belief, Mylan Pharmaceuticals maintains a website, www.mylanpharms.com,

advertising the drug products it manufacturers and/or sells in the United States. According to Mylan Pharmaceuticals' website, Mylan Pharmaceuticals "has one of the largest product portfolios in the U.S., consisting of more than 200 products."

19. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

20. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. For example, Mylan Inc. includes within its Annual Report the activities of its wholly-owned subsidiary Mylan Pharmaceuticals, including the revenues earned. The Mylan Inc. website, appearing at www.mylan.com, provides information about both Mylan Inc. and Mylan Pharmaceuticals. Mylan Inc. is divided into several business units, including the "Generics" business. Upon information and belief, Mylan Pharmaceuticals, in whole or in part, comprises this "Generics" business, particularly within the United States.

21. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

22. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have previously availed themselves of the rights and privileges of this forum for the purpose of

litigating patent disputes. For example, Mylan Inc. and Mylan Pharmaceuticals sought a declaratory judgment of noninfringement, unenforceability, and/or invalidity in *Mylan Pharmaceuticals Inc. v. Eurand, Inc.*, No. 10-306-SLR (D. Del.). Mylan Inc. and/or Mylan Pharmaceuticals have also submitted to this Court's jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Mylan Inc. and/or Mylan Pharmaceuticals admitted jurisdiction for the purpose of the litigation and filed counterclaims in *Forest Laboratories, Inc. v. Dr. Reddy's Laboratories, Inc.*, No. 08-52-GMS-LPS (D. Del.); *AstraZeneca Pharmaceuticals LP v. Mylan Pharmaceuticals, Inc.*, No. 07-805-JJF (D. Del.); *Sciele Pharma, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 07-664-GMS-LPS (D. Del.); *Sanofi-Aventis v. Actavis South Atlantic LLC*, No. 07-572-GMS (D. Del.); *Boehringer Ingelheim International GMBH v. Mylan Pharmaceuticals Inc.*, No. 05-854-JJF (D. Del.); *Janssen Pharmaceutica N.V. v. Mylan Pharmaceuticals Inc.*, No. 05-371-SLR (D. Del.); *AstraZeneca LP v. Mylan Pharmaceuticals, Inc.*, No. 08-453-GMS (D. Del.); and *Abbott Laboratories v. Mylan Inc.*, No. 10-559-SLR (D. Del.).

BACKGROUND

23. SILENOR® is a low-dose (3 mg or 6 mg) oral tablet formulation of doxepin approved by the FDA for the treatment of insomnia. Somaxon sells SILENOR® in the United States pursuant to a New Drug Application approved by the FDA.

24. ProCom One is the owner of the '229 patent, entitled "Treatment of Transient and Short Term Insomnia," which the U.S. Patent and Trademark Office duly and legally issued on April 3, 2001. A true and correct copy of the '229 patent is attached hereto as Exhibit A. The claims of the '229 patent are valid and enforceable. Somaxon is an exclusive licensee of the '229 patent.

25. SILENOR®, or its use or formulation, is covered by one or more claims of the '229 patent. The '229 patent has been listed in connection with SILENOR® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

INFRINGEMENT BY ACTAVIS

26. By letter dated November 2, 2010, Actavis notified Plaintiffs that Actavis had submitted ANDA No. 201951 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of 3 mg and 6 mg doxepin hydrochloride tablets before the expiration of the '229 patent.

27. By filing ANDA No. 201951, Actavis has necessarily represented to the FDA that the components of its generic doxepin hydrochloride tablets have the same active ingredients as those of the corresponding components of SILENOR®, have the same route of administration, dosage form, and strengths as the corresponding components of SILENOR®, and are bioequivalent to the corresponding components of SILENOR®.

INFRINGEMENT BY MYLAN

28. By letter dated November 2, 2010, Mylan notified Plaintiffs that Mylan had submitted ANDA No. 202-337 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of 3 mg and 6 mg doxepin hydrochloride tablets before the expiration of the '229 patent.

29. By filing ANDA No. 202-337, Mylan has necessarily represented to the FDA that the components of its generic doxepin hydrochloride tablets have the same active

ingredients as those of the corresponding components of SILENOR®, have the same route of administration, dosage form, and strengths as the corresponding components of SILENOR®, and are bioequivalent to the corresponding components of SILENOR®.

COUNT I (INFRINGEMENT OF THE '229 PATENT BY ACTAVIS)

30. Each of the preceding paragraphs 1 to 29 is incorporated as if fully set forth.

31. Actavis's submission of ANDA No. 201951 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxepin hydrochloride tablets prior to the expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, use of Actavis's generic doxepin hydrochloride tablets in accordance with and as directed by Actavis's proposed labeling for that product would infringe one or more claims of the '229 patent.

33. Upon information and belief, Actavis knows that its generic doxepin hydrochloride tablets and its proposed labeling for that product are especially made or adapted for use in infringing the '229 patent, and that Actavis's generic doxepin hydrochloride tablets and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Actavis plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 201951.

34. Upon information and belief, Actavis had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 201951 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '229 patent.

35. Upon FDA approval of Actavis's ANDA No. 201951, Actavis will further infringe the '229 patent by making, using, offering to sell, and selling generic doxepin hydrochloride tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

36. If Actavis's infringement of the '229 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '229 PATENT BY MYLAN)

37. Each of the preceding paragraphs 1-36 is incorporated as if fully set forth.

38. Mylan's submission of ANDA No. 202-337 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxepin hydrochloride tablets prior to the expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, use of Mylan's generic doxepin hydrochloride tablets in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '229 patent.

40. Upon information and belief, Mylan knows that its generic doxepin hydrochloride tablets and its proposed labeling for that product are especially made or adapted for use in infringing the '229 patent, and that Mylan's generic doxepin hydrochloride tablets and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to the infringement of the '229 patent immediately and imminently upon approval of ANDA No. 202-337.

41. Upon information and belief, Mylan had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 202-337 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '229 patent.

42. Upon FDA approval of Mylan's ANDA No. 202-337, Mylan will further infringe the '229 patent by making, using, offering to sell, and selling generic doxepin hydrochloride tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

43. If Mylan's infringement of the '229 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that one or more claims of the '229 patent are infringed by Actavis's submission of ANDA No. 201951, and that Actavis's making, using, offering to sell, or selling in the United States, or importing into the United States, of generic doxepin hydrochloride tablets will infringe, actively induces infringement, and/or contributes to the infringement of the '229 patent;

2. A judgment that one or more claims of the '229 patent are infringed by Mylan's submission of ANDA No. 202-337, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States, of generic doxepin hydrochloride tablets will infringe, actively induces infringement, and/or contributes to the infringement of the '229 patent;

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Actavis's ANDA No. 201951 shall be a date which is not earlier than the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

4. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Mylan's ANDA No. 202-337 shall be a date which is not earlier than the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

5. An order permanently enjoining Actavis, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic doxepin hydrochloride tablets until after the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

6. An order permanently enjoining Mylan, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic doxepin hydrochloride tablets until after the expiration date of the '229 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

7. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285 and costs of this litigation.

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Dated: December 15, 2010