IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SOMAXON PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS ELIZABETH LLC, and ACTAVIS, INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Somaxon Pharmaceuticals, Inc. ("Somaxon") by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

This is an action for patent infringement of U.S. Patent No. 7,915,307 ("the '307 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 an Abbreviated New Drug Application ("ANDA") filed by Actavis Elizabeth LLC 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. This action is related to *Somaxon Pharmaceuticals, Inc. et al v. Actavis Elizabeth LLC et al*, 1:10-cv-01100 (SLR), which is pending before Judge Sue Robinson in this District and involves the same ANDA relevant to this action.

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. 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.

3. 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.

4. 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.

5. 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.

JURISDICTION AND VENUE

6. 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).

7. 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.

8. 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.

9. 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.

BACKGROUND

10. 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.

11. Somaxon is the owner of the '307 patent, entitled "Methods of Improving the Pharmacokinetics of Doxepin," which the U.S. Patent and Trademark Office duly and legally

issued on March 29, 2011. A true and correct copy of the '307 patent is attached hereto as Exhibit A. The claims of the '307 patent are valid and enforceable.

12. SILENOR®, or its use or formulation, is covered by one or more claims of the '307 patent. The '307 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

13. By letter dated March 29, 2011, Actavis notified Somaxon 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 '307 patent.

14. 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®.

COUNT I (INFRINGEMENT OF THE '307 PATENT BY ACTAVIS)

15. Each of the preceding paragraphs 1 to 14 is incorporated as if fully set forth.

16. 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 '307 patent constitutes infringement of one or more of the claims of the '307 patent under 35 U.S.C. § 271(e)(2)(A).

17. 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 '307 patent.

18. 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 '307 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 '307 patent immediately and imminently upon approval of ANDA No. 201951.

19. Upon FDA approval of Actavis's ANDA No. 201951, Actavis will further infringe the '307 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.

20. If Actavis's infringement of the '307 patent is not enjoined, Somaxon will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Somaxon prays that this Court grant the following relief:

1. A judgment that one or more claims of the '307 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, will actively induce infringement, and/or will contribute to the infringement of the '307 patent;

2. 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 '307 patent, including any extensions and/or additional periods of exclusivity to which Somaxon is or becomes entitled;

3. 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 '307 patent, including any extensions and/or additional periods of exclusivity to which Somaxon is or becomes entitled;

4. 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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