IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| SOMAXON PHARMACEUTICALS, INC., and PROCOM ONE, INC. | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LIMITED (d/b/a ZYDUS CADILA) | ) | |
| 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 Nos. 6,211,229 ("the '229 patent") and 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 Zydus Pharmaceuticals USA, 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, Zydus Cadila is a company organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015 Gujarat, India. Upon information and belief, Zydus Cadila 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, Zydus Pharmaceuticals USA, Inc ("Zydus USA").

4. Zydus USA is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 73 Route 31 N., Pennington, NJ 08534. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila and is controlled and/or dominated by Zydus Cadila. Upon information and belief, Zydus USA markets and distributes generic drugs for sale and use throughout the United States and in this judicial district at the direction, under the control, and for the benefit of Zydus Cadila.

5. Upon information and belief, Zydus Cadila established Zydus USA, 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, Zydus Cadila and Zydus USA (collectively, "Zydus") work in concert with one another, and with other Zydus subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Zydus Cadila directs the operations, management and activities of Zydus USA in the United States.

6. Upon information and belief, Zydus Cadila and Zydus USA acted collaboratively in the preparation and submission of ANDA No. 202761. Upon information and belief, Zydus USA's preparation and submission of ANDA No. 202761 was done at the direction, under the control, and for the direct benefit of Zydus Cadila.

7. Upon information and belief, following any FDA approval of ANDA No. 202761, Zydus USA and Zydus Cadila will work in concert with one another, and with other Zydus subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 202761 throughout the United States, and/or import such generic products into the United States.

## JURISDICTION AND VENUE

8. 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).

9. This Court has personal jurisdiction over Zydus Cadila and Zydus USA 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. 202761 that has led to foreseeable harm and injury to Somaxon, a Delaware corporation. This Court also has personal jurisdiction over Zydus Cadila and Zydus USA 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.

10. Upon information and belief, Zydus Cadila maintains a website, www.zyduscadila.com, advertising Zydus Cadila's "global operations in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets." According to Zydus Cadila's 2010 Annual Report, Zydus Cadila is "among the top 20 generic companies in the U.S."

11. Upon information and belief, Zydus USA distributes for sale hundreds of drug products throughout the United States, including in this judicial district. Upon information and belief, Zydus USA maintains a website, www.zydususa.com, advertising the drug products it markets and/or sells in the United States. According to Zydus USA's website, Zydus USA "has over 50 years of U.S. generic market experience." The Zydus USA website lists seventy-one authorized distributors, including companies with extensive distribution networks in Delaware, such as CVS Pharmacy, Rite-Aid, Wal-Mart, and Walgreens. Walgreens, for example, has sixty-four locations in Delaware, while Wal-Mart has eighteen.

12. Upon information and belief, Zydus Cadila and Zydus USA 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, Zydus Cadila and Zydus USA have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

13. Upon information and belief, Zydus Cadila has also availed itself of the laws of Delaware and engaged in a course of conduct in Delaware, at least by forming a wholly-owned U.S. subsidiary, Zydus Healthcare USA LLC under Delaware law.

14. Upon information and belief, Zydus Cadila and Zydus USA operate as an integrated, unitary generic pharmaceutical business. For example, Zydus Cadila includes within its Annual Report the activities of its wholly-owned subsidiary Zydus USA, including the revenues earned.

15. Upon information and belief, Zydus Cadila and Zydus USA derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

16. Upon information and belief, Zydus Cadila and Zydus USA have previously availed themselves of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Zydus Cadila and Zydus USA have submitted to this Court's jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Zydus USA and Zydus Cadila admitted jurisdiction for the purpose of the litigation and filed counterclaims in *Shire Development Inc. et al v. Cadila Healthcare Limited et al.*, No. 10-cv-00581-KAJ (D. Del.) (Dkt. Nos. 9, 13 [Answer to Complaint]).

**BACKGROUND**

17. 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.

18. 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.

19. 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 B. The claims of the '307 patent are valid and enforceable.

20. SILENOR®, or its use or formulation, is covered by one or more claims of the '229 and '307 patents. The '229 and '307 patents have 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 ZYDUS**

21. By letter dated May 12, 2011, Zydus notified Plaintiffs that Zydus had submitted ANDA No. 202761 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 and '307 patents.

22. By filing ANDA No. 202761, Zydus 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)**

23. Each of the preceding paragraphs 1 to 22 is incorporated as if fully set forth.

24. Zydus's submission of ANDA No. 202761 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).

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

26. Upon information and belief, Zydus 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 Zydus’s generic doxepin hydrochloride tablets and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to the infringement of the ’229 patent immediately and imminently upon approval of ANDA No. 202761.

27. Upon information and belief, Zydus had actual and constructive knowledge of the ’229 patent prior to filing ANDA No. 202761 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the ’229 patent.

28. Upon FDA approval of Zydus’s ANDA No. 202761, Zydus 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.

29. If Zydus’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 ’307 PATENT)**

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

31. Zydus's submission of ANDA No. 202761 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).

32. Upon information and belief, use of Zydus's generic doxepin hydrochloride tablets in accordance with and as directed by Zydus's proposed labeling for that product would infringe one or more claims of the '307 patent.

33. Upon information and belief, Zydus 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 Zydus's generic doxepin hydrochloride tablets and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to the infringement of the '307 patent immediately and imminently upon approval of ANDA No. 202761.

34. Upon information and belief, Zydus had actual and constructive knowledge of the '307 patent prior to filing ANDA No. 202761 and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '307 patent.

35. Upon FDA approval of Zydus's ANDA No. 202761, Zydus 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.

36. If Zydus'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, Plaintiffs pray that this Court grant the following relief:

1. A judgment that one or more claims of the ’229 patent are infringed by Zydus’s submission of ANDA No. 202761, and that Zydus’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 ’229 patent;

2. A judgment that one or more claims of the ’307 patent are infringed by Zydus’s submission of ANDA No. 202761, and that Zydus’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;

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Zydus’s ANDA No. 202761 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 Zydus’s ANDA No. 202761 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;

5. An order permanently enjoining Zydus, 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 Zydus, 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;

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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P. O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

*Attorneys for Somaxon Pharmaceuticals, Inc. and ProCom One, Inc.*

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

David A. Manspeizer
WILMER, CUTLER, PICKERING,
HALE AND DORR LLP
399 Park Avenue
New York, NY 10022

William G. McElwain
WILMER, CUTLER, PICKERING,
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006

June 16, 2011