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

ELI LILLY AND COMPANY,	
Plaintiff,	Civil Action No. 07-3770 (DMC)
v.	, ,
ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC.	
Defendants.	,))

FIRST AMENDED COMPLAINT

Plaintiff Eli Lilly and Company, (hereinafter "Lilly") for its First Amended Complaint against Defendants Actavis Elizabeth LLC (hereinafter "Actavis"), Glenmark Pharmaceuticals Inc., USA (hereinafter "Glenmark"), Sun Pharmaceutical Industries Limited (hereinafter "Sun"), Sandoz Inc. (hereinafter "Sandoz"), Mylan Pharmaceuticals Inc. (hereinafter "Mylan"), Apotex Inc. (hereinafter "Apotex"), Aurobindo Pharma Ltd. (hereinafter "Aurobindo"), Teva Pharmaceuticals USA, Inc. (hereinafter "Teva"), Synthon Laboratories, Inc. (hereinafter

"Synthon"), and Zydus Pharmaceuticals, USA, Inc. (hereinafter "Zydus") hereby alleges as follows:

Nature of the Action

1. This is a civil action for the infringement of United States Patent No. 5,658,590 ("the '590 patent"). This action relates to Abbreviated New Drug Applications ("ANDAs") filed by Actavis, Glenmark, Sun, Sandoz, Mylan, Apotex, Aurobindo, Teva, Synthon, and Zydus with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Lilly's Strattera® drug products. This action arises under the patent laws of the United States, 35 U.S.C. § 100, et seq.

Parties

- 2. Plaintiff Lilly is an Indiana corporation having a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.
- 3. Upon information and belief, Defendant Actavis is a corporation organized under the laws of Delaware having a principal place of business at 200 Elmora Avenue, Elizabeth, NJ 07207.
- 4. Upon information and belief, Defendant Glenmark is a corporation organized under the laws of Delaware having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.
- 5. Upon information and belief, Defendant Sun is a corporation organized under the laws of India having a principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400 059, India. Upon information and belief, Defendant Sun manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Sun, through its wholly owned subsidiary Sun Pharmaceutical Industries, Inc. (hereinafter "Sun NJ"), owns a facility at 6 Hollywood Court,

South Plainfield, New Jersey 07080, leases a manufacturing facility in Cranbury, New Jersey, and maintains a registered agent, Corporation Service Company, at 830 Bear Tavern Road, West Trenton, New Jersey 08628. Upon information and belief, Sun has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction in Civ. A. No. 2:05-cv-02391-KSG-PS.

- 6. Upon information and belief, Defendant Sandoz is a corporation organized under the laws of Delaware having a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08540.
- 7. Upon information and belief, Defendant Mylan is a corporation organized under the laws of West Virginia having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26504. Upon information and belief, Defendant Mylan is registered to do business in New Jersey and has appointed Corporation Service Company of West Trenton, New Jersey as its registered agent in New Jersey for the receipt of service of process.
- 8. Upon information and belief, Defendant Teva is a corporation organized under the laws of Delaware having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454, and with regular and established places of business in Elmwood Park, Fairfield, Fair Lawn, Englewood Cliffs, Paterson, and Waldwick, New Jersey. Teva is registered to do business in New Jersey and has registered prescription drug products in the *New Jersey Generic Formulary* of the New Jersey Department of Health and Senior Services.
- 9. Upon information and belief, Defendant Apotex is a corporation organized under the laws of Canada having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex is in the business of manufacturing, marketing, importing and selling pharmaceutical products, including generic pharmaceutical

products. Upon information and belief, Apotex, directly or through its wholly owned subsidiaries, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Apotex has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and asserting counterclaims in other civil actions in this jurisdiction.

- 10. Upon information and belief, Defendant Aurobindo is a corporation organized under the laws of India having a principal place of business at Plot # 2, Maitri Vihar, Ameerpet, Hyderabad 500 038, Andhra Pradesh, India, and a place of business at 666 Plainsboro Road, Suite 210, Plainsboro, New Jersey 08536. Upon information and belief, Aurobindo, through its agent Aurobindo Inc., maintains a place of business in the nature of a branch office at 666 Plainsboro Road, Suite 210, Plainsboro, New Jersey 08536.
- 11. Upon information and belief, Defendant Synthon is a corporation organized under the laws of Virginia having a principal place of business at 7130 Heritage Village Plaza, Suite 201, Gainesville, VA 20155.
- 12. Upon information and belief, Defendant Zydus is a corporation organized under the laws of New Jersey having a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08450.

Jurisdiction and Venue

- 13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 14. Upon information and belief, this Court has personal jurisdiction over Actavis by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.

- 15. Upon information and belief, this Court has personal jurisdiction over Glenmark by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.
- 16. Upon information and belief, this Court has personal jurisdiction over Sun by virtue of the presence of its wholly owned subsidiary, Sun NJ, in New Jersey, and its direct and indirect contacts with New Jersey, including through Sun NJ.
- 17. Upon information and belief, this Court has personal jurisdiction over Sandoz by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.
- 18. Upon information and belief, this Court has personal jurisdiction over Mylan by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.
- 19. Upon information and belief, this Court has personal jurisdiction over Teva by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.
- 20. Upon information and belief, this Court has personal jurisdiction over Apotex by virtue of its continuous and systematic contacts with New Jersey.
- 21. Upon information and belief, this Court has personal jurisdiction over Aurobindo by virtue of its presence in New Jersey and its direct and indirect continuous and systematic contacts with New Jersey.
- 22. Upon information and belief, this Court has personal jurisdiction over Synthon by virtue of its continuous and systematic contacts with New Jersey.
- 23. Upon information and belief, this Court has personal jurisdiction over Zydus by virtue of its presence in New Jersey and its continuous and systematic contacts with New Jersey.
- 24. Venue is proper in this judicial district pursuant to, *inter alia*, 28 U.S.C. §§ 1391(b) and/or 1400(b).

Plaintiff's Strattera® Products and Related Patent

- 25. On August 19, 1997, the '590 patent, titled "Treatment of Attention-Deficit/Hyperactivity Disorder," was duly and legally issued to John H. Heiligenstein and Gary D. Tollefson and assigned to Lilly. A true and correct copy of the '590 patent is attached hereto as Exhibit A. The '590 patent claims methods of treating attention-deficit/hyperactivity disorder with tomoxetine. Tomoxetine is now known as atomoxetine. The claims of the '590 patent are valid and enforceable. The '590 patent expires on November 26, 2016.
- 26. Strattera[®] is the brand name for the commercial formulation of atomoxetine hydrochloride developed, manufactured, and sold by Lilly. Lilly submitted a New Drug Application to the FDA for Strattera[®] Capsules for the treatment of attention-deficit/hyperactivity disorder (NDA No. 21-411). NDA No. 21-411 was approved by the FDA on or about November 26, 2002, for Strattera[®] Capsules in strengths of Eq 10 mg, 18 mg, 25 mg, 40 mg, and 60 mg. Strattera[®] Capsules in strengths of Eq 80 mg and 100 mg were approved on or about February 14, 2005.
- 27. The Food And Drug Administration Center For Drug Evaluation And Research Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") lists the '590 patent for each of the strengths of Strattera® approved by the FDA under NDA No. 21-411.
- 28. Pursuant to 21 U.S.C. § 355a, Lilly is entitled to a six-month period of pediatric exclusivity for Strattera® beyond the date of expiration of the '590 patent.

Actavis' ANDA Filing

29. By letter dated June 27, 2007 and a subsequent letter dated August 6, 2007 (the "Actavis Notice Letters"), Actavis notified Lilly that Actavis had submitted ANDA No. 78-940 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the

"Actavis ANDA"). On information and belief, the Actavis ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Actavis Atomoxetine Capsules") — generic versions of each of the FDA-approved Strattera® Capsule strengths — before the expiration date of the '590 patent.

- 30. By filing the Actavis ANDA, Actavis has necessarily represented to the FDA that the Actavis Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].
- 31. In the Actavis Notice Letters, Actavis notified Lilly that the Actavis ANDA contains a paragraph IV certification with respect to the '590 patent. Actavis attached to the Actavis Notice Letters a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Actavis Atomoxetine Capsules.
- 32. Lilly's Complaint was filed before the expiration of forty-five days from the date Lilly received the first of the Actavis Notice Letters, which Lilly received no earlier than June 28, 2007. Lilly's First Amended Complaint is also being filed before the expiration of forty-five days from the date Lilly received the second of the Actavis Notice Letters, which Lilly received no earlier than August 7, 2007.

Glenmark's ANDA Filing

33. By letter dated August 2, 2007 (the "Glenmark Notice Letter"), Glenmark notified Lilly that Glenmark had submitted ANDA No. 79-019 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Glenmark ANDA"). On information and belief, the Glenmark ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Tablets, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80

mg, and 100 mg Atomoxetine (collectively the "Glenmark Atomoxetine Tablets") — generic versions of each of the FDA-approved Strattera® Capsule strengths — before the expiration date of the '590 patent.

- 34. By filing the Glenmark ANDA, Glenmark has necessarily represented to the FDA that the Glenmark Atomoxetine Tablets have the same active ingredient as Strattera[®], have the same route of administration, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling as Strattera[®].
- 35. In the Glenmark Notice Letter, Glenmark notified Lilly that the Glenmark ANDA contains a paragraph IV certification with respect to the '590 patent. Glenmark attached to the Glenmark Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Glenmark Atomoxetine Tablets.
- 36. This action is being brought before the expiration of forty-five days from the date Lilly received the Glenmark Notice Letter, which Lilly received no earlier than August 6, 2007.

Sun's ANDA Filing

- 37. By letter dated August 6, 2007 (the "Sun Notice Letter"), Sun notified Lilly that Sun had submitted ANDA No. 79-020 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Sun ANDA"). On information and belief, the Sun ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Sun Atomoxetine Capsules") generic versions of each of the FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 38. By filing the Sun ANDA, Sun has necessarily represented to the FDA that the Sun Atomoxetine Capsules have the same active ingredient as Strattera®, have the same route of

administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].

- 39. In the Sun Notice Letter, Sun notified Lilly that the Sun ANDA contains a paragraph IV certification with respect to the '590 patent. Sun attached to the Sun Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Sun Atomoxetine Capsules.
- 40. This action is being brought before the expiration of forty-five days from the date Lilly received the Sun Notice Letter, which Lilly received no earlier than August 7, 2007.

Sandoz's ANDA Filing

- 41. By letter dated August 1, 2007 (the "Sandoz Notice Letter"), Sandoz notified Lilly that Sandoz had submitted ANDA No. 79-018 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Sandoz ANDA"). On information and belief, the Sandoz ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Sandoz Atomoxetine Capsules") generic versions of each of the FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 42. By filing the Sandoz ANDA, Sandoz has necessarily represented to the FDA that the Sandoz Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].
- 43. In the Sandoz Notice Letter, Sandoz notified Lilly that the Sandoz ANDA contains a paragraph IV certification with respect to the '590 patent. Sandoz attached to the

Sandoz Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Sandoz Atomoxetine Capsules.

44. This action is being brought before the expiration of forty-five days from the date Lilly received the Sandoz Notice Letter, which Lilly received no earlier than August 6, 2007.

Mylan's ANDA Filing

- 45. By letter dated August 10, 2007 (the "Mylan Notice Letter"), Mylan notified Lilly that Mylan had submitted ANDA No. 79-021 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Mylan ANDA"). On information and belief, the Mylan ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Mylan Atomoxetine Capsules") generic versions of each of the FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 46. By filing the Mylan ANDA, Mylan has necessarily represented to the FDA that the Mylan Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].
- 47. In the Mylan Notice Letter, Mylan notified Lilly that the Mylan ANDA contains a paragraph IV certification with respect to the '590 patent. Mylan attached to the Mylan Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Mylan Atomoxetine Capsules.
- 48. This action is being brought before the expiration of forty-five days from the date Lilly received the Mylan Notice Letter, which Lilly received no earlier than August 13, 2007.

Teva's ANDA Filing

- 49. By letter dated August 13, 2007 (the "Teva Notice Letter"), Teva notified Lilly that Teva had submitted ANDA No. 79-022 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Teva ANDA"). On information and belief, the Teva ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Teva Atomoxetine Capsules") generic versions of each of the FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 50. By filing the Teva ANDA, Teva has necessarily represented to the FDA that the Teva Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].
- 51. In the Teva Notice Letter, Teva notified Lilly that the Teva ANDA contains a paragraph IV certification with respect to the '590 patent. Teva attached to the Teva Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Teva Atomoxetine Capsules.
- 52. This action is being brought before the expiration of forty-five days from the date Lilly received the Teva Notice Letter, which Lilly received no earlier than August 14, 2007.

Apotex's ANDA Filing

53. By letter dated August 13, 2007 (the "Apotex Notice Letter"), Apotex notified Lilly that Apotex had submitted ANDA No. 78-983 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Apotex ANDA"). On information and belief, the Apotex ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80

mg, and 100 mg Atomoxetine (collectively the "Apotex Atomoxetine Capsules") — generic versions of each of the FDA-approved Strattera® Capsule strengths — before the expiration date of the '590 patent.

- 54. By filing the Apotex ANDA, Apotex has necessarily represented to the FDA that the Apotex Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].
- 55. In the Apotex Notice Letter, Apotex notified Lilly that the Apotex ANDA contains a paragraph IV certification with respect to the '590 patent. Apotex attached to the Apotex Notice Letter a statement asserting its opinion that the '590 patent is invalid or will not be infringed by the Apotex Atomoxetine Capsules.
- 56. This action is being brought before the expiration of forty-five days from the date Lilly received the Apotex Notice Letter, which Lilly received no earlier than August 15, 2007.

Aurobindo's ANDA Filing

- 57. By letter dated August 14, 2007 (the "Aurobindo Notice Letter"), Aurobindo notified Lilly that Aurobindo had submitted ANDA No. 79-016 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Aurobindo ANDA"). On information and belief, the Aurobindo ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Aurobindo Atomoxetine Capsules") generic versions of each of the FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 58. By filing the Aurobindo ANDA, Aurobindo has necessarily represented to the FDA that the Aurobindo Atomoxetine Capsules have the same active ingredient as Strattera®,

have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].

- 59. In the Aurobindo Notice Letter, Aurobindo notified Lilly that the Aurobindo ANDA contains a paragraph IV certification with respect to the '590 patent. Aurobindo attached to the Aurobindo Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Aurobindo Atomoxetine Capsules.
- 60. This action is being brought before the expiration of forty-five days from the date Lilly received the Aurobindo Notice Letter, which Lilly received no earlier than August 15, 2007.

Synthon's ANDA Filing

- 61. By letter dated August 16, 2007 (the "Synthon Notice Letter"), Synthon notified Lilly that Synthon had submitted ANDA No. 79-023 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Synthon ANDA"). On information and belief, the Synthon ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Synthon Atomoxetine Capsules") generic versions of each of the FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 62. By filing the Synthon ANDA, Synthon has necessarily represented to the FDA that the Synthon Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].

- 63. In the Synthon Notice Letter, Synthon notified Lilly that the Synthon ANDA contains a paragraph IV certification with respect to the '590 patent. Synthon attached to the Synthon Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Synthon Atomoxetine Capsules.
- 64. This action is being brought before the expiration of forty-five days from the date Lilly received the Synthon Notice Letter, which Lilly received no earlier than August 20, 2007.

Zydus' ANDA Filing

- 65. By letter dated August 16, 2007 (the "Zydus Notice Letter"), Zydus notified Lilly that Zydus had submitted ANDA No. 79-017 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Zydus ANDA"). On information and belief, the Zydus ANDA seeks approval to engage in the commercial manufacture, use or sale of generic Atomoxetine Hydrochloride Capsules, Eq 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg Atomoxetine (collectively the "Zydus Atomoxetine Capsules") generic versions of six of the seven FDA-approved Strattera® Capsule strengths before the expiration date of the '590 patent.
- 66. By filing the Zydus ANDA, Zydus has necessarily represented to the FDA that the Zydus Atomoxetine Capsules have the same active ingredient as Strattera[®], have the same route of administration, dosage form, and strengths as Strattera[®], are bioequivalent to Strattera[®], and have the same or substantially the same proposed labeling and use as Strattera[®].
- 67. In the Zydus Notice Letter, Zydus notified Lilly that the Zydus ANDA contains a paragraph IV certification with respect to the '590 patent. Zydus attached to the Zydus Notice Letter a statement asserting its opinion that the '590 patent is invalid, unenforceable, or will not be infringed by the Zydus Atomoxetine Capsules.

68. This action is being brought before the expiration of forty-five days from the date Lilly received the Zydus Notice Letter, which Lilly received no earlier than August 22, 2007.

COUNT I

Infringement of the '590 Patent by Actavis

- 69. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 70. Actavis' submission of the Actavis ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Actavis Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- Actavis' commercial manufacture, use, offer to sell, sale, or importation of the Actavis Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Actavis' filing of the Actavis ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.
- 72. Upon FDA approval of the Actavis ANDA, Actavis will infringe the '590 patent by making, using, offering to sell, selling, or importing the Actavis Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 73. Lilly will be irreparably harmed if Actavis' infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT II

Infringement of the '590 Patent by Glenmark

- 74. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 75. Glenmark's submission of the Glenmark ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Glenmark Atomoxetine Tablets prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- Glenmark's commercial manufacture, use, offer to sell, sale, or importation of the Glenmark Atomoxetine Tablets for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Glenmark's filing of the Glenmark ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Glenmark Atomoxetine Tablets for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.
- 77. Upon FDA approval of the Glenmark ANDA, Glenmark will infringe the '590 patent by making, using, offering to sell, selling, or importing the Glenmark Atomoxetine

 Tablets in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 78. Lilly will be irreparably harmed if Glenmark's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT III

Infringement of the '590 Patent by Sun

- 79. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 80. Sun's submission of the Sun ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sun Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Sun's filing of the Sun ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sun Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.
- 82. Upon FDA approval of the Sun ANDA, Sun will infringe the '590 patent by making, using, offering to sell, selling, or importing the Sun Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 83. Lilly will be irreparably harmed if Sun's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT IV

Infringement of the '590 Patent by Sandoz

84. Lilly incorporates the preceding paragraphs as if fully set forth herein.

- 85. Sandoz's submission of the Sandoz ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- Sandoz's commercial manufacture, use, offer to sell, sale, or importation of the Sandoz Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Sandoz's filing of the Sandoz ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Sandoz Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.
- 87. Upon FDA approval of the Sandoz ANDA, Sandoz will infringe the '590 patent by making, using, offering to sell, selling, or importing the Sandoz Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 88. Lilly will be irreparably harmed if Sandoz's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT V

Infringement of the '590 Patent by Mylan

- 89. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 90. Mylan's submission of the Mylan ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan Atomoxetine Capsules prior to

the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).

- Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Mylan's filing of the Mylan ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Mylan Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.
- 92. Upon FDA approval of the Mylan ANDA, Mylan will infringe the '590 patent by making, using, offering to sell, selling, or importing the Mylan Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 93. Lilly will be irreparably harmed if Mylan's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT VI

Infringement of the '590 Patent by Teva

- 94. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 95. Teva's submission of the Teva ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Teva Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).

- Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Teva's filing of the Teva ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Teva Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.
- 97. Upon FDA approval of the Teva ANDA, Teva will infringe the '590 patent by making, using, offering to sell, selling, or importing the Teva Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 98. Lilly will be irreparably harmed if Teva's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT VII

Infringement of the '590 Patent by Apotex

- 99. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 100. Apotex's submission of the Apotex ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Apotex Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- 101. Apotex's commercial manufacture, use, offer to sell, sale, or importation of the Apotex Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior

to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Apotex's filing of the Apotex ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Apotex Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.

- 102. Upon FDA approval of the Apotex ANDA, Apotex will infringe the '590 patent by making, using, offering to sell, selling, or importing the Apotex Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 103. Lilly will be irreparably harmed if Apotex's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT VIII

Infringement of the '590 Patent by Aurobindo

- 104. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 105. Aurobindo's submission of the Aurobindo ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Aurobindo Atomoxétine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- 106. Aurobindo's commercial manufacture, use, offer to sell, sale, or importation of the Aurobindo Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Aurobindo's

filing of the Aurobindo ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Aurobindo Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.

- 107. Upon FDA approval of the Aurobindo ANDA, Aurobindo will infringe the '590 patent by making, using, offering to sell, selling, or importing the Aurobindo Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 108. Lilly will be irreparably harmed if Aurobindo's infringement is not enjoined.Lilly does not have an adequate remedy at law.

COUNT IX

Infringement of the '590 Patent by Synthon

- 109. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 110. Synthon's submission of the Synthon ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Synthon Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- 111. Synthon's commercial manufacture, use, offer to sell, sale, or importation of the Synthon Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Synthon's filing of the Synthon ANDA and its intention to engage in the commercial manufacture, use, offer to sell,

sale, or importation of the Synthon Atomoxetine Capsules for the treatment of attentiondeficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.

- 112. Upon FDA approval of the Synthon ANDA, Synthon will infringe the '590 patent by making, using, offering to sell, selling, or importing the Synthon Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 113. Lilly will be irreparably harmed if Synthon's infringement is not enjoined. Lilly does not have an adequate remedy at law.

COUNT X

Infringement of the '590 Patent by Zydus

- 114. Lilly incorporates the preceding paragraphs as if fully set forth herein.
- 115. Zydus'submission of the Zydus ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Zydus Atomoxetine Capsules prior to the expiration of the '590 patent constitutes infringement of one or more of the valid claims of the '590 patent under 35 U.S.C. § 271(e)(2)(A).
- Zydus Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder prior to the expiration of the '590 patent, and its inducement of or contribution to such conduct, would further infringe the '590 patent under 35 U.S.C. §§ 271(a), (b) and/or (c). Zydus' filing of the Zydus ANDA and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Zydus Atomoxetine Capsules for the treatment of attention-

deficit/hyperactivity disorder, and its intention to induce such conduct upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '590 patent.

- 117. Upon FDA approval of the Zydus ANDA, Zydus will infringe the '590 patent by making, using, offering to sell, selling, or importing the Zydus Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.
- 118. Lilly will be irreparably harmed if Zydus' infringement is not enjoined. Lilly does not have an adequate remedy at law.

Prayer for Relief

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

- A. A declaration that the '590 patent is valid and enforceable;
- B. As Against Actavis
- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Actavis Atomoxetine Capsules, that Actavis' submission of the Actavis ANDA is an act of infringement of the '590 patent, that Actavis' making, using, offering to sell, selling, or importing the Actavis Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Actavis ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Actavis and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Actavis Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if

 Actavis engages in the commercial manufacture, use, offer to sell, sale, or importation of the

 Actavis Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to

 six months after the expiration of the '590 patent, and that any such damages or monetary relief

 be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

C. <u>As Against Glenmark</u>

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Glenmark Atomoxetine Tablets, that Glenmark's submission of the Glenmark ANDA is an act of infringement of the '590 patent, that Glenmark's making, using, offering to sell, selling, or importing the Glenmark Atomoxetine Tablets for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Glenmark ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Glenmark and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using,

offering to sell, selling, or importing the Glenmark Atomoxetine Tablets and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if Glenmark engages in the commercial manufacture, use, offer to sell, sale, or importation of the Glenmark Atomoxetine Tablets, or in inducing or contributing to such conduct by others, prior to six months after the expiration of the '590 patent, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

D. As Against Sun

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Sun Atomoxetine Capsules, that Sun's submission of the Sun ANDA is an act of infringement of the '590 patent, that making, using, offering to sell, selling, or importing the Sun Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder by Sun, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Sun ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Sun and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Sun Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if Sun engages in the commercial manufacture, use, offer to sell, sale, or importation of the Sun Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to six months after the expiration of the '590 patent, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

E. As Against Sandoz

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Sandoz Atomoxetine Capsules, that Sandoz's submission of the Sandoz ANDA is an act of infringement of the '590 patent, that Sandoz's making, using, offering to sell, selling, or importing the Sandoz Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Sandoz ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Sandoz and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Sandoz Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if Sandoz engages in the commercial manufacture, use, offer to sell, sale, or importation of the Sandoz Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to six months after the expiration of the '590 patent, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

F. As Against Mylan

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Mylan Atomoxetine Capsules, that Mylan's submission of the Mylan ANDA is an act of infringement of the '590 patent, that Mylan's making, using, offering to sell, selling, or importing the Mylan Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Mylan ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Mylan and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Mylan Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if

 Mylan engages in the commercial manufacture, use, offer to sell, sale, or importation of the

 Mylan Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to

 six months after the expiration of the '590 patent, and that any such damages or monetary relief

 be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

G. As Against Teva

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Teva Atomoxetine Capsules, that Teva's submission of the Teva ANDA is an act of infringement of the '590 patent, that Teva's making, using, offering to sell, selling, or importing the Teva Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Teva ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Teva and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Teva Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if

 Teva engages in the commercial manufacture, use, offer to sell, sale, or importation of the Teva

 Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to six

 months after the expiration of the '590 patent, and that any such damages or monetary relief be
 trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

H. As Against Apotex

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Apotex Atomoxetine Capsules, that Apotex's submission of the Apotex ANDA is an act of infringement of the '590 patent, that Apotex's making, using, offering to sell, selling, or importing the Apotex Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Apotex ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Apotex and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Apotex Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if

 Apotex engages in the commercial manufacture, use, offer to sell, sale, or importation of the

 Apotex Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to
 six months after the expiration of the '590 patent, and that any such damages or monetary relief
 be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

I. <u>As Against Aurobindo</u>

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Aurobindo Atomoxetine Capsules, that Aurobindo's submission of the Aurobindo ANDA is an act of infringement of the '590 patent, that Aurobindo's making, using, offering to sell, selling, or importing the Aurobindo Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Aurobindo ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Aurobindo and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using,

offering to sell, selling, or importing the Aurobindo Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if

 Aurobindo engages in the commercial manufacture, use, offer to sell, sale, or importation of the

 Aurobindo Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior
 to six months after the expiration of the '590 patent, and that any such damages or monetary
 relief be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

J. <u>As Against Synthon</u>

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Synthon Atomoxetine Capsules, that Synthon's submission of the Synthon ANDA is an act of infringement of the '590 patent, that Synthon's making, using, offering to sell, selling, or importing the Synthon Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Synthon ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Synthon and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using,

offering to sell, selling, or importing the Synthon Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if

 Synthon engages in the commercial manufacture, use, offer to sell, sale, or importation of the

 Synthon Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to

 six months after the expiration of the '590 patent, and that any such damages or monetary relief

 be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.

K. As Against Zydus

- (1) A declaration that a claim or claims of the '590 patent are infringed by the manufacture, use, sale, offer for sale or importation of the Zydus Atomoxetine Capsules, that Zydus' submission of the Zydus ANDA is an act of infringement of the '590 patent, that Zydus' making, using, offering to sell, selling, or importing the Zydus Atomoxetine Capsules for the treatment of attention-deficit/hyperactivity disorder, and its inducement of such conduct by others, will infringe the '590 patent;
- (2) An Order providing that the effective date of any approval of the Zydus ANDA shall be a date which is not earlier than six months after the expiration of the '590 patent;
- (3) An Order permanently enjoining Zydus and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, using, offering to sell,

selling, or importing the Zydus Atomoxetine Capsules and from inducing or contributing to such conduct by others, until after six months after the expiration of the '590 patent;

- (4) An Order that damages or other monetary relief be awarded to Lilly if Zydus engages in the commercial manufacture, use, offer to sell, sale, or importation of the Zydus Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to six months after the expiration of the '590 patent, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;
- (5) Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Lilly in this action; and
 - (6) Such further and other relief as this Court deems proper and just.
 - L. Such other relief as the Court deems proper and just.

Respectfully submitted,

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