PEPPER HAMILTON LLP
301 Carnegie Center, Suite 400
Princeton, NJ 08543-5276
Phone: (609) 452-0808
Fax: (609) 452-1147

Attorneys for Plaintiff
Eli Lilly and Company

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

ELI LILLY AND COMPANY **Plaintiff,** **v.** **HETERO DRUGS LTD. and HETERO LABS LTD., UNIT V** **Defendants.**	**Civil Action No. 11-3192 (DMC) (JAD)**

FIRST AMENDED COMPLAINT

Plaintiff Eli Lilly and Company ("Lilly") files this First Amended Complaint against Hetero Drugs Limited ("Hetero Drugs") and Hetero Labs Limited, Unit V (collectively "Hetero") under 35 U.S.C. § 271(e)(2) for patent infringement. This action concerns the pharmaceutical drug product Strattera®. Plaintiff, Lilly, hereby alleges as follows:

Parties, Jurisdiction, and Venue

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Upon information and belief, Defendant Hetero Drugs is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, A.P. India. Upon information and belief, Defendant Hetero Labs Limited, Unit V is one of Hetero Drugs' formulation facilities.

3. On information and belief, Hetero Drugs is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Camber Pharmaceuticals Inc. ("Camber") and Hetero USA Inc. ("Hetero USA").

4. On information and belief, Hetero Drugs maintains Camber as a marketing office at 1031 Centennial Avenue, Piscataway, New Jersey 08854. Camber is a wholly owned subsidiary of Hetero Drugs.

5. On information and belief, Hetero USA is registered to do business in New Jersey with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Drugs.

6. On information and belief, Hetero USA operates as the U.S. agent of Hetero Drugs with regard to several generic drug products for which Hetero Drugs seeks approval from the United States Food and Drug Administration ("FDA") to market in the United States.

7. Hetero Labs Limited, Unit V is the named applicant for Abbreviated New Drug Application No. 20-2682, which Hetero submitted to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (the "Hetero ANDA"). Hetero is subject to personal jurisdiction in this judicial district for the purposes of this action, which arises directly

from the filing of the Hetero ANDA. In addition, this court has personal jurisdiction over Hetero because of its continuous and systematic contacts with the State of New Jersey, and because it regularly transacts business in this judicial district, including by and through its two wholly-owned U.S. subsidiaries Camber and Hetero USA that are headquartered in New Jersey. Further, on information and belief, Hetero develops numerous generic pharmaceutical products for sale in the United States, including this judicial district.

8. This action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(a)-(c) and (e)(2), and the Declaratory Judgment Act. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

Plaintiff's Strattera® Products and Related Patent

10. On August 19, 1997, United States Patent No. 5,658,590 (the "'590 patent"), entitled "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 '590 patent expires on November 26, 2016.

11. Strattera® is the brand name for the commercial pharmaceutical product 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.

12. 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.

13. 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.

Hetero's ANDA Filing

14. By a letter dated April 20, 2011 (the "Hetero Notice Letter"), Hetero notified Lilly that Hetero had submitted the Hetero ANDA. On information and belief, the Hetero ANDA seeks approval to engage in the commercial manufacture, use, or sale of Atomoxetine Hydrochloride Capsules, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, and 100 mg (the "Hetero Atomoxetine Capsules") — the generic version of the FDA-approved Strattera® Capsule strengths — before the expiration date of the '590 patent.

15. By filing the Hetero ANDA, Hetero has necessarily represented to the FDA that the Hetero Atomoxetine Capsules have the same active ingredient as Strattera®, have the same route of administration, dosage form, and strength as Strattera®, are bioequivalent to Strattera®, and have the same or substantially the same proposed labeling and use as Strattera®.

16. In the Hetero Notice Letter, Hetero notified Lilly that the Hetero ANDA contains a paragraph IV certification with respect to the '590 patent. Hetero attached to the Hetero Notice Letter a statement asserting its opinion that the '590 patent is invalid or will not be infringed by the Hetero Atomoxetine Capsules.

17. This action is being brought before the expiration of forty-five days from the date Lilly received the Hetero Notice Letter.

Count I: Patent Infringement

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

19. Under 35 U.S.C. § 271(e)(2)(A), Hetero's submission of the Hetero ANDA to the FDA to obtain approval for the commercial manufacture, use, or sale of the Hetero Atomoxetine Capsules in the United States before the expiration date of the '590 patent constitutes an act of infringement.

20. On information and belief, Hetero filed the Hetero ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell the Hetero Atomoxetine Capsules in the United States for the treatment of attention-deficit/hyperactivity disorder. On information and belief, Hetero knows that physicians will use the Hetero Atomoxetine Capsules in accordance with the indications sought by Hetero, and will therefore infringe one or more claims of the '590 patent under 35 U.S.C. § 271(b) and/or (c) either literally or under the doctrine of equivalents.

21. Upon FDA approval of the Hetero ANDA, Hetero will infringe the '590 patent by making, using, offering to sell, or importing the Hetero Atomoxetine Capsules in the United

States, and by actively inducing and/or contributing to infringement by others, unless enjoined by this Court.

22. Hetero had actual knowledge of the '590 patent prior to the filing of the Hetero ANDA. Hetero's threatened manufacture, use, sale, offer for sale and/or importation of the Hetero Atomoxetine Capsules render this case exceptional under 35 U.S.C. § 285 and constitute actual or threatened willful infringement.

23. Lilly will be substantially and irreparably harmed by Hetero's infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

Count II: Declaratory Judgment

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

25. On or around April 20, 2011, Hetero filed or caused to be filed the Hetero ANDA with the FDA, seeking authorization to commercially manufacture, market, use, offer for sale, and sell the Hetero Atomoxetine Capsules within the United States. On information and belief, Hetero seeks approval of at least one indication claimed in the '590 patent for the Hetero Atomoxetine Capsules.

26. On information and belief, Hetero knows that physicians prescribing or using the Hetero Atomoxetine Capsules according to the indications sought by Hetero will be using the Hetero Atomoxetine Capsules in a manner that would infringe one or more claims of the '590 patent, either literally or under the doctrine of equivalents.

27. On information and belief, Hetero plans to begin marketing, selling, and offering to sell the Hetero Atomoxetine Capsules in the United States soon after the FDA has approved such indications.

28. Such conduct will constitute infringement of one or more claims of the '590 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Hetero's infringing activities have been and will continue to be done in willful disregard of Lilly's patent rights.

30. Hetero's infringing activities complained of herein are imminent and will begin following FDA approval of the Hetero ANDA.

31. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Hetero as to liability for the infringement of the '590 patent. Hetero's actions have created in Lilly a reasonable apprehension of irreparable harm and loss resulting from Hetero's threatened imminent actions.

Prayer for Relief

WHEREFORE, Lilly respectfully requests that this Court enter judgment in its favor as follows:

a) declare that United States Patent No. 5,658,590 is valid and enforceable;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Hetero infringed United States Patent No. 5,658,590 by submitting the Hetero ANDA to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States the Hetero Atomoxetine Capsules prior to the expiration of the '590 patent;

c) declare that Hetero's commercial manufacture, use, offer for sale, sale, or importation into the United States of the Hetero Atomoxetine Capsules prior to the expiration of the

'590 patent, and its inducement and/or contribution of such conduct by others, will infringe United States Patent No. 5,658,590;

d) order that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than six months after the expiration date of United States Patent No. 5,658,590;

e) enjoin Hetero, and all persons acting in concert with Hetero, from commercially manufacturing, using, offering for sale, or selling the Hetero Atomoxetine Capsules within the United States, or importing the Hetero Atomoxetine Capsules into the United States, until six months after the expiration of United States Patent No. 5,658,590;

f) award Lilly damages or other monetary relief if Hetero engages in the commercial manufacture, use, offer to sell, sale, or importation of the Hetero Atomoxetine Capsules, or in inducing or contributing to such conduct by others, prior to six months after the expiration of United States Patent No. 5,658,590, and that any such damages or monetary relief be trebled and awarded to Lilly with prejudgment interest;

g) declare this to be an exceptional case and award Lilly its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

h) award Lilly any further appropriate relief under 35 U.S.C. § 271(e)(4); and

i) award Lilly any further and additional relief that this Court deems just and proper.

Dated: June 23, 2011

Respectfully submitted,

ELI LILLY AND COMPANY

By: /s/ John F. Brenner
John F. Brenner
Melissa Chuderewicz
Pepper Hamilton LLP
Suite 400
301 Carnegie Center
Princeton, NJ 08543-5276
Tel: (609) 452-0808
Fax: (609) 452-1147

Attorneys for Plaintiff
Eli Lilly and Company

Of Counsel:

Charles E. Lipsey
L. Scott Burwell
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190-5675
Tel: (571) 203-2700
Fax: (202) 408-4400

Robert D. Bajefsky
Laura P. Masurovsky
Finnegan, Henderson, Farabow
Garrett & Dunner, LLP
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
Tel: (202) 408-4000
Fax: (202) 408-4400