

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

SHIRE LLC,

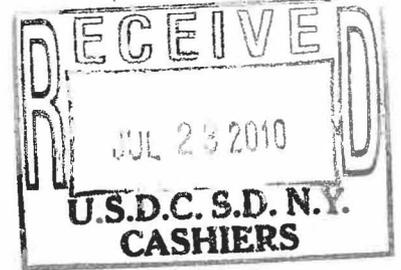
Plaintiff,

v.

TARO PHARMACEUTICAL INDUSTRIES LTD.  
and TARO PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No. \_\_\_\_\_



COMPLAINT

Plaintiff Shire LLC (“Shire”) by its undersigned attorneys, for its Complaint against Defendants Taro Pharmaceutical Industries Ltd. (“Taro Ltd.”) and Taro Pharmaceuticals USA, Inc. (“Taro USA”), herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 5,326,570 (“the ’570 patent”) and 5,912,013 (“the ’013 patent”) (attached as Exhibits A and B, respectively hereto) (collectively “the patents-in-suit”).

THE PARTIES

2. Plaintiff Shire is a corporation organized and existing under the laws of the State of Kentucky, having its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

3. Upon information and belief, Taro Ltd. is a corporation organized and existing

under the laws of Israel, having its principal place of business at Euro Park (Italy Building), Yakum Business Park, Yakum 60972, Israel. Upon information and belief, Taro Ltd. is in the business of developing, manufacturing, and marketing proprietary and generic prescription and over-the-counter pharmaceutical products throughout the world, including the United States and this judicial district. Upon information and belief, stock of Taro Ltd. is publicly traded in the United States.

4. Upon information and belief, Taro USA is a corporation organized and existing under the laws of the State of New York, having its principal place of business at Three Skyline Drive, Hawthorne, New York 10532. Upon information and belief, Taro USA is engaged in the business of manufacturing, distributing, and marketing generic versions of prescription drugs in the United States, including in this judicial district.

5. Upon information and belief, Taro Ltd. owns 96.9% of the equity of Taro USA. Upon information and belief, Taro Ltd. markets its pharmaceutical products in the United States through its subsidiary, Taro USA.

6. Upon information and belief, Taro USA acts under the direction of, under the control of, and for the direct benefit of Taro Ltd. and is controlled and/or dominated by Taro Ltd. Upon information of belief, Taro USA acts as the U.S. agent for Taro Ltd. for purposes of regulatory submissions to the U.S. Food and Drug Administration (“FDA”) seeking approval for generic drugs.

#### **JURISDICTION AND VENUE**

7. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Taro Ltd. because, *inter alia*, of its continuous and systematic contacts with this judicial district. Upon information and belief,

Taro Ltd. markets, sells, and/or distributes pharmaceutical products throughout the United States, including in this judicial district, either directly or through one of its subsidiaries, agents, or distributors, such as Taro USA. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

9. This court has personal jurisdiction over Taro USA. Taro USA has submitted to personal jurisdiction in this Court because, *inter alia*, it is a resident and citizen of the State of New York and has availed itself to the rights and benefits of the laws of New York by virtue of incorporating in New York and engaging in systematic and continuous contacts with New York. The exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

10. Upon information and belief, Taro USA acts as an agent of Taro Ltd. Upon information and belief, Taro USA and Taro Ltd. operate in concert with each other and hold themselves out in the marketplace as one company.

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

### **BACKGROUND**

12. Shire is the owner of New Drug Application (“NDA”) No. 20-712, FDA-approved for the manufacture and sale of extended-release capsules containing carbamazepine for the treatment of epilepsy and trigeminal neuralgia, which are marketed under the name of Carbatrol<sup>®</sup>. Carbatrol<sup>®</sup> is indicated in the treatment of epilepsy and in the treatment of the pain associated with true trigeminal neuralgia.

13. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations”

(commonly known as the “*Orange Book*”) as covering Carbatrol®.

14. Taro prepared and submitted Abbreviated New Drug Application (“ANDA”) No. 201106 (“the Taro ANDA”) to the FDA under § 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 carbamazepine extended-release capsules at the 100 mg, 200 mg, and 300 mg dosage strengths (“Taro’s Proposed Products”).

15. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include “[a] detailed statement of the factual and legal basis of applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement is to include: “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed,” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

16. Taro sent a notice letter addressed to Shire US Inc. and Shire LLC, dated June 9, 2010, purportedly pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)) regarding Taro’s Proposed Products (“the Taro Notice Letter”).

17. In the Taro Notice Letter, Taro did not allege that any claim of the patents-in-suit is invalid or unenforceable.

**FIRST COUNT**

(Infringement of the ’570 Patent by Taro USA and Taro Ltd.)

18. Shire repeats and re-alleges paragraphs 1 through 17 above as if fully set forth

herein.

19. The '570 patent, titled "Advanced Drug Delivery System and Method of Treating Psychiatric, Neurological and Other Disorders with Carbamazepine," was duly and legally issued on July 5, 1994, to Pharmavene, Inc. ("Pharmavene") upon assignment from Edward M. Rudnic and George W. Belendiuk. Upon Pharmavene's merger with and into Shire Laboratories Inc. ("Shire Laboratories"), Shire Laboratories became the owner of the '570 patent. Upon the merger of Shire Laboratories into Shire, Shire became and remains the owner of the '570 patent. The '570 patent claims, *inter alia*, a drug delivery system for the oral administration of carbamazepine.

20. Upon information and belief, Taro seeks FDA approval for the manufacture and/or distribution of Taro's Proposed Products.

21. Upon information and belief, the Taro ANDA includes a paragraph IV certification to the '570 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Taro's Proposed Products before the expiration of the '570 patent.

22. Upon information and belief, Taro USA and/or Taro Ltd. will commercially manufacture, sell, offer for sale, and/or import Taro's Proposed Products immediately upon FDA approval.

23. Upon information and belief, as of the date of the Taro Notice Letter, Taro USA and Taro Ltd. were aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. §314.95(c)(6).

24. The submission and filing of ANDA No. 201106 with a paragraph IV certification to the '570 patent for the purpose of obtaining approval to engage in the commercial

manufacture, use, sale, offer for sale and/or importation of Taro's Proposed Products before the expiration of the '570 patent is an act of infringement by Taro USA and/or Taro Ltd. of one or more claims of the '570 patent under 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Taro's Proposed Products that are the subject of ANDA No. 201106 will infringe one or more claims of the '570 patent.

26. Upon information and belief, the sale or offer for sale of Taro's Proposed Products by Taro USA and/or Taro Ltd. would induce and/or contribute to third-party infringement of one or more claims of the '570 patent under 35 U.S.C. § 271.

27. Upon information and belief, as of the date of the Taro Notice letter, Taro USA and/or Taro Ltd. were aware of the existence of the '570 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '570 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

28. The acts of infringement set forth above will cause Shire irreparable harm for which it will not have adequate remedy at law, unless Taro USA and/or Taro Ltd. are preliminarily and permanently enjoined by this Court.

**SECOND COUNT**

(Induced and/or Contributory Infringement of the '570 Patent by Taro Ltd.)

29. Shire repeats and re-alleges paragraphs 1 through 28 above as if fully set forth herein.

30. Taro Ltd. is jointly and severally liable for Taro USA's infringement of one or more claims of the '570 patent.

31. Upon information and belief, Taro Ltd. knowingly induced Taro USA to infringe and/or contributed to Taro USA's infringement of one or more claims of the '570 patent.

32. Upon information and belief, Taro Ltd. actively induced, encouraged, aided, or abetted Taro USA's preparation and submission and filing of ANDA No. 201106 with a paragraph IV certification to the '570 patent.

33. Taro Ltd.'s inducement, encouragement, aiding, or abetting of Taro USA's preparation, submission, and filing of ANDA No. 201106 with a paragraph IV certification constitutes infringement of the '570 patent under 35 U.S.C. § 271(e)(2)(A). Further, Taro Ltd.'s commercial use, sale, offer for sale, and/or importation of Taro's Proposed Products would induce and/or contribute to Taro USA's infringement of the '570 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

34. Upon information and belief, Taro Ltd.'s inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of Taro's Proposed Products by Taro USA would induce and/or contribute to third-party infringement of one or more claims of the '570 patent under 35 U.S.C. § 271.

35. Upon information and belief, Taro Ltd. has, continues to, and will actively induce, encourage, aid, or abet Taro USA's infringement of the '570 patent with knowledge that it is in contravention of the rights of Shire.

36. Upon information and belief, as of the date of the Taro Notice Letter, Taro Ltd. was aware of the existence of the '570 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to the Taro USA infringement and/or third party infringement of the '570 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

37. The acts of infringement set forth above will cause Shire irreparable harm for which it will not have adequate remedy at law, unless Taro Ltd. is preliminarily and

permanently enjoined by this Court.

**THIRD COUNT**

(Infringement of the '013 Patent by Taro USA and Taro Ltd.)

38. Shire repeats and re-alleges paragraphs 1 through 17 above as if fully set forth herein.

39. The '013 patent, titled "Advanced Drug Delivery System and Method of Treating Psychiatric, Neurological and Other Disorders with Carbamazepine," was duly and legally issued on June 15, 1999, to Shire Laboratories, a predecessor company to Shire. Before the patent issued, the inventors, Edward M. Rudnic, George W. Belendiuk, John McCarty, Sandra Wassink and Richard A. Couch, assigned their interest to Pharmavene, which eventually merged with and into Shire Laboratories. Upon the merger of Shire Laboratories into Shire, Shire became and remains the owner of the '013 patent. The '013 patent claims, *inter alia*, a pharmaceutical formulation containing carbamazepine.

40. Upon information and belief, Taro seeks FDA approval for the manufacture and/or distribution of Taro's Proposed Products.

41. Upon information and belief, the Taro ANDA includes a paragraph IV certification to the '013 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Taro's Proposed Products before the expiration of the '013 patent.

42. Upon information and belief, Taro USA and/or Taro Ltd. will commercially manufacture, sell, offer for sale, and/or import Taro's Proposed Products immediately upon FDA approval.

43. Upon information and belief, as of the date of the Taro Notice Letter, Taro USA and Taro Ltd. were aware of the statutory provisions and regulations set forth in 21 U.S.C. §

355(j)(2)(B)(iv)(II) and 21 C.F.R. §314.95(c)(6).

44. The submission and filing of ANDA No. 201106 with a paragraph IV certification to the '013 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Taro's Proposed Products before the expiration of the '013 patent is an act of infringement by Taro USA and/or Taro Ltd. of one or more claims of the '013 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Taro's Proposed Products that are the subject of ANDA No. 201106 will infringe one or more claims of the '013 patent.

46. Upon information and belief, as of the date of the Taro Notice letter, Taro USA and/or Taro Ltd. were aware of the existence of the '013 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '013 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

47. The acts of infringement set forth above will cause Shire irreparable harm for which it will not have adequate remedy at law, unless Taro USA and/or Taro Ltd. are preliminarily and permanently enjoined by this Court.

**FOURTH COUNT**

(Contributory Infringement of the '013 Patent by Taro Ltd.)

48. Shire repeats and re-alleges paragraphs 1 through 17 and 39 through 47 above as if fully set forth herein.

49. Taro Ltd. is jointly and severally liable for Taro USA's infringement of one or more claims of the '013 patent.

50. Upon information and belief, Taro Ltd. knowingly induced Taro USA to infringe and/or contributed to Taro USA's infringement of one or more claims of the '013 patent.

51. Upon information and belief, Taro Ltd. actively induced, encouraged, aided, or abetted Taro USA's preparation and submission and filing of ANDA No. 201106 with a paragraph IV certification to the '013 patent.

52. Taro Ltd.'s inducement, encouragement, aiding, or abetting of Taro USA's preparation, submission, and filing of ANDA No. 201106 with a paragraph IV certification constitutes infringement of the '013 patent under 35 U.S.C. § 271(e)(2)(A). Further, Taro Ltd.'s commercial use, sale, offer for sale, and/or importation of Taro's Proposed Products would induce and/or contribute to Taro USA's infringement of the '013 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

53. Upon information and belief, Taro Ltd. has, continues to, and will actively induce, encourage, aid, or abet Taro USA's infringement of the '013 patent with knowledge that it is in contravention of the rights of Shire.

54. Upon information and belief, as of the date of the Taro Notice Letter, Taro Ltd. was aware of the existence of the '013 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to the Taro USA infringement of the '013 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

55. The acts of infringement set forth above will cause Shire irreparable harm for which it will not have adequate remedy at law, unless Taro Ltd. is preliminarily and permanently enjoined by this Court.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff respectfully requests the following relief:

- (a) A judgment declaring that the '570 patent is valid and enforceable;
- (b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 201106 with paragraph IV certifications to the FDA to obtain

approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '570 patent was an act of infringement of '570 patent by Taro USA and Taro Ltd., individually and collectively;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '570 patent will constitute an act of infringement of the '570 patent by Taro USA and Taro Ltd., individually and collectively;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Taro Ltd. has and continues to induce and/or contribute to Taro USA's infringement of the '570 patent based on the submission to the FDA of ANDA No. 201106 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '570 patent;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Taro Ltd. would induce and/or contribute to Taro USA's infringement of the '570 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '570 patent;

(f) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 by Taro USA and/or Taro Ltd.

would induce and/or contribute to third-party infringement of the '570 patent;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Taro Ltd.'s inducement, encouragement, aiding, or abetting of Taro USA's commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 would induce and/or contribute to third-party infringement of the '570 patent;

(h) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 201106 shall be no earlier than the date on which the '570 patent expires;

(i) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Taro USA, Taro Ltd., their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 until the expiration of the '570 patent;

(j) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Taro USA and/or Taro Ltd. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201106 prior to the expiration of the '570 patent;

(k) A judgment declaring that Taro USA and Taro Ltd.'s infringement of the '570 patent based on ANDA No. 201106 is willful if Taro USA and/or Taro Ltd. commercially manufacture, use, sell, offer to sell, and/or import any products that are the subject of ANDA No. 201106 prior to the expiration of the '570 patent;

(l) A judgment declaring that the '013 patent is valid and enforceable;

(m) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 201106 with paragraph IV certifications to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '013 patent was an act of infringement of '013 patent by Taro USA and Taro Ltd., individually and collectively;

(n) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '013 patent will constitute an act of infringement of the '013 patent by Taro USA and Taro Ltd., individually and collectively;

(o) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Taro Ltd. has and continues to induce and/or contribute to Taro USA's infringement of the '013 patent based on the submission to the FDA of ANDA No. 201106 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '013 patent;

(p) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Taro Ltd. would induce and/or contribute to Taro USA's infringement of the '013 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 prior to the expiration of the '013 patent;

(q) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 201106 shall be no earlier than the date on which the '013 patent expires;

(r) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Taro USA, Taro Ltd., their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 201106 until the expiration of the '013 patent;

(s) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Taro USA and/or Taro Ltd. commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 201106 prior to the expiration of the '013 patent;

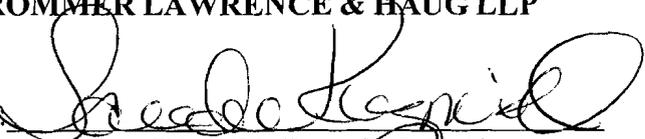
(t) A judgment declaring that Taro USA and Taro Ltd.'s infringement of the '013 patent based on ANDA No. 201106 is willful if Taro USA and/or Taro Ltd. commercially manufacture, use, sell, offer to sell, and/or import any products that are the subject of ANDA No. 201106 prior to the expiration of the '013 patent;

(u) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees and costs;

(v) Such other and further relief as this Court may deem just and proper.

**FROMMER LAWRENCE & HAUG LLP**

Dated: July 23, 2010

By: 

Edgar H. Haug (EH 6243)  
Sandra Kuzmich (SK 5484)  
745 Fifth Avenue  
New York, New York 10151  
Telephone: (212) 588-0800  
Facsimile: (212)588-0500

Attorneys for Plaintiff  
Shire LLC