IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
HETERO USA INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT V,	)	
Defendants.	)	

COMPLAINT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka") files this complaint for patent infringement against Defendants Hetero USA Inc. ("Hetero USA"), Hetero Labs Ltd. ("Hetero Labs"), and Hetero Labs Ltd. Unit V ("Unit V") (collectively "Hetero" or "Defendants") and, in support thereof, alleges as follows:

NATURE OF THE ACTION

1. This action for patent infringement relates to an Abbreviated New Drug Application ("ANDA") submitted by and/or for the benefit of Hetero with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Otsuka's SAMSCA® (tolvaptan) product that is sold in the United States.

PARTIES

2. Otsuka Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka Pharmaceutical Co., Ltd. is engaged in the research, development, manufacture and sale of pharmaceutical products.

3. Upon information and belief, Defendant Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854, and is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South DuPont Highway, Dover, DE 19901) for the receipt of service of process.

4. Upon information and belief, Defendant Hetero Labs is an Indian corporation having a principal place of business at 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad, 500 018 Andhra Pradesh, India.

5. Upon information and belief, Defendant Unit V is a division of Hetero Labs having a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India. Hetero Labs's website, located at http://www.heterodrugs.com/mfg-formulation-facilities.shtml, describes Unit V as a manufacturing facility of Hetero Labs.

6. Upon information and belief, Hetero Labs is the parent corporation of Hetero USA and Unit V.

7. Upon information and belief, the primary business of Hetero Labs and Unit V, directly or through Hetero USA and/or through one or more of its subsidiaries, is marketing and selling pharmaceutical products, including generic versions of brand name prescription drug products, throughout the United States, including Delaware.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. Upon information and belief, Hetero USA is a Delaware corporation, is registered to do business in Delaware, and has extensive contacts with the State of Delaware.

10. Upon information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs in Delaware and throughout the United States.

11. Upon information and belief, the acts of Hetero USA discussed in this Complaint were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs and Unit V. In its February 12, 2014 letter notifying Otsuka of its submission to the FDA of ANDA No. 205646 for Hetero's generic tolvaptan tablets, Hetero USA described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit V" for purposes of making regulatory submissions to the FDA.

12. Upon information and belief, Hetero Labs and Unit V, directly or through Hetero USA and/or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs in Delaware and throughout the United States. Upon information and belief, Hetero Labs and Unit V, either directly or through Hetero USA and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

13. Hetero USA's acts and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs and Unit V, are also attributable to Hetero Labs and Unit V for jurisdictional purposes.

14. Hetero USA and Hetero Labs have previously consented to the personal jurisdiction of this Court on multiple occasions, and have availed themselves of this Court by

asserting declaratory judgment counterclaims for the purpose of litigating other patent disputes. *See Kissei Pharmaceutical Co., Ltd. et al. v. Hetero USA Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit III*, C.A. No. 13-1091 (D. Del. Oct. 3, 2013); *Forest Laboratories, Inc. et al. v. Hetero USA Inc., Hetero Labs Ltd.*, C.A. No. 13-1603 (D. Del. Nov. 22, 2013).

15. Upon information and belief, this court has personal jurisdiction over Hetero USA by virtue of, inter alia: (1) its incorporation in the State of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the receipt of service of process; (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its previous consent to this Court's jurisdiction.

16. Upon information and belief, this Court has personal jurisdiction over Hetero Labs by virtue of, inter alia: (1) its presence in Delaware, including through Hetero USA; (2) its course of conduct that is designed to cause the performance of tortious acts that will result in the foreseeable harm in Delaware; (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (4) its previous consent to this Court's jurisdiction.

17. Upon information and belief, this Court has personal jurisdiction over Unit V by virtue of, inter alia: (1) its presence in Delaware, including through Hetero USA, its "U.S. Regulatory Agent;" and (2) its course of conduct that is designed to cause the performance of tortious acts that will result in the foreseeable harm in Delaware.

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

FACTUAL BACKGROUND

Otsuka's SAMSCA® Product

19. SAMSCA® is an oral medication used to treat hyponatremia (low blood sodium levels) in adults with conditions including congestive heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone. On October 23, 2007, Otsuka America Pharmaceutical, Inc. filed an NDA seeking approval to market SAMSCA® (tolvaptan) (NDA- 22-275). On May 19, 2009, the FDA approved NDA 22-275.

The '677 Patent

20. U.S. Patent No. 5,753,677 ("the '677 patent"), entitled "Benzoheterocyclic Compounds," was duly and legally issued on May 19, 1998 to inventors Hidenori Ogawa, Hisashi Miyamoto, Kazumi Kondo, Hiroshi Yamashita, Kenji Nakaya, Hajime Komatsu, Michinori Tanaka, Shinya Kora, Michiaki Tominaga, and Yoichi Yabuuchi. A true and correct copy of the '677 patent is attached hereto as Exhibit A. The '677 patent claims methods for antagonizing vasopressin in a subject using novel benzoheterocyclic compounds, including the pharmaceutical composition sold as SAMSCA®. The claims of the '677 patent are valid and enforceable. Otsuka Pharmaceutical Co., Ltd. is the assignee of the '677 patent. The '677 patent expires in 2020.

21. The '677 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to SAMSCA® tablets, 15 and 30 mg dosage forms.

Hetero's ANDA Filings and Notice Letter

22. On information and belief, Hetero submitted ANDA No. 205646 ("Hetero's ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §

355(j). Hetero is seeking approval from the FDA to market and sell tolvaptan tablets, 15 and 30 mg ("Hetero's generic tolvaptan tablets"), as a generic version of Otsuka's SAMSCA® product, prior to the expiration of the '677 patent.

23. Hetero previously made, and included in its ANDA No. 205646, a "Paragraph III" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III), alleging that the'677 patent would expire before requested approval for the commercial manufacture, use, or sale of Hetero's generic tolvaptan tablets.

24. By letter dated August 26, 2015 ("Hetero's '677 Notice Letter"), purporting to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Under 21 C.F.R. § 314.95," Hetero USA, as "the U.S. Regulatory Agent for Hetero Labs Limited Unit V," notified Otsuka that it had submitted ANDA No. 205646 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of Hetero's tolvaptan tablet products, which are generic versions of SAMSCA® 15 mg and 30 mg capsules, prior to the expiration of the '677 patent.

25. Otsuka received Hetero's '677 Notice Letter on August 31, 2015.

26. Hetero made, and included in its ANDA No. 205646, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '677 patent are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's generic tolvaptan tablets.

27. Hetero's submission of ANDA No. 205646 to the FDA constitutes infringement of the '677 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, and/or import of Hetero's generic tolvaptan tablets into the United States would infringe the '677 patent under 35 U.S.C. § 271(a)-(c).

28. This suit is being filed within 45 days of Otsuka's receipt of Hetero's '677 Notice Letter.

COUNT I: INFRINGEMENT OF THE '677 PATENT

29. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

30. Hetero's submission of ANDA No. 205646 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Hetero's generic tolvaptan tablet products prior to the expiration of the '677 patent constitutes infringement of one or more of the valid claims of the '677 patent under 35 U.S.C. § 271(e)(2)(A).

31. Hetero's commercial manufacture, use, offer to sell, sale, or importation of its generic tolvaptan tablet product prior to the expiration of the '677 patent, or its inducement of or contribution to such conduct, would further infringe the '677 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

32. Hetero's filing of its ANDA, and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Hetero's generic tolvaptan tablet product upon receiving FDA approval, create an actual case or controversy with respect to infringement of the '677 patent.

33. Upon FDA approval of Hetero's ANDA, Hetero will infringe the '677 patent by making, using, offering to sell, selling, or importing its generic tolvaptan tablet product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

COUNT II: DECLARATORY JUDGMENT AS TO THE '677 PATENT

34. Otsuka incorporates each of the preceding paragraphs as if fully set forth herein.

35. Upon information and belief, Hetero has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import Hetero's generic tolvaptan tablets into the United States prior to expiration of the '677 patent.

36. Upon information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Hetero's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Hetero's generic tolvaptan tablet products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '677 patent.

37. Upon information and belief, Hetero maintains, and Otsuka denies, that the '677 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's generic tolvaptan tablet products. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Otsuka and Hetero regarding whether Hetero's commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero's generic tolvaptan tablet products according to ANDA No. 205646 will infringe one or more claims of the '677 patent. Plaintiffs are thus entitled to a declaration that Hetero's commercial manufacture, use, sale, offer for sale, and importation into the United States of Hetero's generic tolvaptan tablet products according to ANDA No. 205646 will infringe one or more claims of the '677 patent.

PRAYER FOR RELIEF

WHEREFORE, Otsuka requests entry of judgment in its favor and against Hetero and prays that the Court:

A. Enter a declaratory judgment that: (1) a claim or claims of the ’677 patent are infringed by the manufacture, use, sale, offer for sale or importation of Hetero’s generic tolvaptan tablet products; (2) that Hetero’s submission of Hetero’s ANDA No. 205646 is an act of infringement of the ’677 patent; (3) that Hetero’s making, using, offering to sell, selling, or importing Hetero’s generic tolvaptan tablet products, and its inducement of such conduct by others, will infringe the ’677 patent;

B. Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Hetero’s ANDA No. 205646 shall be a date which is not earlier than the expiration of the ’677 patent and any additional period of exclusivity to which Otsuka is or becomes entitled;

C. Permanently enjoin Hetero and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from making, using, offering to sell, selling, or importing Hetero’s generic tolvaptan tablet products and from inducing such conduct by others, until after expiration of the ’677 patents and any additional period of exclusivity to which Otsuka is or may become entitled;

D. Award reasonable attorneys’ fees, filing fees, and costs of suit incurred by Otsuka in this action; and

E. Award such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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

Attorneys for Plaintiff

OF COUNSEL:

Jonathan G. Graves
COOLEY LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190
(703) 456-8000

Susan Krumplitsch
COOLEY LLP
3175 Hanover Street
Palo Alto, CA 94304
(650) 843-5000

Scott Sukenick
COOLEY LLP
1114 Avenue of the Americas
New York, NY 10036
(212) 479-6000

September 15, 2015