IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka") files this complaint for patent infringement against Defendant Par Pharmaceutical, Inc. ("Par") and, in support thereof, alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 5,753,677 ("the '677 patent") and 8,501,730 ("the '730 patent"). This action relates to an Abbreviated New Drug Application ("ANDA") submitted by and/or for the benefit of Par 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, Par is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, NY 10977. Par's primary business is marketing and selling pharmaceutical products, including generic versions of brand name prescription drug products, throughout the United States, including Delaware.

JURISDICTION AND VENUE

4. 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.

5. This Court has personal jurisdiction over Par because, among other reasons, it is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this district. Par consented to the personal jurisdiction of this Court in a previous matter. *See Otsuka Pharm. Co., Ltd. v. Par Pharm., Inc.*, Case No. 1:13-cv-01979, Defendant Par Pharm., Inc.'s Answer and Counterclaims (D.I. 7) at ¶10 (Dec. 18, 2013). Upon information and belief, Par has also previously consented to the personal jurisdiction of this Court on multiple additional occasions and has previously availed itself of this Court by filing suit and asserting counterclaims in other civil actions initiated in this jurisdiction.

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

FACTUAL BACKGROUND

Otsuka's SAMSCA® Product

7. 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

8. 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.

9. 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.

The ’730 Patent

10. The ’730 patent, entitled “Process for preparing benzazepine compounds or salts thereof,” was duly and legally issued on August 6, 2013 to inventors Yasuhiro Torisawa, Kaoru Abe, Yasuaki Muguruma, Shigekazu Fujita, Hidenori Ogawa, Naoto Utsumi, and Masahiro Miyake. A true and correct copy of the ’730 patent is attached hereto as Exhibit B. The ’730 patent claims processes for preparing novel benzazepine compounds. The claims of the ’730 patent are valid and enforceable. Otsuka Pharmaceutical Co., Ltd. is the assignee of the ’730 patent. The ’730 patent expires in 2026.

11. The ’730 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.

Par's ANDA Filings and Notice Letter

12. On information and belief, Par submitted ANDA No. 206119 ("Par's ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). Par is seeking approval from the FDA to market and sell tolvaptan tablets, 15 and 30 mg ("Par's generic tolvaptan tablets"), as a generic version of Otsuka's SAMSCA® product, prior to the expiration of the '677 and '730 patents.

13. On or about October 10, 2013, Par sent a "Notice of Paragraph IV Certification" letters (the "Purported First Notice Letters") to Otsuka, the patent owner, and Otsuka America Pharmaceutical, Inc., the NDA holder, regarding an amendment to Par's ANDA submission (No. 206119) to the FDA under 21 U.S.C. § 355(j)(2)(B)(ii)(II).[1] At the time Par sent its Purported First Notice Letters, Par's ANDA No. 206119 had not yet been accepted for filing by the FDA. As a result, Par's Purported First Notice Letters were premature, improper, and not lawful.

14. Otsuka requested that Par withdraw the invalid Purported First Notice Letters, but Par refused. Accordingly, Otsuka filed suit against Par seeking, *inter alia*, a declaratory judgment that Par's premature notice letter was invalid and without legal effect. On March 10, 2014, the Court in that action granted Otsuka's motion for judgment on the pleadings that Par's Notice letter was premature and improper, and dismissed all other claims of all parties without prejudice. *Otsuka Pharmaceutical Co., Ltd. v. Par Pharm., Inc.*, Case No. 13-cv-01979-RGA, Order (D.I. 24) (March 10, 2014).

15. On information and belief, the FDA subsequently notified Par that its ANDA had been accepted for filing.

[1] Par's Paragraph IV Notice Letters were received by Otsuka Pharmaceutical Co., Ltd., and Otsuka America Pharmaceutical, Inc. on October 15 and October 14, 2013, respectively.

16. By letter dated May 5, 2014 ("Par's Second Notice Letter"), Par again notified Otsuka that it had submitted ANDA No. 206119 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of Par's tolvaptan tablet products, which are generic versions of SAMSCA® 15 mg and 30 mg capsules, prior to the expiration of the '677 and '730 patent.

17. Otsuka received Par's Second Notice Letter on May 8, 2014.

18. Par made, and included in its ANDA No. 206119, "Paragraph IV" certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '677 and '730 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Par's generic tolvaptan tablets.

19. Par's submission of ANDA No. 206119 to the FDA constitutes infringement of the '730 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, and/or import of Par's generic tolvaptan tablets into the United States would infringe the '677 and '730 patents under 35 U.S.C. § 271(a)-(c).

20. This suit is being filed within 45 days of Otsuka's receipt of Par's Second Notice Letter.

COUNT I: INFRINGEMENT OF THE '677 PATENT

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

22. Par's submission of ANDA No. 206119 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Par'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).

23. Par'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).

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

25. Upon FDA approval of Par's ANDA, Par 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.

26. Unless Par is enjoined from infringing the '677 patent and/or actively inducing the infringement of the '677 patent, Otsuka will suffer irreparable injury. Otsuka has no adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '730 PATENT

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

28. Par's submission of ANDA No. 206119 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Par's generic tolvaptan tablet products prior to the expiration of the '730 patent constitutes infringement of one or more of the valid claims of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

29. Par's commercial manufacture, use, offer to sell, sale, or importation of its generic tolvaptan tablet product prior to the expiration of the '730 patent, or its inducement of or

contribution to such conduct, would further infringe the ’730 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

30. Par’s filing of its ANDA, and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Par’s generic tolvaptan tablet product upon receiving FDA approval, create an actual case or controversy with respect to infringement of the ’730 patent.

31. Upon FDA approval of Par’s ANDA, Par will infringe the ’730 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.

32. Unless Par is enjoined from infringing the ’730 patent and/or actively inducing the infringement of the ’730 patent, Otsuka will suffer irreparable injury. Otsuka has no adequate remedy at law.

COUNT III: DECLARATORY JUDGMENT AS TO THE ’677 PATENT

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

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

35. Upon information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Par’s commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Par’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.

36. Upon information and belief, Par 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 Par’s generic tolvaptan tablet products. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Otsuka and Par regarding whether Par’s commercial manufacture, use, sale, offer for sale, or importation into the United States of Par’s generic tolvaptan tablet products according to ANDA No. 206119 will infringe one or more claims of the ’677 patent. Plaintiffs are thus entitled to a declaration that Par’s commercial manufacture, use, sale, offer for sale, and importation into the United States of Par’s generic tolvaptan tablet products according to ANDA No. 206119 will infringe one or more claims of the ’677 patent.

COUNT IV: DECLARATORY JUDGMENT AS TO THE ’730 PATENT

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

38. Upon information and belief, Par has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import Par’s generic tolvaptan tablets into the United States prior to expiration of the ’730 patent.

39. Upon information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Par’s commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Par’s generic tolvaptan tablet products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’730 patent.

40. Upon information and belief, Par maintains, and Otsuka denies, that the ‘730 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Par’s generic tolvaptan tablet products. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Otsuka and Par

regarding whether Par's commercial manufacture, use, sale, offer for sale, or importation into the United States of Par's generic tolvaptan tablet products according to ANDA No. 206119 will infringe one or more claims of the '730 patent. Plaintiffs are thus entitled to a declaration that Par's commercial manufacture, use, sale, offer for sale, and importation into the United States of Par's generic tolvaptan tablet products according to ANDA No. 206119 will infringe one or more claims of the '730 patent.

PRAYER FOR RELIEF

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

A. Enter a declaratory judgment that: (1) a claim or claims of the '677 and '730 patents are infringed by the manufacture, use, sale, offer for sale or importation of Par's generic tolvaptan tablet products; (2) that Par's submission of Par's ANDA No. 206119 is an act of infringement of the '677 and '730 patents; (3) that Par's making, using, offering to sell, selling, or importing Par's generic tolvaptan tablet products, and its inducement of such conduct by others, will infringe the '677 and '730 patents;

B. Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Par's ANDA No. 206119, or any product or compound that infringes the '677 or '730 patents, shall be a date which is not earlier than the expiration of the '677 and '730 patents and any additional period of exclusivity to which Otsuka is or becomes entitled;

C. Permanently enjoin Par and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from making, have made, using, offering to sell, selling, marketing, distributing, or importing Par's generic tolvaptan tablet products, or any product or compound that infringes the '677 or '730 patents, and from inducing such conduct by others,

until after expiration of the '677 and '730 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.

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