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 declaratory relief, or in the alternative, for patent infringement against Defendant Par Pharmaceutical, Inc. ("Par") and, in support thereof, alleges as follows:

NATURE OF THE ACTION

1. In this action, Otsuka seeks to block Par's premature and improper triggering of the litigation process carefully constructed by Congress for resolving patent disputes when a drug company seeks approval to market a generic version of a branded drug by filing an Abbreviated New Drug Application ("ANDA"), as described in more detail in paragraphs 12-20 below.

2. Upon information and belief, as of October 10, 2013, Par did not have an ANDA with respect to Otsuka's SAMSCA® (tolvaptan) that had been accepted for review by the United States Food and Drug Administration ("FDA"). The acceptance of an ANDA by the FDA is a prerequisite that must be satisfied before Par can send Otsuka proper notification that an ANDA containing a "Paragraph IV certification" has been filed. Such a notice letter, if it were valid, would start a time period in which Otsuka must sue for patent infringement in order to obtain a

30-month statutory period during which the FDA cannot approve Par's ANDA. Because, upon information and belief, Par's ANDA had not yet been accepted by the FDA, Par could not send a valid notice letter to Otsuka, and therefore could not trigger Otsuka's statutory right to sue for infringement or commence the 30-month stay.

3. Nonetheless, on or about October 10, 2013, Par sent purported "Notice of Paragraph IV Certification" letters (the "Purported Notice Letters") to Otsuka, the patent owner, and Otsuka America Pharmaceutical, Inc., the NDA holder, regarding an amendment to Par's not-yet-accepted ANDA submission (No. 206119) to the FDA under 21 U.S.C. § 355(j)(2)(B)(ii)(II).[1] Par's Purported Notice Letters state that Otsuka's patents related to SAMSCA® (tolvaptan) are either invalid or will not be infringed by Par's generic tolvaptan tablet product. Because, upon information and belief, Par's initial ANDA submission has not yet been accepted for review by the FDA, it necessarily follows that Par's amendment could not have yet been accepted for review. As a result, Par's Purported Notice Letters were premature, improper, and not lawful. Par's letters therefore cannot trigger Otsuka's right or obligation to sue Par or begin the 30-month stay of ANDA approval under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3).

4. Par has refused to withdraw its improper letters.

5. Because Par's premature attempt to trigger the ANDA patent litigation process is in violation of federal law, this Court should declare Par's actions improper and without legal effect.

6. In addition, because Par's proposed generic product would infringe United States Patent Nos. 5,753,677 (the "'677 patent") and 8,501,730 B2 (the "'730 patent"), the filing of a

[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.

proper ANDA which is accepted for filing by the FDA is an act of infringement under 35 U.S.C. 271(e)(2). Accordingly, in the alternative, if the purported Paragraph IV notification received by Otsuka is deemed sufficient by the Court to trigger the deadline for Otsuka to sue Par under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3), Otsuka seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 et. seq. and other applicable laws for Par's infringement of its patents.

PARTIES

7. 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.

8. 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

9. 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.

10. 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. Upon information and belief, Par has previously consented to the personal jurisdiction of this Court on multiple occasions and has previously availed itself of this Court by filing suit and asserting counterclaims in other civil actions initiated in this jurisdiction.

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

FACTUAL BACKGROUND

The Drug Approval Process

12. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to the FDA. The FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(l) and (c)(2).

13. A company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may rely on the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug.

14. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. §

355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This certification is known as a "Paragraph IV Certification."

15. When an applicant submits an ANDA to the FDA, the FDA has 60 days to preliminarily review it to ensure that it is sufficiently complete to permit substantive review. 21 C.F.R.§ 314.101. Only after the FDA notifies the applicant that its ANDA is substantially complete is the ANDA deemed to have been "received" by the FDA. *Id.*

16. The applicant of an ANDA which is accepted for review by the FDA that contains a Paragraph IV Certification must provide notice to both the owner of the listed patent and the holder of the NDA for the reference listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid and/or not infringed by the proposed generic product. *See* 21 U.S.C. § 355(j)(2)(B); 21C.F.R.§ 314.95. Federal regulations specifically govern the timing of such Paragraph IV Notifications by directing that the sending of such notices should occur only after FDA has officially received the ANDA as "sufficiently complete" for review. *See* 21 U.S.C. § 355(j)(2)(B)(ii); 21 C.F.R. § 314.95(b).

17. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a proper Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to innovator companies, such as Otsuka, because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. The innovator company is thus assured of a 30-month

period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

18. There are powerful incentives for generic companies to obtain the earliest possible filing date by "jumping the gun" with incomplete ANDA filings. The earliest ANDA filer may be entitled to 180 days of generic market exclusivity, during which time no other ANDA filer may come to market with a competing generic product. *See* 21 U.S.C. § 355(j)(5)(B)(iv). By filing prematurely or notifying the NDA holder or patent owner prematurely, the first ANDA filer may also be able to manipulate the rules surrounding the 30-month stay to its advantage and reach the market sooner than would otherwise be permitted.

19. Accordingly, one of the important protections built into the ANDA process is that a generic applicant may not even send a Paragraph IV Notice until it "receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

20. This safeguard makes simple common sense. Incomplete ANDAs risk burdening the judicial system with premature, and perhaps entirely unnecessary, patent infringement litigation. If the incomplete ANDA is never completed, forcing the parties and the courts to conduct infringement litigation will be unnecessary and generate unnecessary litigation costs. Even if the incomplete ANDA is eventually completed, the premature filing would prejudice not only the innovator company, but also other ANDA filers. Accordingly, the ANDA applicant may not trigger the litigation process by serving a Paragraph IV Notice unless and until it has an ANDA on file that the FDA has accepted for substantive review.

Otsuka's SAMSCA® Product

21. 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

22. The '677 patent, entitled "Benzohetercyclic 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.

The '730 Patent

23. 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, including the active ingredient, tolvaptan, of the pharmaceutical composition sold as SAMSCA®. 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.

Par's ANDA Filings and Notice Letter

24. On information and belief, Par submitted ANDA No. 206119 ("Par's ANDA") seeking approval from the FDA to market Tolvaptan Tablets, a generic version of Otsuka's SAMSCA® product.

25. On information and belief, as of October 10, 2013, the FDA had not notified Par that Par's ANDA was sufficiently complete to be accepted for review.

26. Nevertheless, on or about October 10, 2013, Par sent Otsuka its Purported Notice Letters, advising Otsuka of its assertion that the '677 patent is invalid, and that the '730 patent is invalid and not infringed by Par's proposed generic product.

27. Otsuka confirmed with the FDA that as of November 14, 2013, Par's ANDA No. 206119 had not been accepted by the FDA for review.

28. Otsuka has requested that Par withdraw its premature and ineffective notice, but Par has so far refused to do so. *See* Exhibits C, D.

29. This suit is being filed within 45 days of Otsuka's receipt of Par's improper Purported Notice Letters.

COUNT I: DECLARATORY JUDGMENT

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

31. At the time of its Purported Notice Letters, Par did not have an ANDA for its generic tolvaptan tablet product that had been accepted by the FDA as sufficiently complete for substantive review. Because Par did not (and, on information and belief, does not) have an

ANDA that has been accepted by the FDA, Par has no legitimate basis to trigger the ANDA patent litigation process.

32. As a consequence, Par's Purported Notice Letters to Otsuka were improper, null, void, and without legal effect.

33. Otuska has asked Par to withdraw the improper notice, but Par has refused.

34. An actual, substantial and justiciable controversy exists between Par and Otsuka regarding whether Par's Purported Notice Letters were null, void, and without legal effect and, as a consequence, whether Par improperly triggered the ANDA litigation process.

35. The controversy concerning the validity and effectiveness of Par's Purported Notice Letters has caused, and will continue to cause, Otsuka to suffer substantial prejudice and unnecessary legal fees and costs unless the controversy and the surrounding cloud of uncertainty is resolved by the Court.

36. Accordingly, Otsuka is entitled to a declaration that: (1) Par's Purported Notice Letters are improper, null, void, and without legal effect, and that Par was not entitled to trigger the ANDA patent litigation process; (2) this Court has no subject matter jurisdiction over Otsuka's alternative claims regarding infringement of the '677 and '730 patents because Par's Purported Notice Letters are null, void, and without legal effect; (3) the Purported Notice Letters served by Par did not commence the 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when the FDA accepts Par's ANDA, Par must serve new and valid Paragraph IV Notices on Otsuka pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) the 30-month stay and 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) will not begin until Par has sent valid Paragraph IV Notices to Otsuka following FDA acceptance of Par's ANDA.

COUNT II: INFRINGEMENT OF THE '677 PATENT

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

38. If proper, Par's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Par's generic tolvaptan tablet product 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).

39. Par's commercial manufacture, use, offer to sell, sale, or importation of Par's 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). 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.

40. 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.

COUNT III: INFRINGEMENT OF THE '730 PATENT

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

42. If proper, Par's submission of Defendants' ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Par's generic tolvaptan tablet product 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).

43. 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). 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.

44. 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.

PRAYER FOR RELIEF

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

A. Preliminarily and permanently enjoin Par (1) to withdraw its improper and ineffective Purported Notice Letters, and (2) to refrain from sending any new Paragraph IV Notice letters to Otsuka unless and until the FDA has notified Par that its ANDA is sufficiently complete to be deemed received for review.

B. Enter a declaratory judgment that: (1) Par's Purported Notice Letters are improper, null, void, and without legal effect and that Par was not entitled to trigger the ANDA patent litigation process; (2) this Court has no jurisdiction over Otsuka's alternative claims regarding the '677 and '730 patents because Par's Purported Notice Letters are null, void, and without legal effect; (3) the Purported Notice Letters served by Par did not commence the 45 day

period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(S)(B)(iii); (4) if and when the FDA accepts Par's ANDA, Par must serve new and valid Paragraph IV Notices on Otsuka pursuant to 21 U.S.C. § 355(j)(2)(A)(vii); and (5) the 30-month stay and 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) will not begin until Par has sent valid Paragraph IV Notices to Otsuka following FDA acceptance of Par's ANDA.

E. In the alternative, enter judgment that a claim or claims of the '677 patent are infringed by the manufacture, use, sale, offer for sale or importation of Par's Tolvaptan Tablet products, that Par's submission of Par's ANDA is an act of infringement of the '677 patent, that Par's making, using, offering to sell, selling, or importing Par's Tolvaptan Tablet product, and its inducement of such conduct by others, will infringe the '677 patent;

F. In the alternative, enter judgment that a claim or claims of the '730 patent are infringed by the manufacture, use, sale, offer for sale or importation of Par's Tolvaptan Tablet products, that Par's submission of Par's ANDA is an act of infringement of the '730 patent, that Par's making, using, offering to sell, selling, or importing Par's Tolvaptan Tablet product, and its inducement of such conduct by others, will infringe the '730 patent;

G. Order that the effective date of any approval of Par's ANDA 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;

H. Permanently enjoin Par and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from making, using, offering to sell, selling, or importing Par's Tolvaptan Tablet product 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;

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

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

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