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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIONOGI & CO., LTD. and SHIONOGI INC., Plaintiffs, v. APOTEX CORP. and APOTEX INC., Defendants.	Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Shionogi & Co., Ltd. and Shionogi Inc. (collectively, "Plaintiffs" or "Shionogi"), for their Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), allege as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e), and the Declaratory Judgment Act, 28 U.S.C., §§ 2201-02. This action relates to Abbreviated New Drug Application ("ANDA") No. 207819 filed with the United States Food and Drug Administration ("FDA") for approval to market generic copies of Shionogi's DORIBAX® pharmaceutical products that are sold in the United States.

2. United States Patent No. 8,247,402 ("the '402 patent"), entitled "Crystal Form of Pyrrolidylthiocarbapenem Derivative," was duly and legally issued by the United States Patent and Trademark Office on August 21, 2012. Shionogi holds all substantial rights in the '402 patent and has the right to sue for infringement thereof. The claims of the '402 patent encompass the active ingredient in Doribax® (doripenem), its administration, and use. A true and correct copy of the '402 patent is attached as Exhibit A.

Parties

3. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha, is a corporation organized and existing under the laws of Japan, with a principle place of business at 1-8, Doshomachi 3-chome, Chuo Ku, Osaka, 541-0045, Japan.

4. Plaintiff Shionogi Inc., a wholly-owned subsidiary of Plaintiff Shionogi & Co., Ltd., is a corporation organized and existing under the laws of the State of Delaware, with a principle place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

5. On information and belief, Defendant Apotex Inc. is a corporation organized under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

6. On information and belief, Defendant Apotex Corp. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is a wholly-owned subsidiary and agent of Apotex Inc.

Background

7. Shionogi is a pharmaceutical company that develops and commercializes innovative pharmaceutical products to address unmet clinical needs.

8. DORIBAX® (doripenem for injection) is a prescription drug used as an antibacterial agent. The DORIBAX® product label provides information regarding the administration and use of DORIBAX®.

9. Shionogi, among other things, manufactures, markets, promotes, educates the public and physicians about, and conducts research and development on existing and new indications for doripenem for injection. Shionogi financially benefits from sales of DORIBAX® in the United States, including sales in the State of New Jersey.

10. Shionogi Inc. is the holder of New Drug Application ("NDA") No. 022106, by which the FDA granted approval for the marketing and sale of doripenem for injection, 250 mg/vial & 500 mg/vial, marketed under the trade name DORIBAX®.

Jurisdiction and Venue

11. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

12. Apotex consents to personal jurisdiction in this judicial district for purposes of this action, but reserves the right to challenge personal jurisdiction in this judicial district in any other matter.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Count I

Direct Infringement of United States Patent No. 8,247,402

14. Plaintiffs incorporate by reference paragraphs 1-13 of this Complaint as if fully set forth herein.

15. Shionogi listed the '402 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1), and the FDA published that listing on the FDA's Internet Website.

16. Upon information and belief, on or before December 23, 2014, Apotex submitted ANDA No. 207819 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of doripenem for injection.

17. Upon information and belief, Apotex's generic doripenem for injection products will contain a copy of the active ingredient in Doribax®. That active ingredient is covered by the '402 patent. Upon information and belief, Apotex's generic doripenem for injection products will be sold with a product label that will contain substantially the same instructions for administration and use as the Doribax® product label. The administration and use of doripenem is covered by the '402 patent.

18. Upon information and belief, the Apotex ANDA was submitted to the FDA in the name of Apotex Inc.

19. On or about December 26, 2014, Shionogi received a letter dated December 23, 2014 ("notice letter"), stating that Apotex Inc. had submitted the Apotex ANDA and that Apotex Inc. was seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of doripenem for injection before expiration of the '402 patent and thereby infringing the '402 patent.

20. Apotex's ANDA notice letter states that the Apotex ANDA certifies, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '402 patent are invalid, unenforceable, and/or not infringed ("paragraph IV certification"), thereby seeking approval to market and sell generic doripenem for injection in the United States, including this judicial district, before expiration of the '402 patent.

21. Under 35 U.S.C. § 271(e)(2)(A), Apotex's submission of the Apotex ANDA including a paragraph IV certification constitutes infringement of one or more claims of the '402 patent, either literally or under the doctrine of equivalents.

22. Apotex had actual and constructive notice of the '402 patent prior to submitting the Apotex ANDA and sending the notice letter and knowingly infringed the '402 patent. On information and belief, Apotex Inc. submitted the Apotex ANDA to the FDA despite an objectively high likelihood that its submission constituted infringement of a valid patent, and this risk was either known to Apotex or so obvious that it should have been known.

23. Shionogi will be irreparably harmed if the FDA's approval of the Apotex ANDA is not enjoined and if Apotex is not enjoined from infringing the '402 patent. Shionogi does not have an adequate remedy at law.

Count 2

Indirect Infringement of United States Patent No. 8,247,402

24. Plaintiffs incorporate by reference paragraphs 1-23 of this Complaint as if fully set forth herein.

25. Upon information and belief, if approved by the FDA, use of Apotex's doripenem for injection products will constitute direct infringement of one or more claims of the '402 patent, either literally or under the doctrine of equivalents. Through its product label, marketing materials, and other instructions provided to patients, hospitals, and practitioners, Apotex will actively induce, encourage, aid, and abet that conduct, with specific intent that the conduct will be in contravention of the Plaintiffs' rights under the '402 patent.

26. Shionogi will be irreparably harmed if the FDA's approval of the Apotex ANDA is not enjoined and if Apotex is not enjoined from actively inducing or contributing to infringement of the '402 patent. Shionogi does not have an adequate remedy at law.

Count 3

Declaratory Judgment of Infringement of United States Patent No. 8,247,402

27. Plaintiffs incorporate by reference paragraphs 1-26 of this Complaint as if fully set forth herein.

28. There is an actual and continuing controversy between Shionogi and Apotex as to Apotex's infringement of the '402 patent. Apotex is seeking FDA approval to sell a generic version of doripenem for injection prior to the expiration of the '402 patent.

29. Upon information and belief, Apotex has made substantial preparations to commercially manufacture, import into, market, offer for sale, and sell in the United States generic doripenem for injection and intends to commence the commercial manufacture,

importation into, marketing, offering for sale, and sale in the United States of generic doripenem for injection immediately upon approval of the Apotex ANDA by the FDA with its associated product label.

30. Upon information and belief, Apotex's doripenem for injection is not a staple article or commodity of commerce suitable for substantial noninfringing use, because Apotex's doripenem will only be approved for uses described in its product label. For the same reasons, Apotex's doripenem for injection is especially adapted for infringing uses when combined with pharmaceutically acceptable ingredients such as saline during administration in accordance with the product label. Thus, if approved by the FDA, Apotex's generic doripenem for injection will be prescribed and administered in the same or substantially similar manner as directed by the DORIBAX® (doripenem for injection) product label, which uses will constitute infringement of the '402 patent either literally or under the doctrine of equivalents. Apotex's notice of paragraph IV certification demonstrates Apotex's knowledge of the '402 patent and its claims. Thus, upon information and belief, these uses will occur with Apotex's specific intent and encouragement, and will be uses that Apotex will actively induce, encourage, aid, and abet and uses that Apotex knows or should know will occur in contravention of Plaintiffs' rights in the '402 patent as a consequence of, at least, the product labeling associated with Apotex's generic doripenem for injection.

31. Upon information and belief, the commercial manufacture, use, sale, or offer for sale in the United States, or the importation into the United States, of the Apotex doripenem for injection products during the term of the '402 patent will infringe one or more claims of the '402 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g), either literally or under the doctrine of equivalents.

32. Shionogi will be irreparably harmed if the FDA's approval of the Apotex ANDA is not enjoined and if Apotex is not enjoined from actively inducing or contributing to infringement of the '402 patent. Shionogi does not have an adequate remedy at law.

PRAYER FOR RELIEF

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

(1) holding that the claims of the '402 patent are valid and enforceable;

(2) holding that the submission of ANDA No. 207819 by Apotex infringes one or more claims of the '402 patent;

(3) declaring that, if the FDA approves ANDA No. 207819, Apotex will infringe or induce or contribute to the infringement of one or more claims of the '402 patent;

(5) ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Apotex doripenem for injection products shall be no earlier than the expiration date of the '402 patent;

(6) enjoining Apotex, and all persons acting in concert with it, from importing, using, or commercially offering for sale or selling the Apotex doripenem for injection products within the United States prior to the expiration of the '402 patent;

(7) declaring this to be an exceptional case and awarding Shionogi its attorney fees under 35 U.S.C. § 285;

(8) awarding Shionogi its costs and expenses in this action; and

(9) awarding Shionogi any further and additional relief as this Court deems just and proper.

Dated: January 30, 2015

MCCARTER & ENGLISH, LLP

s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by its undersigned counsel, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding, with the exception of the following related lawsuits involving DORIBAX® (doripenem for injection):

- *Janssen Pharmaceuticals, Inc., Peninsula Pharmaceuticals, Inc., and Shionogi & Co. Ltd. v. Sandoz, Inc.*, Civil Action No. 3:11-cv-07247 (FLW) (LHG) (D.N.J.).
- *Shionogi & Co. Ltd. v. Sandoz, Inc.*, Civil Action No. 3:12-cv-07907 (FLW) (LHG) (D.N.J.).
- *Shionogi & Co. Ltd. v. Hospira Inc.*, Civil Action No. 3:13-cv-02400 (FLW)(LHG) (D.N.J.).
- *Shionogi & Co. Ltd. and Shionogi Inc. v. Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A., Inc.*, Civil Action No. 3:15-cv-00319 (MAS)(LHG) (D.N.J.).
- *Shionogi & Co. Ltd. and Shionogi Inc. v. Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A., Inc.*, Civil Action No. 15-cv-478 (N.D. Ill.).

Dated: January 30, 2015

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s/ John E. Flaherty

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