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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIONOGI & CO., LTD.,

Plaintiff,

v.

HOSPIRA INC.,

Defendant.

Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Shionogi & Co., Ltd. ("Plaintiff"), for its Complaint against Defendant Hospira Inc. ("Hospira"), alleges 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. 203539 filed by Hospira 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.

Parties

2. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha ("Shionogi"), 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.

3. On information and belief, Defendant Hospira is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois, USA.

Background

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

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

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

Jurisdiction and Venue

7. 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.

8. Upon information and belief, Hospira agrees to personal jurisdiction in this judicial district for purposes of this action only.

9. Upon information and belief, Hospira agrees to venue in this judicial district for purposes of this action only.

Count I

Infringement of the '402 Patent Under 35 U.S.C. § 271(e)

10. Plaintiff incorporates by reference paragraphs 1-9 of this Complaint as if fully set forth herein.

11. 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. A true and correct copy of the '402 patent is attached as Exhibit A.

12. 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.

13. Upon information and belief, on or before February 28, 2013, Hospira submitted Abbreviated New Drug Application ("ANDA") No. 203539 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), ("Hospira ANDA") seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of doripenem for injection.

14. On or about February 28, 2013, Shionogi received a letter dated February 28, 2013 ("notice letter"), stating that Hospira had submitted the Hospira ANDA No. 203539 and that Hospira 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.

15. Upon information and belief, the Hospira ANDA was submitted to the FDA in the name of Hospira.

16. Hospira's ANDA notice letter states that the Hospira 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.

17. Upon information and belief, if the FDA approves ANDA No. 203539, the commercial manufacture, use, sale, and offer for sale of Hospira's generic doripenem for injection in the United States with its associated product label before expiration of the '402

patent will infringe one or more claims of the '402 patent, either literally or under the doctrine of equivalents.

18. Upon information and belief, if approved by the FDA, Hospira'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. Upon information and belief, these uses will occur with Hospira's specific intent and encouragement, and will be uses that Hospira will actively induce, encourage, aid, and abet and uses that Hospira knows or should know will occur in contravention of Plaintiff's rights in the '402 patent as a consequence of, at least, the product labeling associated with Hospira's generic doripenem for injection.

19. Under 35 U.S.C. § 271(e)(2)(A), Hospira's submission of ANDA No. 203539 which, upon information and belief, includes the paragraph IV certification seeking approval for the commercial manufacture, use, offer for sale, or sale of doripenem for injection before the expiration of the '402 patent constitutes infringement of one or more claims of the '402 patent, either literally or under the doctrine of equivalents.

20. Hospira had actual and constructive notice of the '402 patent prior to submitting the Hospira ANDA and sending the notice letter and knowingly infringed the '402 patent. On information and belief, Hospira submitted ANDA No. 203539 to the FDA despite an objectively high likelihood that Hospira's submission of ANDA No. 203539 constitutes infringement of a valid patent, and this risk was either known to Hospira or so obvious that it should have been known.

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

Count 2

Declaratory Judgment of Infringement of the '402 Patent

22. Plaintiff incorporates by reference paragraphs 1-21 of this Complaint as if fully set forth herein.

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

24. Upon information and belief, Hospira 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 ANDA No. 203539 by the FDA with its associated product label.

25. Upon information and belief, if approved by the FDA, Hospira'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. Upon information and belief, these uses will occur with Hospira's specific intent and encouragement, and will be uses that Hospira will actively induce, encourage, aid, and abet and

uses that Hospira knows or should know will occur in contravention of Plaintiff's rights in the '402 patent as a consequence of, at least, the product labeling associated with Hospira's generic doripenem for injection.

26. 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 Hospira 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.

27. Shionogi will be irreparably harmed if FDA's approval of the Hospira ANDA is not enjoined and if Hospira 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. 203539 by Hospira infringes one or more claims of the '402 patent;

(3) declaring that, if the FDA approves ANDA No. 203539, the commercial manufacture, use, sale, or offer for sale in the United States, or the importation into the United States, of the Hospira doripenem for injection products will infringe one or more claims of the '402 patent;

(4) declaring that, if the FDA approves ANDA No. 203539, Hospira will induce 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 Hospira doripenem for injection products shall be no earlier than the expiration date of the '402 patent and any additional periods of exclusivity applicable to DORIBAX® (doripenem for injection);

(6) enjoining Hospira, and all persons acting in concert with it, from commercially manufacturing, importing into, using, offering for sale, or selling the Hospira doripenem for injection products within the United States prior to the expiration of the '402 patent and any additional periods of exclusivity applicable to DORIBAX® (doripenem for injection);

(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: April 15, 2013

MCCARTER & ENGLISH, LLP

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff, by its undersigned counsel, hereby certifies 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).
- *Shionogi & Co. Ltd. v. Sandoz, Inc.*, Civil Action No. 3:12-cv-07907 (FLW) (LHG).

Dated: April 15, 2013

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