John E. Flaherty
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Of Counsel:

Gregory L. Diskant
Scott B. Howard
Scott Caplan
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC., PENINSULA PHARMACEUTICALS, INC., and SHIONOGI & CO. LTD.,	)	
Plaintiffs,	)	Civ. Action No. _____
v.	)	
SANDOZ, INC.,	)	
Defendant	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc., Peninsula Pharmaceuticals, Inc. and Shionogi & Co. Ltd. (collectively "Plaintiffs"), by their attorneys, for their complaint against Sandoz, Inc. ("Sandoz") allege as follows:

The Parties

1. Janssen Pharmaceuticals, Inc. ("Janssen") is a corporation organized and existing under the laws of the State of Pennsylvania and has its principal place of business at 1125 Trenton-Harbouton Road, Titusville, New Jersey.

2. Peninsula Pharmaceuticals, Inc. ("Peninsula") is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 6500 Paseo Padre Pky, Fremont, California.

3. Shionogi & Co. Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha, ("Shionogi"), is a corporation organized and existing under the laws of Japan and has its principal place of business at 1-8 Doshomachi 3-chome, Chuo-Ku, Osaka-Shi, Osaka, 541-0045, in Osaka, Japan.

4. On information and belief, Sandoz is a corporation organized under the laws of Colorado having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

Jurisdiction And Venue

5. This action is based upon the Patent Law of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,317,016 ("the '016 patent") and the Federal Declaratory Judgment Act, Title 28 of the United States Code, §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, Sandoz is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its continuous and systematic contacts with New Jersey, including having a principal place of business in New Jersey, and as evidenced by its intent to market and sell the accused drug in New Jersey.

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

Count I: Patent Infringement

8. Plaintiffs reallege paragraphs 1 through 7 above as if fully set forth herein.

9. On May 31, 1994, the United States Patent and Trademark Office ("the PTO") issued the '016 patent, entitled "Pyrrolidylthiocarbapenem Derivative." A true and correct copy of the '016 patent is attached as Exhibit A.

10. Shionogi holds title to the '016 patent.

11. Peninsula is the exclusive licensee of the '016 patent under a license from Shionogi. Under the terms of that license, Peninsula has the right to join Shionogi as a party plaintiff to any patent infringement action seeking to enforce the '016 patent.

12. The United States Food & Drug Administration ("FDA") has approved a New Drug Application filed by Janssen under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for doripenem, a product covered by the '016 patent and sold by Janssen in powder form for constitution and intravenous infusion under the trade name DORIBAX®.

13. Pursuant to 21 U.S.C. § 355(b)(1), the '016 patent is identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), as covering DORIBAX®.

14. Janssen filed the NDA for DORIBAX®, and is the exclusive United States distributor of DORIBAX®.

15. Upon information and belief, on or before November 18, 2011, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 203440 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), ("Sandoz ANDA") seeking FDA

approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of doripenem for injection.

16. On or about November 21, 2011, Janssen and Shionogi received a letter dated November 18, 2011 stating that Sandoz had submitted the Sandoz ANDA and that the Sandoz ANDA includes a paragraph IV certification against the '016 patent ("Sandoz's ANDA certification letter"). With its paragraph IV certification, Sandoz is seeking approval to manufacture, use and sell a generic version of doripenem for injection before the expiration of the '016 patent.

17. Upon information and belief, the Sandoz ANDA was filed in the name of Sandoz.

18. Sandoz's ANDA certification letter states that the Sandoz ANDA certifies, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '016 patent is invalid or not infringed ("paragraph IV certification").

19. Sandoz is liable for the infringement of the '016 patent under 35 U.S.C. § 271(e)(2)(A) by filing the Sandoz ANDA which, upon information and belief, includes the paragraph IV certification.

20. Sandoz had actual and constructive notice of the '016 patent prior to filing the Sandoz ANDA.

21. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing or contributing to infringement of the '016 patent. Plaintiffs do not have an adequate remedy at law.

Count II: Declaratory Judgement of Patent Infringement

22. Plaintiffs reallege paragraphs 1 through 21 above as if fully set forth herein.

23. Sandoz is seeking FDA approval to sell a generic version of doripenem for injection prior to the expiration of the '016 patent and, upon information and belief, Sandoz intends to market the generic product immediately upon FDA approval.

24. The manufacture, use, sale, or offer for sale in the United States, or the importation into the United States, of a generic version of doripenem for injection during the term of the '016 patent will constitute patent infringement under 35 U.S.C. § 271(a), (b) and/or (c).

25. There is an actual controversy and continuing controversy between Plaintiffs and Sandoz as to Sandoz's infringement of the '016 patent. Sandoz's manufacture and sales in the United States and/or importation into the United States will result in infringement of the '016 patent and will result in substantial economic harm to Plaintiffs. This threatened harm will be redressed by the Court's declaration of the parties' rights and liabilities.

Prayer For Relief

WHEREFORE, Plaintiffs pray for:

A. A judgment providing that the effective date of any FDA approval for the making, using, selling, offering for sale, or importing of the Sandoz Product as described in Sandoz's ANDA certification letter and the Sandoz ANDA be no earlier than the date on which the '016 patent expires (including any patent term extension granted to the '016 patent);

B. A judgment declaring that the making, using, selling, offering to sell in the United States, or importing into the United States of the Sandoz Product as described in Sandoz's ANDA certification letter and the Sandoz ANDA would constitute infringement of the '016 patent, or inducing or contributing to such conduct, by Sandoz pursuant to 35 U.S.C. § 271(a), (b) and (c);

C. A judgment permanently enjoining Sandoz and each of its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the Sandoz Product (as described in Sandoz's ANDA certification letter and the Sandoz ANDA) or any product that infringes or induces or contributes to the infringement of the '016 patent.

D. A declaration that this case is exceptional;

E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

Dated: December 13, 2011

MCCARTER & ENGLISH, LLP

s/John E. Flaherty
John E. Flaherty
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

Attorneys for Plaintiffs

Of Counsel:

PATTERSON BELKNAP WEBB & TYLER LLP
Gregory L. Diskant
Scott B. Howard
Scott Caplan
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000