Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

OF COUNSEL:
Bruce M. Wexler
Joseph M. O'Malley, Jr.
Preston K. Ratliff II
Gary Ji
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

Paul D. Matukaitis
MERCK SHARP & DOHME CORP.
One Merck Drive
Whitehouse Station, NJ 08889

Edward W. Murray
Richard C. Billups
MERCK SHARP & DOHME CORP.
126 E. Lincoln Avenue
Rahway, NJ 07065

Attorneys for Plaintiff
Merck Sharp & Dohme Corp.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Merck Sharp & Dohme Corp. ("Merck") for its Complaint against Defendant Sandoz Inc. ("Sandoz") hereby alleges as follows:

THE PARTIES

1. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

3. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

4. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

5. Upon information and belief, Sandoz manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District.

6. Upon information and belief, Sandoz is licensed to do business with the New Jersey Department of Health and Senior Services as a "Manufacturer and Wholesaler" of pharmaceuticals in the State of New Jersey, registration No. 5003732.

7. Upon information and belief, Sandoz has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction.

8. This Court has personal jurisdiction over Sandoz based upon, *inter alia*, its presence and sales in this District.

CLAIM FOR RELIEF

9. Merck is the holder of New Drug Application ("NDA") No. 22-023, by which the United States Food and Drug Administration ("FDA") granted approval for single dose glass vials containing sterile lyophilized powder of fosaprepitant dimeglumine for intravenous use after reconstitution and dilution, in 115 mg and 150 mg dosage strengths. Fosaprepitant dimeglumine described in Merck's NDA is indicated, *inter alia*, for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and to prevent nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Merck markets the single dose glass vials in the United States under the tradename "EMEND® (fosaprepitant dimeglumine) for Injection" ("EMEND® IV").

10. Merck owns United States Patent No. 5,691,336 ("the '336 patent"), which was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on November 25, 1997, and is titled "Morpholine compounds are prodrugs useful as tachykinin receptor antagonists." A copy of the '336 patent is attached as Exhibit A.

11. Merck owns United States Patent No. 5,716,942 ("the '942 patent"), which was duly and legally issued by the USPTO on February 10, 1998, and is titled "Treatment of migraine with morpholine tachykinin receptor antagonists." A copy of the '942 patent is attached as Exhibit B.

12. Upon information and belief, Sandoz submitted to the FDA Abbreviated New Drug Application No. 203939 ("ANDA") seeking approval to manufacture, use, and sell single dose vials containing fosaprepitant dimeglumine IV powder, 150 mg base/vial dosage strength ("the Sandoz ANDA product") prior to the expiration of the '336 patent. Upon information and belief, Sandoz's ANDA contains a certification with respect to the '336 patent

under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Sandoz has not submitted to the FDA an Abbreviated New Drug Application with respect to a 115 mg dosage strength fosaprepitant dimeglumine IV powder product.

13. Sandoz sent a letter dated April 23, 2012 ("Sandoz Notice Letter") to Merck, which was delivered thereafter, in which Sandoz represented that it had filed an ANDA for the Sandoz ANDA product containing a certification with respect to the '336 patent, and that it sought approval of its ANDA prior to the expiration of the '336 patent.

14. This action was commenced within 45 days of the date of the Sandoz Notice Letter.

FIRST COUNT
INFRINGEMENT BY SANDOZ OF U.S. PATENT NO. 5,691,336

15. Plaintiff re-alleges paragraphs 1-14 as if fully set forth herein.

16. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '336 patent before its expiration including its patent term extension, Sandoz has infringed the '336 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

17. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Sandoz ANDA product, if approved by the FDA, prior to the expiration of the '336 patent including its patent term extension, would infringe the '336 patent under 35 U.S.C. § 271. Merck is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sandoz's ANDA No. 203939 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO

pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '336 patent to which Merck is or becomes entitled.

18. Plaintiff will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

19. Upon information and belief, Sandoz was aware of the existence of the '336 patent and was aware that the filing of its ANDA and certification with respect to the '336 patent constituted an act of infringement of that patent.

SECOND COUNT
INFRINGEMENT BY SANDOZ OF U.S. PATENT NO. 5,716,942

20. Plaintiff re-alleges paragraphs 1-19 as if fully set forth herein.

21. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '942 patent before its expiration, Sandoz has infringed the '942 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

22. Upon information and belief, the commercial manufacture, offer to sell, sale, or import of the Sandoz ANDA product, if approved by the FDA, prior to the expiration of the '942 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '942 patent. Merck is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Sandoz's ANDA No. 203939 be a date that is not earlier than the expiration of the '942 patent, or any later expiration of exclusivity for the '942 patent to which Merck is or becomes entitled.

23. Plaintiff will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

24. Upon information and belief, Sandoz was aware of the existence of the '942 patent and was aware that the filing of its ANDA constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment be entered that Defendant has infringed the '336 and '942 patents by submitting the aforesaid ANDA;

B. Preliminary and permanent injunctions be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendant, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs, or from inducing and/or encouraging the use of methods, claimed in the '336 and '942 patents;

C. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 203939 be a date that is not earlier than the expiration of the '336 and '942 patents, including any extensions thereof and any later expiration of exclusivity for those patents to which Merck is or becomes entitled;

D. An Order be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

E. Such other and further relief as the Court may deem just and proper.

Dated: May 31, 2012

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 31, 2012

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