

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp. (hereinafter “Plaintiffs”), by way of Complaint against Sandoz Inc. allege as follows:

THE PARTIES

1. Merck & Co., Inc. is a corporation organized and existing under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck & Co., Inc. is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

2. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc., and is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. On information and belief, Sandoz Inc. (“Sandoz”) is incorporated under the laws of the state of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz is in the business of developing and manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

5. On information and belief, Sandoz assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application (“ANDA”) No. 200833 concerning a proposed generic drug product, Caspofungin Acetate Injectable, 50 mg/vial and 70 mg/vial.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

7. Sandoz is subject to jurisdiction in New Jersey because it manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within New Jersey.

8. Sandoz is subject to personal jurisdiction in New Jersey because it regularly and systematically conducts business within New Jersey and has offices within New Jersey.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c) and 28 U.S.C. § 1400(b).

CANCIDAS[®]

10. Merck & Co., Inc. holds approved new drug application (“NDA”) 21-227 for CANCIDAS[®], the active ingredient of which is caspofungin acetate. CANCIDAS[®] is approved for the treatment of certain types of fungal infections.

11. Merck Sharp & Dohme Corp. is the owner of U.S. Patent No. 5,378,804 (“the ’804 patent”) and U.S. Patent No. 5,514,650 (“the ’650 patent”) (Patents attached as Exhibits A and B respectively).

SANDOZ ANDA

12. On or about May 3, 2010, Merck & Co., Inc. received from Sandoz a letter, dated April 30, 2010 (the “April 30th letter”), stating that Sandoz had submitted an ANDA, assigned as No. 200833, to the FDA to seek approval to market Caspofungin Acetate Injectable, in 50 mg/vial and 70 mg/vial forms (“the Sandoz Products”).

13. In its April 30th letter, Sandoz stated that, in its ANDA, it had included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '804 and '650 patents would not be infringed by the manufacture, use, or sale of the Sandoz Products.

14. The Sandoz ANDA refers to and relies upon the Merck & Co., Inc. NDA and contains data that, according to Sandoz, demonstrates the bioequivalence of the Sandoz Products and CANCIDAS®.

INFRINGEMENT OF U.S. PATENT NO. 5,378,804

15. Plaintiffs repeat and reallege paragraphs 1-14 above as if fully set forth herein.

16. By filing its ANDA No. 200833 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Sandoz Products before the expiration of the '804 patent, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

17. If Sandoz commercially makes, uses, offers to sell, or sells the Sandoz Products within the United States, or imports the Sandoz Products into the United States, or induces or contributes to any such conduct during the term of the '804 patent, it would further infringe the '804 patent under 35 U.S.C. § 271.

18. Merck will be irreparably harmed if Sandoz is not enjoined from infringing the '804 patent. Merck does not have an adequate remedy at law.

19. Sandoz's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '804 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

INFRINGEMENT OF U.S. PATENT NO. 5,514,650

20. Plaintiffs repeat and reallege paragraphs 1-14 above as if fully set forth herein.

21. By filing its ANDA No. 200833 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Sandoz Products before the expiration of the '650 patent, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

22. If Sandoz commercially makes, uses, offers to sell, or sells the Sandoz Products within the United States, or imports the Sandoz Products into the United States, or induces or contributes to any such conduct during the term of the '650 patent, it would further infringe the '650 patent under 35 U.S.C. § 271.

23. Merck will be irreparably harmed if Sandoz is not enjoined from infringing the '650 patent. Merck does not have an adequate remedy at law.

24. Sandoz's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '650 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Sandoz Inc. has infringed one or more claims of the '804 patent by filing ANDA No. 200833 relating to Sandoz's generic caspofungin acetate products;

B. A permanent injunction restraining and enjoining Sandoz Inc. and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or

importation into the United States, of generic caspofungin acetate products as claimed in the '804 patent;

C. An order that the effective date of any approval of ANDA No. 200833 relating to Sandoz's generic caspofungin acetate products be a date that is not earlier than the expiration date of the '804 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

D. Judgment that Sandoz Inc. has infringed one or more claims of the '650 patent by filing ANDA No. 200833 relating to Sandoz's generic caspofungin acetate products;

E. A permanent injunction restraining and enjoining Sandoz Inc. and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic caspofungin acetate products as claimed in the '650 patent;

F. An order that the effective date of any approval of ANDA No. 200833 relating to Sandoz's generic caspofungin acetate products be a date that is not earlier than the expiration date of the '650 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

G. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, expenses, and disbursements of this action; and

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

Dated: May 6, 2010

Respectfully submitted,

By: s/ Sheila F. McShane

David E. De Lorenzi, Esq.
Sheila F. McShane, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500

Of Counsel:

Dominick A. Conde, Esq.
Brian V. Slater, Esq.
FITZPATRICK, CELLA,
HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

Edward W. Murray, Esq.
Karen Stoffan, Esq.
MERCK & CO., INC.
RY28-320
P.O. Box 2000
Rahway, New Jersey 07065-0900
(732) 594-0436

Attorneys for Plaintiffs,
MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.