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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK & CO., INC., Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiff Merck & Co., Inc., for its Complaint against Defendant Sandoz Inc., hereby alleges as follows:

THE PARTIES

1. Merck & Co., Inc. ("Merck") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

2. Upon information and belief, Defendant Sandoz Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado, having a principal 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. This Court has personal jurisdiction over Sandoz based upon, *inter alia*, its presence and sales in this District.

CLAIM FOR RELIEF

7. Merck is the holder of New Drug Application ("NDA") No. 21-549, by which the United States Food and Drug Administration ("FDA") granted approval for 40 mg, 80 mg, and 125 mg aprepitant capsules. The aprepitant capsules described in Merck's NDA are indicated, *inter alia*, for use in combination with other antiemetic agents to prevent 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. The aprepitant capsules are also indicated for the prevention of postoperative nausea and vomiting.

Merck markets 40 mg, 80 mg, and 125 mg aprepitant capsules in the United States under the tradename "EMEND®."

8. Merck owns United States Patent No. 5,719,147 ("the '147 patent"), which was duly and legally issued on February 17, 1998, and is titled "Morpholine and Thiomorpholine Tachykinin Receptor Antagonists." A copy of the '147 patent is attached as Exhibit A.

9. Merck owns United States Patent No. 6,048,859 ("the '859 patent"), which was duly and legally issued on April 11, 2000, and is titled "Morpholine and Thiomorpholine Tachykinin Receptor Antagonists." A copy of the '859 patent is attached as Exhibit B.

10. Merck owns United States Patent No. 6,096,742 ("the '742 patent"), which was duly and legally issued on August 1, 2000, and is titled "Polymorphic Form of a Tachykinin Receptor Antagonist." A copy of the '742 patent is attached as Exhibit C.

11. Merck owns United States Patent No. 6,235,735 ("the '735 patent"), which was duly and legally issued on May 22, 2001, and is titled "Morpholine and Thiomorpholine Tachykinin Receptor Antagonists." A copy of the '735 patent is attached as Exhibit D.

12. Upon information and belief, Sandoz submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 90-999, which included a certification with respect to the '147, '859, '742, and '735 patents (collectively, "the patents-in-suit") under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to manufacture, use, and sell 40 mg, 80 mg, and 125 mg aprepitant capsules ("the Sandoz ANDA products") prior to the expiration of the patents-in-suit.

13. On or about January 15, 2009, Sandoz sent a letter ("Notice Letter") to Merck in which Sandoz represented that it had filed an ANDA for the Sandoz ANDA products, including certifications with respect to the '147, '859, '742, and '735 patents, and that it sought approval of its ANDA prior to the expiration of the patents-in-suit.

FIRST COUNT FOR INFRINGEMENT
BY SANDOZ OF U.S. PATENT NO. 5,719,147

14. Plaintiff re-alleges paragraphs 1-13 as if fully set forth herein.

15. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product as claimed in the '147 patent before its expiration, Sandoz has infringed the '147 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

16. The Sandoz ANDA products are within the literal scope of at least claims 15-17 and 19 of the '147 patent. To the extent that Sandoz fails to prove that claims 15-17 and 19 are invalid or unenforceable, the Sandoz ANDA products infringe claims 15-17 and 19.

17. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Sandoz ANDA products would infringe at least claims 15-17 and 19 of the '147 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 be a date that is not earlier than the expiration of the patent term extension granted by the United States Patent and Trademark Office pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '147 patent to which Merck is or becomes entitled.

18. Upon information and belief, Sandoz was aware of the existence of the '147 patent and was aware that the filing of its ANDA and certification with respect to the '147 patent constituted an act of infringement of that patent.

19. This case is an exceptional one, and Merck is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

SECOND COUNT FOR INFRINGEMENT
BY SANDOZ OF U.S. PATENT NO. 6,048,859

20. Plaintiff realleges 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 as claimed in the '859 patent before its expiration, Sandoz has infringed the '859 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

22. The use of the Sandoz ANDA products in accordance with the proposed labeling for the products is within the literal scope of at least claims 15-17, 20, and 21 of the '859 patent. To the extent that Sandoz fails to prove that claims 15-17, 20, and 21 of the '859 patent are invalid or unenforceable, the Sandoz ANDA products infringe claims 15-17, 20, and 21.

23. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Sandoz ANDA products would infringe and/or induce the infringement of at least claims 15-17, 20, and 21 of the '859 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 be a date that is not earlier than the expiration date of the '859 patent, or any later expiration of exclusivity for the '859 patent to which Merck is or becomes entitled.

24. Upon information and belief, Sandoz was aware of the existence of the '859 patent and was aware that the filing of its ANDA and certification with respect to the '859 patent constituted acts of infringement and inducement of infringement of that patent.

25. This case is an exceptional one, and Merck is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

THIRD COUNT FOR INFRINGEMENT
BY SANDOZ OF U.S. PATENT NO. 6,096,742

26. Plaintiff realleges paragraphs 1-25 as if fully set forth herein.

27. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product as claimed in the '742 patent before its expiration, Sandoz has infringed the '742 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Sandoz ANDA products would infringe and/or induce the infringement of the '742 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 be a date that is not earlier than the expiration date of the '742 patent, or any later expiration of exclusivity for the '742 patent to which Merck is or becomes entitled.

29. Upon information and belief, Sandoz was aware of the existence of the '742 patent and was aware that the filing of its ANDA and certification with respect to the '742 patent constituted acts of infringement and inducement of infringement of that patent.

30. This case is an exceptional one, and Merck is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

FOURTH COUNT FOR INFRINGEMENT
BY SANDOZ OF U.S. PATENT NO. 6,235,735

31. Plaintiff realleges paragraphs 1-30 as if fully set forth herein.

32. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product as claimed in the '735 patent before its expiration, Sandoz has infringed the '735 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

33. The use of the Sandoz ANDA products in accordance with the proposed labeling for the products is within the literal scope of at least one claim of the '735 patent. To

the extent that Sandoz fails to prove that the claims of the ’735 patent are invalid or unenforceable, the Sandoz ANDA products infringe the ’735 patent.

34. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or import of the Sandoz ANDA products would infringe and/or induce the infringement of the ’735 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 be a date that is not earlier than the expiration date of the ’735 patent, or any later expiration of exclusivity for the ’735 patent to which Merck is or becomes entitled.

35. Upon information and belief, Sandoz was aware of the existence of the ’735 patent and was aware that the filing of its ANDA and certification with respect to the ’735 patent constituted acts of infringement and inducement of infringement of that patent.

36. This case is an exceptional one, and Merck is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

37. Plaintiff requests that:

a. Judgment be entered that Defendant has infringed the ’147, ’859, ’735, and ’742 patents by submitting the aforesaid ANDA;

b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendant, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the ’147, ’859, ’735, and ’742 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. 90-999 be a date that is not earlier than the expiration dates of the '147, '859, '735, and '742 patents, or any later expiration of exclusivity for those patents to which Plaintiff is or becomes entitled;

d. Judgment be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorney fees pursuant to 35 U.S.C. § 285; and

e. Such other and further relief as the Court may deem just and proper under the circumstances be ordered.

Dated: February 27, 2009

By: /s William J. Heller

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