IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. RANBAXY INC., and RANBAXY LABORATORIES LIMITED, Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck & Co., Inc. ("Merck"), by its undersigned attorneys, brings this action against defendants, Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Defendants"), for patent infringement, and alleges as follows:

PARTIES

1. Plaintiff Merck is a corporation incorporated under the laws of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. On information and belief, defendant Ranbaxy Inc. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 600 College Road East, Princeton, New Jersey 08540. On information and belief, Ranbaxy Inc. is engaged in the development, manufacturing, marketing and sale of pharmaceutical products in the United States, and conducts business in the state of Delaware.

3. On information and belief, defendant Ranbaxy Laboratories Limited ("Ranbaxy Labs") is a corporation organized and existing under the laws of India, having its principal place of business at Plot No. 90, Sector 32, Gurgaon-122 001, Haryana, India. On information and belief, Ranbaxy Labs is engaged in the development, manufacture, marketing

and sale of pharmaceutical products in the United States, and conducts business in the state of Delaware. On information and belief, Ranbaxy Inc. is the wholly owned subsidiary of Ranbaxy Labs and is the agent of Ranbaxy Labs in the United States.

4. On information and belief, the acts of Ranbaxy Inc. asserted herein were done at the direction of, or with the cooperation, participation and assistance of, Ranbaxy Labs.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*, and for declaratory judgment of patent infringement arising under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 101, *et seq.* This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and pursuant to 28 U.S.C. §§ 2201 and 2202.

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

MERCK'S PATENT

7. On September 15, 1992, the United States Patent and Trademark Office ("Patent Office") duly and lawfully issued United States Patent No. 5,147,868 ("the '868 patent," a copy of which is attached as Exhibit A), entitled THIENAMYCIN RENAL PEPTIDASE INHIBITORS, to Merck as assignee of the inventors Donald W. Graham, Edward F. Rogers and Frederick M. Kahan. At all times subsequent to issuance of the '868 patent, Merck has been the owner of the entire right, title and interest in and to the '868 patent, including the right to sue and recover for infringement. The term of the '868 patent expires September 15, 2009. The claims of the '868 patent cover, *inter alia*, the compounds cilastatin and cilastatin sodium.

8. Merck currently sells PRIMAXIN® I.M. which is an injectable suspension containing imipenem and cilastatin sodium. Merck also currently sells PRIMAXIN® I.V., which is an injection containing imipenem and cilastatin sodium.

9. Merck is the holder of approved New Drug Applications ("NDAs") under Section 505 of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355, for imipenem and cilastatin for injectable suspension (NDA 50-630) and imipenem and cilastatin for injection (NDA 50-587).

DEFENDANTS' ACTIONS

10. On information and belief, Defendants filed an Abbreviated New Drug Application ("ANDA") for imipenem-cilastatin and associated drug master file(s), seeking approval to engage in the commercial manufacture, use, and sale of injectable products comprising imipenem and cilastatin sodium ("ANDA products") before the '868 patent expires.

11. By letter dated January 22, 2007, Defendants sent written notice of their filing to Merck, which notice was received by Merck. The notice alleged that Defendants' ANDA products will not infringe any valid claim of the '868 patent. Defendants also informed Merck that Defendants are seeking approval from the FDA to market the ANDA products before the '868 patent expires and that Defendants plan to begin marketing the ANDA products immediately upon approval. Defendants sought a covenant from Merck not to sue under the '868 patent. Merck did not give Defendants a covenant not to sue.

12. On information and belief, Defendants are systematically attempting to meet the applicable regulatory requirements to obtain FDA approval for the ANDA products. On information and belief, Defendants have developed and tested the ANDA products. On information and belief, Ranbaxy Labs already manufactures and sells a pharmaceutical

composition containing cilastatin or cilastatin sodium outside the United States. On information and belief, Defendants are preparing to import the ANDA products into the United States or manufacture the ANDA products in the United States. On information and belief, Defendants have the capacity to begin marketing and manufacturing the ANDA products immediately upon receiving regulatory approval from the FDA.

COUNT I - DECLARATORY JUDGMENT

13. Merck restates and incorporates by reference the allegations of the foregoing paragraphs 1-12 as though fully set forth herein.

14. On information and belief, Defendants have made meaningful preparations for, and engaged in activities directed toward, infringing the '868 patent.

15. The acts of Defendants indicate a refusal to change the course of their actions in the face of acts by Merck sufficient to create a reasonable apprehension that a suit by Merck will be forthcoming.

16. Defendants' manufacture, use, sale or offer for sale of the ANDA products in the United States or importation of the ANDA products into the United States will constitute patent infringement under 35 U.S.C. § 271 (a), (b) or (c).

17. An actual controversy now exists between Merck and Defendants with respect to the infringement of the '868 patent.

18. Merck will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '868 patent.

19. Merck does not have an adequate remedy at law.

20. Merck should be granted relief provided by 35 U.S.C. §283 and by 28 U.S.C. §§ 2201 and 2202, including an order of this Court declaring that Defendants' ANDA

products will infringe the '868 patent and an order of this Court preliminarily and permanently enjoining them from manufacturing, using, selling and offering for sale the ANDA products.

21. On information and belief, Defendants were aware of the existence of the '868 patent and were aware that the marketing, manufacture, use, offer for sale and sale of the ANDA products would constitute an act of infringement of the '868 patent.

22. Defendants' written notice of the factual and legal bases for its opinion regarding the alleged invalidity and noninfringement of the '868 patent is devoid of an objective good faith basis in either the facts or the law.

23. On information and belief, Defendants have acted with willful disregard for Merck's patent rights.

24. This case is an exceptional one, and Merck should be granted an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II - PATENT INFRINGEMENT

25. Merck restates and incorporates by reference the allegations of the foregoing paragraphs 1-24 as though fully set forth herein.

26. On information and belief, Defendants filed an ANDA under Section 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j), for a drug claimed in the '868 patent.

27. Defendants seek approval of their ANDA to engage in the commercial manufacture, use or sale of a drug or drug formulation claimed in the '868 patent before it expires.

28. Defendants have infringed the '868 patent under 35 U.S.C. § 271(e)(2).

29. Merck should be granted relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Ranbaxy's ANDA be a date that is not earlier than the present expiration date of the '868 patent, or any later expiration of exclusivity to which Merck is or becomes entitled and an order of this Court preliminarily and permanently enjoining Defendants from commercially manufacturing, using, selling and offering for sale the ANDA products.

30. On information and belief, Defendants were aware of the existence of the '868 patent and were aware that the manufacture, use, offer for sale and sale of the ANDA products would constitute an act of infringement of the '868 patent.

31. Defendants' written notice of the factual and legal bases for its opinion regarding the alleged invalidity and noninfringement of the '868 patent is devoid of an objective good faith basis in either the facts or the law.

32. On information and belief Defendants have acted with willful disregard for Merck's patent rights and have willfully infringed the '868 patent.

33. This case is an exceptional one, and Merck should be granted an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Merck respectfully requests that:

a. Judgment be entered that Defendants have infringed the '868 patent by submitting the aforesaid ANDA;

b. Judgment be entered that Defendants will infringe the '868 patent by marketing, manufacturing, using, offering for sale or selling Defendants' ANDA products;

c. A preliminary and permanent injunction be issued, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and 28 U.S.C. §§ 2201 and 2202, restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of compounds or formulations as claimed in the '868 patent, or from practicing any method as claimed in the '868 patent, or from actively inducing or contributing to infringement of the '868 patent;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendants' ANDA be a date which is not earlier than the present expiration date for the '868 patent, or any later expiration of exclusivity to which the '868 patent is or becomes entitled to;

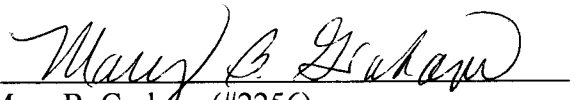
e. Judgment be entered that Defendants acted with willful disregard for Merck's rights under the '868 patent;

f. Judgment be entered that Defendants have willfully infringed the '868 patent;

g. Judgment be entered that this case is an exceptional one and that Merck should be awarded its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

h. Such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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Dated: April 30, 2007