IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp., by way of Complaint against Hospira, Inc., alleges as follows:

THE PARTIES

1. Merck Sharp & Dohme Corp. ("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, Whitehouse Station, New Jersey 08889. Merck 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. On information and belief, Hospira, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045-2510.

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

JURISDICTION AND VENUE

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

5. Hospira is subject to personal jurisdiction in this District because it is a corporation organized and existing under the laws of the State of Delaware.

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

MERCK'S NDA AND ASSERTED PATENT

7. Merck filed New Drug Application ("NDA") No. 021337, pursuant to which the U.S. Food and Drug Administration ("FDA") granted approval for lyophilized powder in vials containing 1.046 g ertapenem sodium equivalent to 1g ertapenem for intravenous infusion or for intramuscular injection. The ertapenem described in NDA No. 021337 is an antibacterial product approved for use in adults and pediatric patients for the treatment of complicated intra-abdominal infections; complicated skin and skin structure infections; community acquired pneumonia; complicated urinary tract infections; and acute pelvic infections. The ertapenem of NDA No. 021337 is also approved in adults for the prophylaxis of surgical site infection following elective colorectal surgery. Ertapenem is sold by Merck under the trade name Invanz®.

8. Merck is the owner of U.S. Patent No. 5,952,323 (the "'323 patent") which is attached as Exhibit A. The '323 patent discloses and claims stabilized forms of the ertapenem compound, and methods of stabilizing the ertapenem compound.

9. Pursuant to 21 U.S.C. §355(b)(1), Merck has submitted information concerning the '323 patent to the FDA in connection with its NDA No. 021337, identifying it as

a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '323 patent has been listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Invanz.

HOSPIRA'S ANDA AND NOTICE LETTER

10. By letter ("Hospira Notice Letter") dated May 29, 2014, and received by Merck on May 30, 2014, Hospira gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 206480 to the FDA under 21 U.S.C. §355(j) seeking approval to manufacture, use and sell ertapenem for injection 1g (the "Hospira Generic Product"), prior to the expiration of the '323 patent.

11. The Hospira Notice Letter informed Merck that Hospira's ANDA contained a "Paragraph IV Certification" that the '323 patent is invalid.

12. This action is being filed within 45 days of Merck's receipt of Hospira's Notice Letter.

COUNT I – INFRINGEMENT OF '323 PATENT

13. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-12.

14. Hospira submitted ANDA No. 206480 to the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the Hospira Generic Product prior to the expiration of the '323 patent. By submitting this application, Hospira has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

15. On information and belief, Hospira was aware of the existence of the '323 patent and was aware that the filing of its ANDA and certification with respect to the '323 patent constituted an act of infringement of that patent.

16. On information and belief, the Hospira Generic Product contains the stabilized form of ertapenem described and claimed in the '323 patent.

17. On information and belief, the manufacture of the Hospira Generic Product requires the performance of every step of at least method claim 4 of the '323 patent.

18. On information and belief, the commercial manufacture, use, or sale of the Hospira Generic Product prior to the expiration of the '323 patent will directly infringe the '323 patent under 35 U.S.C. §271(a), will actively induce infringement of the '323 patent under 35 U.S.C. §271(b), will constitute contributory infringement of the '323 patent under 35 U.S.C. §271(c), and will infringe the '323 patent under 35 U.S.C. §271(g).

19. Merck will be substantially and irreparably harmed if Hospira's infringement of the '323 patent is not enjoined. Merck does not have an adequate remedy at law.

20. Merck is entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of the approval of Hospira's ANDA be a date that is not earlier than the expiration date of the '323 patent, or the date of any later expiration of exclusivity to which Merck is or becomes entitled.

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

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF '323 PATENT

22. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-21.

23. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202.

24. There is an actual case or controversy such that the Court may entertain Merck's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of right by this Court.

25. On information and belief, Hospira has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Hospira Generic Product.

26. Hospira's Notice Letter indicates a refusal to change the course of its actions directed to obtaining FDA approval for and commercially marketing the Hospira Generic Product prior to the expiration of the '323 patent.

27. In the Detailed Statement of the Factual and Legal Bases for its Opinion that U.S. Patent No. 5,952,323 Is Invalid, Unenforceable, and/or Not Infringed by the Manufacture, Use, Importation, Sale or Offer for Sale of the Hospira Generic Product, which accompanies the Hospira Notice Letter, Hospira does not assert that the Hospira Generic Product will not infringe the '323 patent, or that the '323 patent is unenforceable.

28. On information and belief, in its ANDA No. 206480, Hospira has represented to the FDA that the Hospira Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

29. On information and belief, the Hospira Generic Product contains the stabilized form of ertapenem described and claimed in the '323 patent.

30. On information and belief, the manufacture of the Hospira Generic Product requires the performance of every step of at least method claim 4 of the '323 patent.

31. On information and belief, the commercial manufacture, use, or sale of the Hospira Generic Product prior to the expiration of the '323 patent will directly infringe the '323 patent under 35 U.S.C. §271(a), will actively induce infringement of the '323 patent under 35 U.S.C. §271(b), will constitute contributory infringement of the '323 patent under 35 U.S.C. §271(c), and will infringe the '323 patent under 35 U.S.C. §271(g).

32. Merck is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Hospira's Generic Product will infringe the '323 patent.

PRAYER FOR RELIEF

33. Merck requests that:

a. Judgment be entered that Hospira has infringed the '323 patent by submitting ANDA No. 206480;

b. Judgment be entered that the commercial manufacture, use, offer for sale, sale, and/or importation of Hospira's Generic Product will infringe the '323 patent under 35 U.S.C. §271(a), (b), (c), and/or (g);

c. A permanent injunction be issued, pursuant to 35 U.S.C. §271(e)(4)(B), restraining and enjoining Hospira, its 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 the

Hospira Generic Product prior to the expiration date of the '323 patent, or the date of any later expiration of exclusivity to which Merck is or becomes entitled.

d. An order be issued pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of any approval of ANDA No. 206480 be a date which is not earlier than the later of the expiration date of the '323 patent, or the date of any later expiration of exclusivity to which Merck is or becomes entitled; and

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

f. For such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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