IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-915 (RGA)
	)	CONSOLIDATED
HOSPIRA, INC.	)	
	)	
Defendant.	)	
	)	REDACTED - PUBLIC VERSION
MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-916 (RGA)
	)	
SANDOZ, INC.	)	
	)	
Defendant.	)	

AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp., by way of Complaint against Sandoz 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, 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 Drive, Suite 400, Princeton, New Jersey 08540.

3. 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.

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. On information and belief, Sandoz is subject to personal jurisdiction in this District.

6. On information and belief, and as stated in its ANDA Notice Letter, Sandoz's ANDA No. 205198 was prepared and filed with the intention of seeking to market a generic version of Merck's Invanz® product. On further information and belief, Sandoz intends to sell its generic version of Merck's Invanz® product in the state of Delaware, list its generic version of Merck's Invanz® product on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Merck's Invanz® product in Delaware.

7. On information and belief, Sandoz has purposefully availed itself of the privilege of doing business in the State of Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or selling, directly or through its agents, pharmaceutical products in Delaware. On further information and belief, Sandoz holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0000260, and a Distributor-Manufacturer License for Controlled Substances from the State of Delaware under License No. DS0131.

8. In the alternative, Sandoz is subject to the jurisdiction of this Court pursuant to 10 Del. C. §3104. Specifically, Sandoz causes tortious injury in or outside of

Delaware, namely from the tort of patent infringement, and Sandoz regularly does or solicits business, engages in a persistent course of conduct in Delaware and this District, and derives substantial revenue from things used or consumed in Delaware and this District.

9. On information and belief, personal jurisdiction over Sandoz is also proper because Sandoz has previously availed itself of this jurisdiction for the purpose of litigating its patent suits. *See, e.g., Sandoz Inc. v. Pfizer Inc.*, C.A. No. 10-104 (D. Del.). In addition, Sandoz has previously been sued in this District, has not contested personal jurisdiction, and has availed itself of this forum by asserting counterclaims in patent infringement disputes. *See, e.g., Cephalon, Inc. v. Sandoz Inc.*, C.A. No. 13-2104 (D. Del.); *Genzyme Corp. v. Sandoz Inc.*, C.A. No. 13-1507 (D. Del.); *UCB Inc. v. Sandoz Inc.*, C.A. No. 13-1216 (D. Del.); *Glaxosmithkline Intellectual Property Management Ltd. et al. v. Sandoz, Inc.*, C.A. No. 11-1284 (D. Del.); *Aventis Pharma S.A. v. Sandoz Inc.*, C.A. No. 11-043 (D. Del.).

10. 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 PATENTS

11. 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®.

12. 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.

13. 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.

14. Merck is the owner of U.S. Patent No. 6,486,150 (the "'150 patent") which is attached as Exhibit B. The '150 patent discloses and claims a process for preparing a final formulation of certain compounds, including ertapenem.

15. Merck is the owner of U.S. Patent No. 6,548,492 (the "'492 patent") which is attached as Exhibit C. The '492 patent discloses and claims a process for stabilizing beta-lactam carbapenem formulations, including ertapenem formulations.

SANDOZ'S ANDA AND NOTICE LETTER

16. By letter ("Sandoz Notice Letter") dated August 23, 2013, and received by Merck on August 25, 2013, Sandoz gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 205198 to the FDA under 21 U.S.C. §355(j) seeking approval to manufacture, use and sell ertapenem for injection 1g (the "Sandoz Generic Product"), prior to the expiration of the '323 patent.

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

COUNT I – INFRINGEMENT OF '323 PATENT

18. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-17.

19. Sandoz submitted ANDA No. 205198 to the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the Sandoz Generic Product prior to the expiration of the '323 patent. By submitting this application, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

20. On information and belief, Sandoz 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.

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

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

23. On information and belief, the commercial manufacture, use, or sale of the Sandoz 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).

24. Sandoz has stipulated, for purposes of this litigation only, that "[u]pon final approval of ANDA No. 205198, the commercial manufacture, use, sale or offer for sale within the United States, or importation into the United States, of Sandoz's ANDA Product

would infringe asserted claims 2 and 4-6 of the '323 patent, as currently drafted, under 35 U.S.C. §271(a), (b), (c) and/or (g), if those claims are adjudged not to be invalid or unenforceable."

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

26. 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 Sandoz'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.

27. 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

28. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-27.

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

30. 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.

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

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

33. 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 Sandoz Generic Product, which accompanies the Sandoz Notice Letter, Sandoz does not assert that the Sandoz Generic Product will not infringe the '323 patent, or that the '323 patent is unenforceable.

34. On information and belief, in its ANDA No. 205198, Sandoz has represented to the FDA that the Sandoz Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

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

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

37. On information and belief, the commercial manufacture, use, or sale of the Sandoz 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).

38. Sandoz has stipulated, for purposes of this litigation only, that "[u]pon final approval of ANDA No. 205198, the commercial manufacture, use, sale or offer for sale within the United States, or importation into the United States, of Sandoz's ANDA Product

would infringe asserted claims 2 and 4-6 of the '323 patent, as currently drafted, under 35 U.S.C. §271(a), (b), (c) and/or (g), if those claims are adjudged not to be invalid or unenforceable."

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

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT OF '150 PATENT

40. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-39.

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

42. 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.

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

44. Sandoz's Notice Letter indicates a refusal to change the course of its actions directed to obtaining FDA approval for and commercially marketing the Sandoz Generic Product prior to the expiration of the '150 patent.

45. On information and belief, in its ANDA No. 205198, Sandoz has represented to the FDA that the Sandoz Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

46. On information and belief, the manufacture of the Sandoz Generic Product as described in ANDA No. 205198 carries out every step of at least claims [redacted] of the '150 patent.

47. On information and belief, the commercial manufacture, use, sale, and/or importation of the Sandoz Generic Product prior to the expiration of the '150 patent will directly infringe the '150 patent under 35 U.S.C. §271(a) and/or §271(g).

48. Merck is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product will infringe the '150 patent.

COUNT IV - DECLARATORY JUDGMENT OF INFRINGEMENT OF '492 PATENT

49. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-48.

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

51. 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.

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

53. Sandoz's Notice Letter indicates a refusal to change the course of its actions directed to obtaining FDA approval for and commercially marketing the Sandoz Generic Product prior to the expiration of the '492 patent.

54. On information and belief, in its ANDA No. 205198, Sandoz has represented to the FDA that the Sandoz Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

55. On information and belief, the manufacture of the Sandoz Generic Product as described in ANDA No. 205198 carries out every step of at least claims [redacted] of the '492 patent.

56. On information and belief, the commercial manufacture, use, sale, and/or importation of the Sandoz Generic Product prior to the expiration of the '492 patent will directly infringe the '492 patent under 35 U.S.C. §271(a) and/or §271(g).

57. Merck is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product will infringe the '492 patent.

PRAYER FOR RELIEF

58. Merck requests that:

a. Judgment be entered that Sandoz has infringed the '323 patent by submitting ANDA No. 205198;

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

c. Judgment be entered that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product will infringe the '150 patent under 35 U.S.C. §271(a) and/or (g).

d. Judgment be entered that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product will infringe the '492 patent under 35 U.S.C. §271(a) and/or (g).

e. An order be issued pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of any approval of ANDA No. 205198 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

f. A permanent injunction be issued, pursuant to 35 U.S.C. §271(e)(4)(B), restraining and enjoining Sandoz, 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 Sandoz 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.

g. A permanent injunction be issued, pursuant to 35 U.S.C. §283, restraining and enjoining Sandoz, 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 Sandoz Generic Product prior to the expiration date of the '150 patent, or the date of any later expiration of exclusivity to which Merck is or becomes entitled.

h. A permanent injunction be issued, pursuant to 35 U.S.C. §283, restraining and enjoining Sandoz, 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 Sandoz

Generic Product prior to the expiration date of the '492 patent, or the date of any later expiration of exclusivity to which Merck is or becomes entitled.

i. 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;

j. 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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