IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

MERCK SHARP & DOHME CORP. Plaintiff, v. SAVIOR LIFETEC CORP. Defendant.	)	Civil Action No. 5:15-cv-00415-BO

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by way of Complaint against Savior Lifetec Corp. ("Savior"), alleges as follows:

THE PARTIES

1. Merck is a corporation organized and existing under the laws of the state of New Jersey, having a 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, Savior is a corporation organized and existing under the laws of Taiwan, Republic of China, with its principal place of business at No. 29, Kejhong Rd., Chunan Township, Miaoli County 350, Taiwan.

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

4. Savior has designated Dr. Susan Sponner, of INC Research LLC, 3201 Beechleaf Court, Suite 660, Raleigh, NC 27604-1547, to accept service of process on Savior's behalf pursuant to 21 C.F.R. § 314.95(c)(7).

JURISDICTION AND VENUE

5. 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).

6. Because Savior had designated Dr. Susan Sponner, of INC Research LLC, 3201 Beechleaf Court, Suite 660, Raleigh, NC 27604-1547, as Savior's agent authorized to accept service of process for Savior in this action, it has consented to personal jurisdiction in this district.

7. 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

8. 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®.

9. 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.

10. 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®.

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

12. 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.

SAVIOR'S ANDA AND NOTICE LETTER

13. By letter ("Savior Notice Letter") dated July 9, 2015, and received by Merck on July 10, 2015, Savior gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 207647 to the FDA under 21 U.S.C. §355(j) seeking approval to manufacture, use and sell ertapenem for injection 1g (the "Savior Generic Product"), prior to the expiration of the '323 patent.

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

15. This action was filed within 45 days of Merck's receipt of Savior's Notice Letter.

COUNT I – INFRINGEMENT OF '323 PATENT

16. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-15.

17. Savior submitted ANDA No. 207647 to the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the Savior Generic Product prior to the expiration of the '323 patent. By submitting this application, Savior has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

18. On information and belief, Savior 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.

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

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

21. On information and belief, the commercial manufacture, use, or sale of the Savior 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), and will constitute contributory infringement of the '323 patent under 35 U.S.C.

§271(c); the importation of the Savior Generic Product into the United States for commercial sale will infringe the '323 patent under 35 U.S.C. §271(g).

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

23. 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 Savior '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.

24. 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

25. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-24.

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

27. 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.

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

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

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

31. On information and belief, in its ANDA No. 207647, Savior has represented to the FDA that the Savior Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

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

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

34. On information and belief, the commercial manufacture, use, or sale of the Savior 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), and will constitute contributory infringement the '323 patent under 35 U.S.C. §271(c); the importation of the Savior Generic Product into the United States for commercial sale will infringe the '323 patent under 35 U.S.C. §271(g).

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

COUNT III – DECLARATORY JUDGMENT
OF INFRINGEMENT OF '150 PATENT

36. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-35.

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

38. Savior has alleged, and Merck does not contest, that there is an actual case or controversy between Merck and Savior with respect to Savior's infringement of the '150 patent such that the Court may entertain Merck's request for declaratory relief consistent with Article III of the United States Constitution.

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

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

41. On information and belief, in its ANDA No. 207647, Savior has represented to the FDA that the Savior Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

42. Savior has asserted counterclaims in this action asserting that there is an actual case or controversy between Merck and Savior with respect to Savior's infringement of

the ‘150 patent. In view of Savior’s assertion that an actual controversy exists with respect to the infringement of the ‘150 patent, the chemistry of the ertapenem molecule, and the necessity of stabilizing that molecule to obtain a product that is stable at room temperature, Merck, on information and belief, alleges infringement of the ‘150 patent and resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief that Savior’s process for the manufacture of its Generic Product satisfies one or more claims of the ‘150 patent.

COUNT IV – DECLARATORY JUDGMENT
OF INFRINGEMENT OF ‘492 PATENT

43. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-42.

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

45. Savior has alleged, and Merck does not contest, that there is an actual case or controversy between Merck and Savior with respect to Savior’s infringement of the ‘492 patent such that the Court may entertain Merck’s request for declaratory relief consistent with Article III of the United States Constitution.

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

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

48. On information and belief, in its ANDA No. 207647, Savior has represented to the FDA that the Savior Generic Product is pharmaceutically and therapeutically equivalent to Merck's Invanz® product.

49. Savior has asserted counterclaims in this action asserting that there is an actual case or controversy between Merck and Savior with respect to Savior's infringement of the '492 patent. In view of Savior's assertion that an actual controversy exists with respect to the infringement of the '492 patent, the chemistry of the ertapenem molecule, and the necessity of stabilizing that molecule to obtain a product that is stable at room temperature, Merck, on information and belief, alleges infringement of the '492 patent and resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief that Savior's process for the manufacture of its Generic Product satisfies one or more claims of the '492 patent.

PRAYER FOR RELIEF

50. Merck requests that:

(a) Judgment be entered that Savior has infringed the '323 patent by submitting ANDA No. 207647;

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

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

(f) An order be issued pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of any approval of ANDA No. 207647 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;

(g) A permanent injunction be issued, pursuant to 35 U.S.C. §283, restraining and enjoining Savior, 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 Savior 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 Savior, 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 Savior 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; and

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

Dated: October 5, 2015

/s/ Timothy G. Barber
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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of October, 2015, I electronically filed the foregoing using the Court's CM/ECF system, which will serve electronic notification to the following counsel of record:

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