IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. WATSON LABORATORIES, INC., WATSON PHARMA, INC., and ACTAVIS, INC., Defendants.	)	C.A. No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendants Watson Laboratories, Inc., ("Watson Labs"), Watson Pharma, Inc. ("Watson Pharma"), and Actavis, Inc. ("Actavis") (collectively, "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

2. Plaintiff Sanofi U.S. is a wholly owned U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. On information and belief, defendant Watson Labs is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108.

4. On information and belief, defendant Watson Pharma is a corporation organized and existing under the laws of the State of Delaware, having its principal place of

business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Watson Pharma is a wholly owned subsidiary of defendant Actavis and does business in Delaware and elsewhere under the name "Actavis Pharma, Inc."

5. On information and belief, defendant Actavis is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code and for a declaratory judgment of patent infringement arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Watson Labs. On information and belief, Watson Labs is a corporation organized and existing under the laws of Delaware and Watson Labs has a registered agent for service of process in Delaware.

8. On information and belief, Watson Labs directly or through its affiliates and agents, manufactures, markets, and sells drug products throughout the United States and in this judicial district. On information and belief, Watson Labs holds a pharmacy wholesale license for the state of Delaware under License No. A4-0001263 and a distributor/manufacturer license for controlled substances for the state of Delaware under License No. DS0499.

9. On information and belief, Watson Labs regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives

substantial revenue from services or things used or consumed in Delaware, demonstrating that Watson Labs has continuous and systematic contacts with Delaware.

10. On information and belief, Watson Labs has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including at least the following cases: *Watson Laboratories Inc., v. Barr Laboratories, Inc. et al.* (1:08-cv-00793-GMS), *Kissei Pharmaceutical Co. Ltd. et al. v. Hetero USA Inc., et al.* (1:13-cv-01091-LPS), and *Kissei Pharmaceutical Co. Ltd. et al. v. Sandoz Inc.* (1:13-cv-01092-LPS). On information and belief, Watson Labs has also previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *Reckitt Benckiser et al. v. Watson Laboratories, Inc.* (1:13-cv-01674-RGA).

11. On information and belief, this Court found that Watson Labs was subject to general personal jurisdiction in Delaware in *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 1:08-cv-330-SLR, 629 F. Supp. 2d 338 (D. Del. 2009).

12. This court has personal jurisdiction over Watson Pharma. On information and belief, Watson Pharma is a corporation organized and existing under the laws of Delaware and Watson Pharma has a registered agent for service of process in Delaware.

13. On information and belief, Watson Pharma is in the business of distributing and/or selling generic pharmaceutical products in the United States and in this judicial district, including but not limited to products made by Watson Labs. On information and belief, Watson Pharma holds pharmacy wholesale licenses for the state of Delaware under the name "Actavis Pharma, Inc." bearing License Nos. A4-0000627 and A4-000683. On information and belief, Watson Pharma holds distributor/ manufacturer licenses for controlled

substances for the state of Delaware under the name "Actavis Pharma Inc." bearing License Nos. DS0503 and DS0319.

14. On information and belief, Watson Pharma regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Watson Labs has continuous and systematic contacts with Delaware.

15. On information and belief, Watson Pharma has previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *UCB Inc. et al. v. Watson Laboratories Inc. – Florida et al.* (1:13-cv-01219-LPS).

16. This Court has personal jurisdiction over Actavis. On information and belief, Actavis is in the business of, among other things, formulating, developing, manufacturing, marketing, and selling generic pharmaceutical products for the United States market. On information and belief, Actavis directly, or through its wholly owned subsidiaries (including Delaware corporations Watson Labs and Watson Pharma), develops, manufactures, markets, and sells generic pharmaceutical products throughout the United States and in this judicial district.

17. On information and belief, Actavis directly and/or through its wholly owned subsidiaries regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Actavis has continuous and systematic contacts with Delaware.

18. On information and belief, Actavis has previously availed itself of this forum by filing lawsuits in this judicial district as a plaintiff, including at least the following

cases: *Kissei Pharmaceutical Co. Ltd. et al v. Hetero USA Inc., et al.* (1:13-cv-01091-LPS) and *Kissei Pharmaceutical Co. Ltd. et al v. Sandoz Inc.* (1:13-cv-01092-LPS). On information and belief, Actavis has also previously availed itself of this forum by submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction including, for example, *UCB Inc. et al. v. Watson Laboratories Inc. – Florida et al.* (1:13-cv-01219-LPS).

19. On information and belief, this Court further has personal jurisdiction over Defendants because Defendants regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware and committed the tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to plaintiff Sanofi U.S., a Delaware corporation.

20. On information and belief, upon approval of Watson Labs' Abbreviated New Drug Application (ANDA) No. 205682, Defendants and/or their affiliates or agents will market and sell Watson Labs' dronedarone hydrochloride tablets, 400 mg ("Watson Labs' Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

21. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the above-mentioned facts.

22. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

23. Sanofi U.S. holds approved New Drug Application ("NDA") No. 022425 for dronedarone tablets, 400 mg, which are prescribed and sold in the United States under the trademark Multaq®. The U.S. Food and Drug Administration ("FDA") approved NDA No. 022425 on July 1, 2009. Multaq® tablets are indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

24. United States Patent No. 8,318,800 ("the '800 patent," copy attached as Exhibit A) is entitled "Solid Pharmaceutical Compositions Containing Benzofuran Derivatives" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on November 27, 2012. The '800 patent claims, *inter alia*, pharmaceutical compositions containing dronedarone. The '800 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Multaq® tablets (NDA No. 022425).

25. The named inventors on the '800 patent are Bernard Abramovici, Jean-Claude Gautier, Jean-Claude Gromenil, and Jean-Marie Marrier. The '800 patent is assigned to Sanofi.

26. United States Patent No. 8,410,167 ("the '167 patent," copy attached as Exhibit B) is entitled "Use of Dronedarone for the Preparation of a Medicament for Use in the Prevention of Cardiovascular Hospitalization or of Mortality" and was duly and legally issued by the USPTO on April 2, 2013. The '167 patent claims, *inter alia*, methods of decreasing the risk of cardiovascular hospitalization in certain patients by administering dronedarone. The '167 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

27. The named inventors on the '167 patent are Davide Radzik, Martin Van Eickels, Nacéra Hamdani, and Christophe Gaudin. The '167 patent is assigned to Sanofi.

28. United States Patent No. 8,602,215 ("the '215 patent," copy attached as Exhibit C) is entitled "Methods for Reducing the Risk of an Adverse Dronedarone/Beta-Blockers Interaction in a Patient Suffering from Atrial Fibrillation" and was duly and legally issued by the USPTO on December 10, 2013. The '215 patent claims, *inter alia*, methods for managing the risk of dronedarone/beta-blocker interaction in patients with paroxysmal or persistent atrial fibrillation or atrial flutter. The '215 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425).

29. The named inventor on the '215 patent is Davide Radzik. The '215 patent is assigned to Sanofi.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

30. Watson Labs submitted ANDA No. 205682 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of dronedarone hydrochloride tablets, 400 mg ("Watson Labs' Proposed Generic Product").

31. On information and belief, ANDA No. 205682 seeks FDA approval of Watson Labs' Proposed Generic Product for the indication of reducing the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

32. On information and belief, Watson Pharma and Actavis actively participated in and/or directed activities related to the submission of ANDA No. 205682 and the development of Watson Labs' Proposed Generic Product, were actively involved in preparing the ANDA, and/or intend to directly benefit from and have a financial stake in the approval of

the ANDA. On information and belief, upon approval of ANDA No. 205682, Watson Pharma and Actavis will be involved in the manufacture, marketing, and/or distribution of Watson Labs' Proposed Generic Product.

33. By letter dated January 16, 2014, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Watson Labs notified Plaintiffs that it had submitted ANDA No. 205682 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Watson Labs' Proposed Generic Product before the expiration of the '800 patent and the '167 patent.

34. In its January 16, 2014 letter, Watson Labs notified Plaintiffs that, as a part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '800 patent and the '167 patent. On information and belief, Watson Labs certified that, in its opinion and to the best of its knowledge, the '800 patent and the '167 patent are invalid and/or will not be infringed by the manufacture, use, or sale of Watson Labs' Proposed Generic Product.

35. On information and belief, Watson Labs' ANDA did not contain a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) for the '215 patent.

36. Pursuant to 21 U.S.C. § 355(j) and 21 C.F.R. § 314.94, Watson Labs is required to make a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) to the '215 patent.

37. On information and belief, based upon, *inter alia,* Watson Labs' Paragraph IV certifications to the earlier expiring '800 and '167 patents, Watson Labs' is seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product before the expiration of the '215 patent.

COUNT I
Infringement of U.S. Patent No. 8,318,800 Under 35 U.S.C. §271(e)(2)

38. Plaintiffs repeat and reallege paragraphs 1 through 37 as if fully set forth herein.

39. By submitting ANDA No. 205682 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product throughout the United States prior to the expiration of the '800 patent, Defendants committed an act of infringement of the '800 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the '800 patent at the time the ANDA was submitted.

40. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product, for which Watson Labs seeks approval in ANDA No. 205682, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '800 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

41. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

COUNT II
Infringement of U.S. Patent No. 8,410,167 Under 35 U.S.C. §271(e)(2)

42. Plaintiffs repeat and reallege paragraphs 1 through 41 as if fully set forth herein.

43. By submitting ANDA No. 205682 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product throughout the United States prior to the expiration of the '167 patent, Defendants committed an act of infringement of the

'167 patent under 35 U.S.C. §271(e)(2). On information and belief, Defendants were aware of the '167 patent at the time the ANDA was submitted.

44. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product, for which Watson Labs seeks approval in ANDA No. 205682, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '167 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

45. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

COUNT III
Infringement of U.S. Patent No. 8,602,215 Under 35 U.S.C. §271(e)(2)

46. Plaintiffs repeat and reallege paragraphs 1 through 45 as if fully set forth herein.

47. By submitting ANDA No. 205682 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product throughout the United States prior to the expiration of the '215 patent, Defendants committed an act of infringement of the '215 patent under 35 U.S.C. §271(e)(2).

48. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product, for which Watson Labs seeks approval in ANDA No. 205682, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '215 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

49. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

COUNT IV
Declaratory Judgment of Infringement of U.S. Patent No. 8,602,215 Under 35 U.S.C. §271(a), (b), or (c)

50. Plaintiffs repeat and reallege paragraphs 1 through 49 as if fully set forth herein.

51. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

53. Defendants have made and will continue to make substantial preparation in the United Sates to manufacture, use, sell, offer to sell, and/or import Watson Labs' Proposed Generic Product prior to the expiration of the '215 patent.

54. The Defendants' actions, including but not limited to filing, maintaining, and not withdrawing ANDA No. 205682 containing Paragraph IV Certifications to the '800 patent and the '167 patent, evince a refusal to change their course of action in the face of acts by Plaintiffs, including but not limited to Plaintiffs' timely listing of the '215 patent in the Orange Book prior to Watson Labs' January 16, 2014 notice letter.

55. The commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product, for which Watson Labs seeks approval in ANDA No. 205682, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '215 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

56. Plaintiffs are entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic

Product prior to the expiration of the '215 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '215 patent.

57. Plaintiffs will be irreparably harmed by Defendants' infringing activities and do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '800 patent by submitting ANDA No. 205682 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product before the expiration of the '800 patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product will infringe the '800 patent;

C. A judgment declaring that the '800 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product until the expiration of the '800 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of Watson Labs' ANDA No. 205682 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '800 Patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

F. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '167 patent by submitting ANDA No. 205682 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product before the expiration of the '167 patent;

G. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product will infringe the '167 patent;

H. A judgment declaring that the '167 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product until the expiration of the '167 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

J. An order that the effective date of any approval of Watson Labs' ANDA No. 205682 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '167 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

K. A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '215 patent by submitting ANDA No. 205682 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product before the expiration of the '215 patent;

L. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product will infringe the '215 patent;

M. A declaration under 28 U.S.C. § 2201 that if Defendants and/or their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product prior to the expiration of the '215 patent, it will constitute an act of infringement of the '215 patent;

N. A judgment declaring that the '215 patent remains valid and enforceable;

O. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Watson Labs' Proposed Generic Product until the expiration of the '215 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

P. An order that the effective date of any approval of Watson Labs' ANDA No. 205682 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration of the '215 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

Q. A determination that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

R. Costs and expenses in this action; and

S. Such other and further relief as the Court may deem just and proper.

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