IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI and SANOFI-AVENTIS U.S. LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No.: _____
	)	
AUROBINDO PHARMA USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi and Sanofi-Aventis U.S. LLC ("Sanofi U.S.") (collectively, "Plaintiffs") for their Complaint against defendant Aurobindo Pharma USA, Inc. ("Aurobindo" or "Defendant") 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 Aurobindo is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279, Princeton-Hightstown Rd., East Windsor, NJ 08520-1401 USA.

JURISDICTION AND VENUE

4. 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. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338.

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

6. On information and belief, Aurobindo, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical products, including generic drug products, throughout the United States and in this judicial district. On information and belief, Aurobindo holds a Delaware controlled substances distributor/manufacturer license (No. DM0006550) and a Delaware pharmacy wholesale license (No. A4-0001270).

7. On information and belief, Aurobindo 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 Aurobindo has continuous and systematic contacts with Delaware.

8. On information and belief, Aurobindo has previously consented to personal jurisdiction in this judicial district, including but not limited to *Astellas Pharma Inc. v. Actavis Elizabeth LLC, et al.*, 16-cv-905-SLR (D. Del. 2016).

9. On information and belief, this Court further has personal jurisdiction over Aurobindo because Aurobindo 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 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.

10. On information and belief, upon approval of Aurobindo's Abbreviated New Drug Application (ANDA) No. 210678, Aurobindo and/or its affiliates or agents will market and sell Aurobindo's dronedarone hydrochloride tablets, 400 mg ("Aurobindo's Proposed Generic Product") in Delaware and throughout the United States and will derive substantial revenue therefrom.

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

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b). *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S.Ct. 1514 (2017).

THE PATENTS-IN-SUIT

13. Sanofi 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.

14. United States Patent No. 8, 410,167 ("the '167 patent," copy attached as Exhibit A) is entitled "Use of Dronedarone for the Preparation of a Medicament for Use in the Prevention of Cardiovascular Hospitalization or Mortality" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on April 2, 2013. The '167 patent claims, *inter alia*, methods of decreasing risk of cardiovascular hospitalization in patients in

sinus rhythm with a history of paroxysmal or persistent atrial fibrillation using dronedarone. The '167 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Multaq® tablets (NDA No. 022425). The Orange Book lists the expiration of the '167 patent as April 16, 2029.

15. 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.

16. United States Patent No. 9,107,900 ("the '900 patent," copy attached as Exhibit C) is entitled "Use of Dronedarone for the Preparation of a Medicament for Use in the Prevention of Cardiovascular Hospitalization or of Morality [sic]" and was duly and legally issued by the USPTO on August 18, 2015. The '900 patent claims, *inter alia*, methods of reducing risk of cardiovascular hospitalization in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation using dronedarone. The '900 patent is listed in the Orange Book for Multaq® tablets (NDA No. 022425). The Orange Book lists the expiration of the '900 patent as April 16, 2029.

17. The named inventors on the '900 patent are Davide Radzik, Martin Van Eickels, Nacéra Hamdani, and Christophe Gaudin. The '900 patent is assigned to Sanofi.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

18. Aurobindo submitted ANDA No. 210678 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Proposed Generic Product.

19. On information and belief, Aurobindo, through its ANDA No. 210678, seeks FDA approval of Aurobindo's 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.

20. On information and belief, Aurobindo actively participated in and/or directed activities related to the submission of ANDA No. 210678 and the development of Aurobindo's Proposed Generic Product, was actively involved in preparing ANDA No. 210678, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA No. 210678. On information and belief, upon approval of ANDA No. 210678, Aurobindo will be involved in the manufacture, distribution, and/or marketing of Aurobindo's Proposed Generic Product.

21. By letter dated July 20, 2017 ("Aurobindo's Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Aurobindo notified Plaintiffs that it had submitted ANDA No. 210678 to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Aurobindo's Proposed Generic Product before the expiration of the '167 patent and the '900 patent.

22. In its letter Aurobindo 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 '167 patent and the '900 patent. On information and belief, Aurobindo certified that, in its opinion and to the best of its knowledge, the '167 patent and the '900 patent are invalid and/or will not be infringed by the manufacture, use, or sale of Aurobindo's Proposed Generic Product.

23. The submission of ANDA No. 210678 to the FDA constituted an act of infringement by Aurobindo of the '167 patent and the '900 patent under 35 U.S.C. § 271(e)(2).

24. Plaintiffs are commencing this action within 45 days of receiving Aurobindo's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

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

25. Plaintiffs repeat and reallege paragraphs 1 through 24 as if fully set forth herein.

26. Pursuant to 35 U.S.C. § 271(e)(2), Aurobindo's submission of ANDA No. 210678 to the FDA seeking approval of Aurobindo's Proposed Generic Product under the Food, Drug, and Cosmetic Act was an act of infringement of at least claims 1-4, 6, 8-13, and 16 of the '167 patent.

27. Aurobindo was aware of the '167 patent at the time ANDA No. 210678 was submitted.

28. If Aurobindo's Proposed Generic Product is approved by the FDA and is sold by Aurobindo, its use by healthcare providers and/or patients will directly infringe one or more claims of the '167 patent, including at least claims 1-4, 6, 8-13, and 16.

29. Aurobindo's proposed label for Aurobindo's Proposed Generic Product explicitly instructs healthcare providers and/or patients to use Aurobindo's Proposed Generic Product in a manner that will directly infringe one or more of the claims of the '167 patent, including at least claims 1-4, 6, 8-13, and 16.

30. Any use of Aurobindo's Proposed Generic Product by patients will be performed at the direction and control of healthcare providers reducing risk of cardiovascular hospitalization in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation, who in turn are instructed by Aurobindo in its proposed label for Aurobindo's Proposed Generic Product.

31. If Aurobindo's Proposed Generic Product is approved by the FDA, Aurobindo will actively induce others including, e.g., healthcare providers and/or patients, to

directly infringe one or more claims of the '167 patent, including at least claims 1-4, 6, 8-13, and 16. Aurobindo has acted with knowledge that the induced acts would constitute infringement of the '167 patent.

32. Aurobindo specifically intends to cause the acts that constitute direct infringement by others, e.g., healthcare providers and/or patients.

33. If and when the FDA approves ANDA No. 210678, Aurobindo will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Aurobindo's proposed label, to use Aurobindo's Proposed Generic Product in a manner that directly infringes one or more claims of the '167 patent, including at least claims 1-4, 6, 8-13, and 16. Thus Aurobindo will encourage, recommend and/or promote others, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '167 patent, and Aurobindo will affirmatively and specifically intend to cause the acts that constitute direct infringement.

34. Aurobindo's actions will constitute inducement of infringement of the '167 patent pursuant to 35 U.S.C. § 271(b).

35. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities and do not have an adequate remedy at law.

COUNT II
(Infringement of U.S. Patent No. 9,107,900 Under § 271(e)(2))

36. Plaintiffs repeat and reallege paragraphs 1 through 35 as if fully set forth herein.

37. Pursuant to 35 U.S.C. § 271(e)(2), Aurobindo's submission of ANDA No. 210678 to the FDA seeking approval of Aurobindo's Proposed Generic Product under the Food,

Drug, and Cosmetic Act was an act of infringement of at least claims 1, 6-9 and 14 of the ’900 patent.

38. Aurobindo was aware of the ’900 patent at the time ANDA No. 210678 was submitted.

39. If Aurobindo’s Proposed Generic Product is approved by the FDA and is sold by Aurobindo, its use by healthcare providers and/or patients will directly infringe one or more claims of the ’900 patent, including at least claims 1, 6-9 and 14.

40. Aurobindo’s proposed label for Aurobindo’s Proposed Generic Product explicitly instructs healthcare providers and/or patients to use Aurobindo’s Proposed Generic Product in a manner that will directly infringe one or more of the claims of the ’900 patent, including at least claims 1, 6-9 and 14.

41. Any use of Aurobindo’s Proposed Generic Product by patients will be performed at the direction and control of healthcare providers reducing risk of cardiovascular hospitalization in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation, who in turn are instructed by Aurobindo in its proposed label for Aurobindo’s Proposed Generic Product.

42. If Aurobindo’s Proposed Generic Product is approved by the FDA, Aurobindo will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the ’900 patent, including at least claims 1, 6-9 and 14. Aurobindo has acted with knowledge that the induced acts would constitute infringement of the ’900 patent.

43. Aurobindo specifically intends to cause the acts that constitute direct infringement by others, e.g., healthcare providers and/or patients.

44. If and when the FDA approves ANDA No. 210678, Aurobindo will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Aurobindo's proposed label, to use Aurobindo's Proposed Generic Product in a manner that directly infringes one or more claims of the '900 patent, including at least claims 1, 6-9 and 14. Thus Aurobindo will encourage, recommend and/or promote others, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '900 patent, and Aurobindo will affirmatively and specifically intend to cause the acts that constitute direct infringement.

45. Aurobindo's actions will constitute inducement of infringement of the '900 patent pursuant to 35 U.S.C. § 271(b).

46. Plaintiffs will be irreparably harmed by Aurobindo's 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 Aurobindo and respectfully request the following relief:

A. A judgment that under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '167 patent by submitting ANDA No. 210678 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Proposed Generic Product before the expiration of the '167 patent.

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

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

D. A permanent injunction restraining and enjoining Aurobindo and its 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 Aurobindo's Proposed Generic Product until the expiration of the '167 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 Aurobindo's ANDA No. 210678 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;

F. A judgment that under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '900 patent by submitting ANDA No. 210678 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Proposed Generic Product before the expiration of the '900 patent.

G. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Aurobindo's Proposed Generic Product will infringe the '900 patent;

H. A judgment declaring that the '900 patent remains valid and enforceable;

I. A permanent injunction restraining and enjoining Aurobindo and its 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 Aurobindo's Proposed Generic Product until the expiration of the '900 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 Aurobindo's ANDA No. 210678 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 '900 patent or any later date of exclusivity to which Plaintiffs and/or this patent are or become entitled;

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

L. Costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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August 31, 2017