IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., MSD INTERNATIONAL BUSINESS GMBH, MSD INTERNATIONAL GMBH, PFIZER INC., and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Merck Sharp & Dohme Corp. ("Merck"), MSD International Business GmbH ("MSD International Business"), MSD International GmbH ("MSD International"), Pfizer Inc. ("Pfizer"), and PF PRISM IMB B.V. ("PRISM") (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively "Aurobindo") of Abbreviated New Drug Application ("ANDA") No. 216947 to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Steglatro® (ertugliflozin) in 5 and 15 mg strength tablets ("Aurobindo's Proposed ANDA Product") prior to the expiration of U.S. Patent No. 8,080,580 ("the '580 patent"). Aurobindo notified Plaintiffs that it had submitted its ANDA by a letter dated February 8, 2022 ("Aurobindo Notice Letter").

PARTIES

2. Merck is a corporation organized and existing under the laws of New Jersey, having a place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. MSD International Business is a limited liability company organized and existing under the laws of Switzerland, having a place of business at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

4. MSD International is a limited liability company organized and existing under the laws of Switzerland, having a place of business at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

5. Pfizer is a corporation organized and existing under the laws of Delaware having a place of business at 235 E 42nd St., New York, New York 10017.

6. PRISM is a limited liability company organized and existing under the laws of the Netherlands, having a registered office at Rivium Westlaan 142, 2909 LD Capelle aan den IJssel, the Netherlands.

7. Upon information and belief, Aurobindo Pharma Limited ("Aurobindo Pharma") is a corporation organized and existing under the laws of the Republic of India, having a place of business at Galaxy, Plot No. 1 22nd-24th Floor Survey No.83/1, Hyderabad Knowledge City Raidurg Panmaktha, Ranga Reddy District, Hyderabad 500032, Telangana, India.

8. Upon information and belief, Aurobindo Pharma USA, Inc. ("Aurobindo Pharma USA") is a corporation organized and existing under the laws of Delaware, having a place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Aurobindo Pharma USA because, upon information and belief, Aurobindo Pharma USA is a corporation organized and existing under the laws of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, Aurobindo Pharma USA has purposefully availed itself of the privileges of conducting business in Delaware and consented to general jurisdiction in Delaware.

11. This Court has personal jurisdiction over Aurobindo Pharma because, *inter alia*, Aurobindo Pharma, itself and through its subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Aurobindo Pharma, itself and through its subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. In addition, this Court has personal jurisdiction over Aurobindo Pharma USA and Aurobindo Pharma because, among other things, upon information and belief: (1) Aurobindo Pharma and its subsidiary Aurobindo Pharma USA, collectively and/or in concert with each other, developed Aurobindo's ANDA product that is the subject of ANDA No. 216947 and submitted ANDA No. 216947 for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in the United States of Aurobindo's Proposed ANDA Product, including in Delaware; (2) upon approval of Aurobindo's ANDA, Aurobindo Pharma and its subsidiary

Aurobindo Pharma USA, collectively and/or in concert with each other will market, distribute, offer for sale, and sell in the United States, and/or import into the United States, including in Delaware, Aurobindo's Proposed ANDA Product, and will derive substantial revenue from the use or consumption of Aurobindo's Proposed ANDA Product in Delaware; (3) upon approval of Aurobindo's ANDA, Aurobindo's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, and sold in Delaware, and/or imported into Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware. By submitting Aurobindo's ANDA, Aurobindo Pharma and Aurobindo Pharma USA have shown that they will use distribution channels to direct sales of Aurobindo's Proposed ANDA Product into Delaware.

13. In addition, this Court has personal jurisdiction over Aurobindo Pharma USA and Aurobindo Pharma because they have committed, aided, abetted, induced, contributed to, or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Pfizer, a Delaware corporation.

14. In addition, this Court has personal jurisdiction over Aurobindo Pharma USA and Aurobindo Pharma because both regularly engage in patent litigation concerning Aurobindo's ANDA products in this District, have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of ANDAs, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in such cases. *See, e.g.*, *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd., et al.*, C.A. No. 21-1735-WCB (D. Del.), *Newron Pharmaceuticals S.p.A., et al., v. Aurobindo Pharma Limited, et al.*, C.A. No. 21-843-RGA (D. Del.), *Pfizer Inc., et al., v. Aurobindo Pharma, Ltd., et al.*, C.A. No. 21-022-CFC (D. Del.).

15. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma under Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Aurobindo Pharma is a foreign company not subject to jurisdiction in any state's courts of general jurisdiction and (c) Aurobindo Pharma has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Pharma satisfies due process.

16. Venue is proper in this District with respect to Aurobindo Pharma USA pursuant to 28 U.S.C. §§ 1391 and 1400(b), at least because, upon information and belief, Aurobindo Pharma USA is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

17. Venue is proper in this Court under 28 U.S.C. § 1391(c)(3) with respect to Aurobindo Pharma, at least because, upon information and belief, Aurobindo Pharma is a foreign corporation that may be sued in any judicial district.

BACKGROUND

STEGLATRO® (ERTUGLIFLOZIN)

18. Steglatro® is indicated to improve glycemic control in adults with type 2 diabetes mellitus, as an adjunct to diet and exercise.

19. Merck sells Steglatro® in the United States pursuant to New Drug Application ("NDA") No. 209803, which has been approved by the FDA.

20. Merck is the holder of approved NDA No. 209803 for Steglatro®.

21. The '580 patent is listed for NDA No. 209803 for Steglatro® in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

22. The '580 patent, titled "Dioxa-bicyclo[3.2.1]octane-2,3,4-triol derivatives," was duly and legally issued on December 20, 2011. A copy of the '580 patent is attached as Exhibit A.

23. Pfizer is the assignee of the '580 patent.

24. MSD International, MSD International Business, and PRISM are licensees and hold exclusive rights under the '580 patent.

25. There is an actual case or controversy between the parties regarding Aurobindo's liability for infringement of the '580 patent.

AUROBINDO'S ANDA

26. According to Aurobindo's Notice Letter, ANDA No. 216947 includes a certification pursuant to the Food, Drug, & Cosmetic Act ("FDCA") 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '580 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of Aurobindo's Proposed ANDA Product.

27. Aurobindo was aware of the '580 patent when ANDA No. 216947 was filed with a Paragraph IV Certification.

28. Upon information and belief, ertugliflozin is the active ingredient in Aurobindo's Proposed ANDA Product.

29. Upon information and belief, ANDA No. 216947 refers to and relies upon the NDA for Steglatro® and contains data that, according to Aurobindo, demonstrate bioequivalence of Aurobindo's Proposed ANDA Product and Steglatro®, *see* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7), or Aurobindo has sought a waiver of the requirement to demonstrate bioequivalence of its Proposed ANDA Product and Steglatro®.

30. Upon information and belief, Aurobindo intends to have healthcare providers and patients administer its Proposed ANDA Product, if approved, as set forth in Aurobindo's proposed

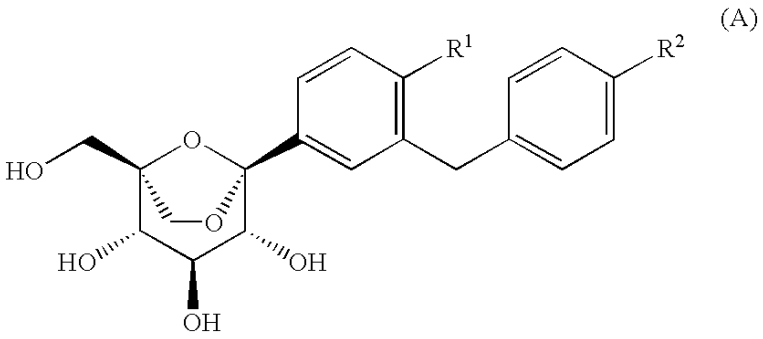
label for this ANDA product. Upon information and belief, Aurobindo's proposed label will instruct healthcare providers to prescribe Aurobindo's Proposed ANDA Product in the manner set forth in the label.

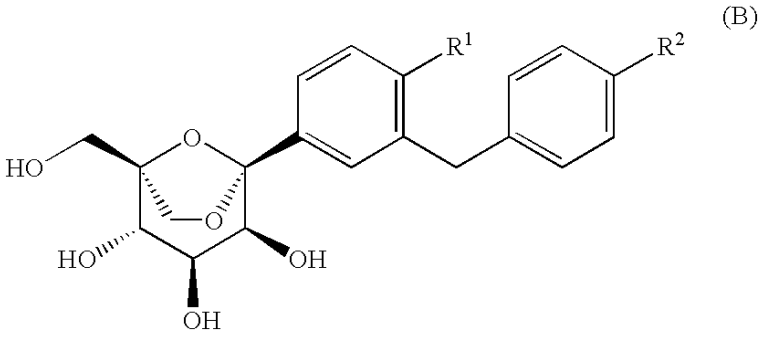
31. This action is being filed within 45 days of Plaintiffs' receipt of Aurobindo's Notice Letter.

CLAIM FOR RELIEF
(Infringement of the '580 Patent)

32. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

33. Claim 1 of the '580 patent covers "[a] compound of Formula (A) or Formula (B)





wherein R^1 is H, (C_1-C_4)alkyl, (C_1-C_4)alkoxy, Cl, F, cyano, fluoro-substituted (C_1-C_2)alkyl, (C_1-C_4)alkyl-SO_2—, or (C_3-C_6)cycloalkyl; and R^2 is (C_1-C_4)alkyl, (C_1-C_4)alkoxy, (C_2-C_4)alkynyl, 3-oxetanyloxy, 3-tetrahydrofuranyloxy, Cl, F, cyano, fluoro-substituted (C_1-C_2)alkyl, (C_1-C_4)alkyl-SO_2—, (C_3-C_6)cycloalkyl, or a (C_5-C_6)heterocycle having 1 or 2 heteroatoms each independently selected from N, O, or S."

34. Upon information and belief, Aurobindo's Proposed ANDA Product and its use are covered by one or more of the claims of the '580 patent, including at least claim 1.

35. Upon information and belief, the commercial manufacture, sale, offer for sale, and/or importation of Aurobindo's Proposed ANDA Product, and/or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed label for that product, will infringe one or more claims of the '580 patent, including at least claim 1, either literally or under the doctrine of equivalents.

36. Upon information and belief, Aurobindo submitted as part of ANDA No. 216947 a Paragraph IV Certification, asserting that the claims of the '580 patent are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's Proposed ANDA Product.

37. Aurobindo did not contend in its Notice Letter that Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed label for that product, would not infringe claims 1-8, 10-14, 16, 18, and 20 of the '580 patent.

38. The purpose of submitting ANDA No. 216947 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '580 patent.

39. Aurobindo's submission of ANDA No. 216947 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's Proposed ANDA Product prior to the expiration of the '580 patent was an act of infringement of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Aurobindo intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's Proposed ANDA Product and the proposed label immediately and imminently upon the approval of ANDA No. 216947 and any amendments thereto, *i.e.*, prior to the expiration of the '580 patent.

41. Upon information and belief, Aurobindo has knowledge of the '580 patent at least because the '580 patent is listed in the FDA's Orange Book: *Approved Drug Products with Therapeutic Equivalence Evaluations* for Plaintiffs' Steglatro® drug product. Notwithstanding this knowledge, Aurobindo continues to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's Proposed ANDA Product and the proposed label therefor immediately and imminently upon the approval of ANDA No. 216947.

42. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '580 patent when ANDA No. 216947 is approved, and will do so with specific intent to induce infringement of the '580 patent. Further upon information and belief, Aurobindo plans and intends to, and will, do so immediately and imminently upon approval.

43. Upon information and belief, Aurobindo knows that Aurobindo's Proposed ANDA Product is especially made or adapted for use in patented methods of the '580 patent, and that Aurobindo's Proposed ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '580 patent immediately and imminently upon approval of ANDA No. 216947.

44. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '580 patent, active inducement of infringement of the '580 patent, and contribution to the infringement by others of the '580 patent, either literally or under the doctrine of equivalents.

45. Aurobindo has no reasonable basis to believe that Aurobindo's Proposed ANDA Product, or the use of Aurobindo's Proposed ANDA Product in accordance with and as directed by Aurobindo's proposed label for that product, would not infringe one or more valid claims of the '580 patent.

46. Unless Aurobindo is enjoined from infringing the '580 patent, actively inducing infringement of the '580 patent and contributing to the infringement by others of the '580 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Aurobindo has infringed the '580 patent under 35 U.S.C. § 271(e)(2)(A) and will infringe, actively induce infringement of, and/or contribute to infringement by others of the '580 patent under 35 U.S.C. §§ 271(a), (b) and (c);

(b) A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's Proposed ANDA Product, or any product the use of which infringes the '580 patent, be not earlier than the expiration date of the '580 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) enjoining Aurobindo, and all persons acting in concert with Aurobindo, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's Proposed ANDA Product, or any product the use of which infringes the '580 patent, or the inducement of or contribution to any of the foregoing, prior to the expiration date of the '580 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Aurobindo's Proposed ANDA Product, or any product the use of which infringes the '580 patent, prior to the expiration date of the '580 patent, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by others of the '580 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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