IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS INCORPORATED,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiff Vertex Pharmaceuticals Incorporated ("Vertex"), by its undersigned attorneys, for its Complaint against Defendant Sun Pharmaceutical Industries Limited ("Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 214027 to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Vertex's KALYDECO® (ivacaftor) tablets prior to the expiration of a patent which covers, *inter alia*, KALYDECO® and its use.

2. In ANDA No. 214027, Defendant seeks approval to commercially market a generic version of Vertex's KALYDECO® tablets prior to the expiration of United States Patent No. 10,646,481 ("the '481 patent"), which is owned by Vertex.

THE PARTIES

3. Plaintiff Vertex is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 50 Northern Avenue, Boston, MA 02210. Vertex is a biopharmaceutical company committed to improving the lives of patients

worldwide. Vertex focuses on the pursuit of medical research to create transformative medicines for people with serious and life-threatening diseases, such as cystic fibrosis.

4. Upon information and belief, Defendant is a company organized and existing under the laws of India, with its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400 063. Upon information and belief, Defendant is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the United States market, alone and/or through its wholly owned subsidiaries and agents.

THE PATENT-IN-SUIT

5. On May 12, 2020, the United States Patent and Trademark Office duly and legally issued the '481 patent, entitled "Pharmaceutical Composition and Administrations Thereof," to Vertex as assignee. A copy of the '481 patent is attached to this Complaint as Exhibit A.

6. Vertex is the lawful owner of and holds right, title, and interest in the patent-in-suit.

KALYDECO®

7. Vertex holds approved New Drug Application No. 203188 for the use of ivacaftor 150 mg tablets for the treatment of cystic fibrosis in patients age six and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data. Vertex sells the ivacaftor tablets under the trade name KALYDECO®.

8. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the '481 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to New Drug Application No. 203188.

DEFENDANT'S ANDA

9. Upon information and belief, Defendant has submitted ANDA No. 214027 ("Defendant's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 150 mg ivacaftor tablets ("Defendant's Product"), which are based on Vertex's KALYDECO® 150 mg tablets, before the expiration of the '481 patent.

10. Upon information and belief, Defendant's ANDA refers to and relies upon Vertex's New Drug Application No. 203188 and contains data that, according to Defendant, demonstrates the bioequivalence of Defendant's Product to KALYDECO® 150 mg tablets.

11. By letter to Vertex, dated June 10, 2020 ("Defendant's Paragraph IV Notice Letter"), Defendant stated that Defendant's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '481 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of Defendant's Product (the "Paragraph IV Certification"). Defendant attached a memorandum to its June 10, 2010 letter, in which it purported to allege the factual and legal bases for its Paragraph IV Certification.

12. Upon information and belief, if the FDA approves Defendant's ANDA, Defendant will manufacture, distribute, import, offer for sale and/or sell Defendant's Product throughout the United States, including within the State of Delaware.

13. This action is being filed within 45 days of Vertex's receipt of Defendant's Paragraph IV Notice Letter.

JURISDICTION AND VENUE

14. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Defendant because of Defendant's regular transaction and/or solicitation of business in this State. Furthermore, by continuously placing its products into the stream of commerce for distribution and consumption in Delaware, and throughout the United States, Defendant has engaged in the regular conduct of business within this judicial district.

16. In addition, this Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Upon information and belief, Sun Pharmaceutical Industries, Inc., a wholly-owned subsidiary of Defendant, is incorporated in Delaware.

17. Upon information and belief, Defendant has previously consented to suit in this judicial district and has not challenged personal jurisdiction. Defendant has further availed itself of the jurisdiction of this Court by previously asserting counterclaims in this jurisdiction. *See, e.g.*, *Millennium Pharm., Inc. v. Sun Pharm. Indus. Ltd.*, No. 20-289, D.I. 9 (D. Del. May 4, 2020); *Pfizer Inc. v. Sun Pharm. Indus., Ltd.*, No. 19-758, D.I. 11 (D. Del. July 10, 2019); *Salix Pharm., Ltd. et al. v. Sun Pharm. Indus., Ltd.*, No. 19-734, D.I. 15 (D. Del. June 24, 2019).

18. Venue is proper in this Court under 28 U.S.C. § 1391(c)(3), because Defendant, on information and belief, is not a resident of the United States and may thus be sued in any judicial district.

CLAIM FOR RELIEF
INFRINGEMENT OF U.S. PATENT NO. 10,646,481

19. Defendant has infringed one or more claims of the '481 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting and maintaining Defendant's ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Defendant's Product prior to the expiration of the '481 patent.

20. Defendant's commercial manufacture, sale, offer for sale, or use of Defendant's Product within the United States, or importation of Defendant's Product into the United States, during the term of the '481 patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '481 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

21. Upon information and belief, Defendant has acted with full knowledge of the '481 patent and without a reasonable basis for believing that it would not be liable for infringement of the '481 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendant's Product with its proposed labeling immediately and imminently upon approval of Defendant's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '481 patent.

22. Upon information and belief, if the FDA approves Defendant's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '481 patent, and will do so immediately and imminently upon approval.

23. Upon information and belief, Defendant knows that Defendant's Product is especially made or adapted for use in infringing the '481 patent, and that Defendant's Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '481 patent immediately and imminently upon approval of Defendant's ANDA.

24. Vertex will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '481 patent.

25. Vertex has no adequate remedy at law.

26. Vertex is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Vertex prays for a judgment in its favor and against Defendant and respectfully requests the following relief:

A. A judgment that Defendant has infringed the '481 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining Defendant's ANDA No. 214027;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of Defendant's ANDA No. 214027 shall be a date not earlier than the expiration of the '481 patent, or any later expiration of exclusivity to which Vertex is or becomes entitled;

C. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Defendant's Product will directly infringe, induce and/or contribute to infringement of the '481 patent;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendant, its officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling Defendant's Product within the United States, or importing Defendant's Product into the United States, prior to the expiration of the '481 patent, or any later expiration of exclusivity to which Vertex is or becomes entitled;

E. If Defendant commercially manufactures, uses, offers to sell, or sells Defendant's Product within the United States, or imports Defendant's Product into the United States, prior to the expiration of the '481 patent, including any extensions, a judgment awarding damages to Vertex resulting from such infringement, together with interest;

F. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Vertex its attorneys' fees incurred in this action;

G. A judgment awarding Vertex costs and expenses incurred in this action; and

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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