IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE UK LTD. and VIIV HEALTHCARE CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs ViiV Healthcare UK Ltd. and ViiV Healthcare Co. for their Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. hereby allege as follows:

THE PARTIES

1. Plaintiff ViiV Healthcare UK Ltd., a wholly owned subsidiary of ViiV Healthcare Limited, is a company organized and existing under the laws of England and having an office and place of business at 980 Great West Road, Brentford Middlesex, TW89GS, United Kingdom.

2. Plaintiff ViiV Healthcare Co., a wholly-owned subsidiary of ViiV Healthcare Limited, is a Delaware corporation having a trading address at Five Moore Drive, Research Triangle Park, North Carolina 27709. Plaintiffs ViiV Healthcare UK Ltd. and ViiV Healthcare Co. are hereinafter collectively referred to as "ViiV."

3. On information and belief, Defendant Aurobindo Pharma Ltd. is a publicly-traded company organized under the laws of India, having an office and place of business at Plot no. 2, Maitri Vihar, Ameerpet, Hyderabad - 500038, Andhra Pradesh, India.

4. On information and belief Aurobindo Pharma Ltd. manufactures numerous generic drugs, including, among others, cefprozil, lisinopril, meloxicam, ramipril, gabapentin, fluconazole, and simvastatin, for sale and use throughout the United States, including in this judicial district.

5. On information and belief, Defendant Aurobindo Pharma USA, Inc. (hereinafter "Aurobindo USA"), is a corporation organized under the laws of Delaware and a wholly-owned subsidiary of Defendant Aurobindo Pharma Ltd., having an office and place of business at 6 Wheeling Road, Dayton, N.J. 08810. Defendants Aurobindo Pharma Ltd. and Aurobindo USA are hereinafter collectively referred to as "Aurobindo."

6. On information and belief, Aurobindo USA is the United States agent for Aurobindo Pharma Ltd. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

7. On information and belief, Aurobindo USA is also the United States marketing and sales agent for Aurobindo Pharma Ltd. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Aurobindo Pharma Ltd. manufactures and supplies the approved generic drug product to Aurobindo USA, which then markets and sells the product throughout the United States, including in this judicial district.

8. On information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of the ANDA at issue in this action, Aurobindo

Pharma Ltd. will sell the generic product accused of infringement in this action through Aurobindo USA throughout the United States, including in this judicial district.

THE NATURE OF THE ACTION

9. This is a civil action for infringement of United States Patent No. 6,294,540 ("the '540 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Aurobindo because, *inter alia*, it has availed itself of the rights and benefits of Delaware law, including incorporation, and has engaged in substantial and continuing contacts with the State. Aurobindo also does business and sells its products in this judicial district as well as throughout the United States. In particular, Aurobindo markets and sells its generic pharmaceuticals in this judicial district. Furthermore, Aurobindo Pharma Ltd. and Aurobindo USA have previously submitted to the jurisdiction of this Court. *See, e.g.*, *UCB Inc. et al v. Aurobindo Pharma Ltd. et al*, 1:13-cv-01210-LPS, ECF 14 (D. Del. filed July 10, 2013, date of last filing March 10, 2014); *see also Helsinn Healthcare S.A. et al v. Aurobindo Pharma Ltd. et al*, 1:13-cv-00688-GMS, ECF 12 (D. Del. filed April 16, 2013, date of last filing June 17, 2014).

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT

13. The ’540 patent, entitled “Carbocyclic Nucleoside Hemisulfate and its Use in Treating Viral Infections,” was duly and legally issued on September 25, 2001, and claims, *inter alia*, the hemisulfate salt of (1S,4R)-cis-4-[2-amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol (a/k/a abacavir).

14. ViiV Healthcare Co. is the owner of the entire right, title and interest in the ’540 patent pursuant to a 2009 assignment from GlaxoSmithKline LLC. Alternatively, ViiV Healthcare UK Ltd. is the owner of that patent pursuant to the 2011 recorded assignment from GlaxoSmithKline LLC, and ViiV Healthcare Co. is the exclusive licensee and has the right to sue and to recover for any infringement of that patent. A true and correct copy of the ’540 patent is attached hereto as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

15. The FDA granted approval of New Drug Application (“NDA”) No. 21-652 in August 2004 to sell an oral tablet dosage form containing 600 mg of abacavir as abacavir sulfate and 300 mg of lamivudine for use in treating Human Immunodeficiency Virus (“HIV”) infection in humans. The tablets approved under NDA No. 21-652 are prescribed and sold in the United States under the tradename Epzicom®. ViiV Healthcare Co. is the owner of NDA No. 21-652.

16. The ’540 patent is listed in the U.S. Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for Epzicom®.

17. On information and belief, on or before May 20, 2014, Aurobindo Pharma Ltd., through its subsidiary and agent Aurobindo USA, submitted ANDA No. 206-151 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

18. ANDA No. 206-151 seeks FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale of a generic version of Epzicom® ("the Generic Product"), prior to the expiration of the '540 patent.

19. ANDA No. 206-151 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act that the claims of the '540 patent are either invalid and/or not infringed by the manufacture, use, or sale of the Generic Product. ViiV received written notification of ANDA No. 206-151 and its § 505(j)(2)(A)(vii)(IV) allegations on May 22, 2014.

20. On information and belief, and consistent with its practice with respect to other generic products, Aurobindo Pharma Ltd. has designated Aurobindo USA as its agent in the United States for purposes of filing ANDA No. 206-151 and for marketing and selling the Generic Product in the United States, including in this judicial district, upon approval of ANDA No. 206-151.

21. Aurobindo Pharma Ltd.'s submission of ANDA No. 206-151 with its § 505(j)(2)(A)(vii)(IV) allegations to the FDA through its subsidiary and agent Aurobindo USA constitutes infringement of the '540 patent under 35 U.S.C. § 271(e)(2)(A).

22. Aurobindo USA is jointly and severally liable for the infringement of the '540 patent. On information and belief, Aurobindo USA participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 206-151 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

23. Aurobindo USA's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 206-151 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitute infringement of the '540 patent under 35 U.S.C. § 271(e)(2)(A).

24. ViiV is entitled to full relief from Aurobindo's acts of infringement under 35 U.S.C. § 271(e)(4), including an order by this Court that the effective date of any approval of Aurobindo's ANDA be a date that is not earlier than the expiration date for the '540 patent, or any other expiration of exclusivity to which ViiV is or becomes entitled.

25. Aurobindo had actual and constructive notice of the '540 patent prior to filing ANDA No. 206-151 and, on information and belief, was aware that the filing of ANDA No. 206-151 with its § 505(j)(2)(A)(vii)(IV) allegations with the FDA constituted an act of infringement of the '540 patent.

26. ViiV will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. ViiV does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the '540 patent has been infringed by Aurobindo;

B. A judgment under 35 U.S.C. § 271(e)(4)(A) declaring that the effective date of any FDA approval of Aurobindo's ANDA No. 206-151, or any product or compound that infringes the '540 patent, shall not be earlier than the expiration of the '540 patent, including any extensions and additional periods of exclusivity;

C. An order under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Aurobindo, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, or importing the Generic Product, or any product or compound that infringes the '540 patent, or inducing the infringement of the '540 patent, until the expiration of the '540 patent.

D. An order that this is an exceptional case and an award of attorneys' fees, costs and expenses under 35 U.S.C. §§ 285 and 271(e)(4); and

E. Such other and further relief as this Court may deem proper.

Dated: July 2, 2014

Respectfully submitted,

FARNAN LLP

By: /s/ Brian E. Farnan

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