IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE UK LTD. and VIIV HEALTHCARE CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs ViiV Healthcare UK Ltd. and ViiV Healthcare Co. for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., hereby allege as follows:

THE PARTIES

1. Plaintiff ViiV Healthcare UK Ltd. 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 UK Ltd., 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 Teva Pharmaceuticals USA, Inc. (hereinafter "Teva USA") is a corporation organized and existing under the laws of the State of

Delaware, and having an office and place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

4. On information and belief, Teva Pharmaceutical Industries Ltd. (hereinafter "Teva Ltd." and collectively with Teva USA "Teva") is a corporation organized and existing under the laws of Israel, and having its principal place of business located at 5 Basel Street, St. Petach Tikva 49131, Israel. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

5. On information and belief, the acts of Teva USA complained of herein were done at the direction of and with the authorization, cooperation, participation, and assistance of Teva Ltd. and, further, were done at least in part for the benefit of Teva Ltd.

THE NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent No. 6,417,191 ("the '191 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Teva USA because, *inter alia*, it is incorporated in the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with the State. Teva USA also does business and sells its products in this judicial district as well as throughout the United States. In particular, Teva USA markets and sells its generic pharmaceuticals in this judicial district.

9. This Court has personal jurisdiction over Teva Ltd. because, on information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), manufactures, markets, and sells generic drugs, and otherwise conducts business throughout the United States and in this judicial district. Teva Ltd. has previously submitted to the jurisdiction of this Court and has also previously availed itself of the protections of this Court by filing suit here and by asserting counterclaims in other civil actions initiated in this judicial district.

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

THE PATENT

11. The '191 patent, entitled "Synergistic Combinations of Zidovudine, 1592U89 and 3TC," was duly and legally issued on July 9, 2002 and claims, *inter alia*, a combination of 1592U89 (a/k/a abacavir) and 3TC (a/k/a lamivudine).

12. ViiV Healthcare UK Ltd. is the owner of the entire right, title and interest in the '191 patent including the right to sue and to recover for any infringement of that patent. A true and correct copy of the '191 patent is attached hereto as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

13. 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 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.

14. The '191 patent is listed in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Epzicom®.

15. On information and belief, on or before June 24, 2011, Teva USA, at the direction and with the assistance of Teva Ltd., submitted ANDA No. 079-246 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

16. ANDA 079-246 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic oral tablet dosage form containing 600 mg of abacavir sulfate and 300 mg of lamivudine for use in treating HIV infection in humans ("the Generic Product"), prior to the expiration of the '191 patent.

17. ANDA 079-246 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act that the claims of the '191 patent are either invalid, unenforceable, and/or not infringed by the manufacture, use, or sale of the Generic Product. ViiV received written notification of ANDA 079-246 and its § 505(j)(2)(A)(vii)(IV) allegations on June 27, 2011.

18. On information and belief, and consistent with its practice with respect to other generic products, Teva Ltd. has designated Teva USA as its agent in the United States for purposes of filing ANDA 079-246 and for marketing and selling the Generic Product in the United States, including in this judicial district, upon any approval of ANDA 079-246.

19. Teva USA's submission of ANDA 079-246 with its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '191 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Teva USA commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '191 patent, it would further infringe that patent under 35 U.S.C. § 271(a), (b) and/or (c).

20. Teva Ltd. is jointly and severally liable for the infringement of the '191 patent. On information and belief, Teva Ltd. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 079-246 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

21. Teva Ltd.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 079-246 with its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitute infringement of the '191 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Teva Ltd. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '191 patent, it would further infringe that patent under 35 U.S.C. § 271(a), (b) and/or (c).

22. ViiV is entitled to full relief from Teva'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 Teva's ANDA be a date that is not earlier than the expiration date for the '191 patent, or any other expiration of exclusivity to which ViiV is or becomes entitled.

23. Teva had actual and constructive notice of the '191 patent prior to filing ANDA 079-246 and, on information and belief, was aware that the filing of ANDA 079-246 with its § 505(j)(2)(A)(vii)(IV) allegations with the FDA constituted an act of infringement of the '191 patent.

24. ViiV will be irreparably harmed by Teva'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 '191 patent has been infringed by Teva;

B. A judgment declaring that the effective date of any approval of Teva's ANDA No. 079-246 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be no earlier than the expiration date of the '191 patent, including any extensions and additional periods of exclusivity;

C. Pursuant to 35 U.S.C. § 271(e)(4)(B), a permanent injunction against any infringement of the '191 patent by Teva, its officers, agents, attorneys and employees, and those acting in privity or concert with them;

D. An accounting for damages if Teva commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct prior to the expiration of the '191 patent, including any extensions and additional periods of exclusivity, and that any such monetary relief be awarded to ViiV with prejudgment interest;

E. A judgment holding that Teva's infringement is willful if Teva commercially manufactures, uses, offers for sale or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct prior to the expiration of the '191 patent, including any extensions and additional periods of exclusivity, and trebling of damages pursuant to 35 U.S.C. § 284;

F. A judgment that ViiV be awarded the attorneys' fees, costs and expenses that it incurs prosecuting this action under 35 U.S.C. § 285; and

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

Dated: August 5, 2011

Respectfully submitted,

By: /s/ Brian E. Farnan

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