**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| VIIV HEALTHCARE UK LTD. and VIIV HEALTHCARE CO., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs ViiV Healthcare UK Ltd. and ViiV Healthcare Co. for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, 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 Lupin Ltd. is a publicly-traded company organized under the laws of India, having an office and place of business at Laxmi Towers, 'B' Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra - 400 051, India.

4. On information and belief Lupin Ltd. manufactures numerous generic drugs, including, among others, cefprozil, lisinopril, lovastatin, meloxicam, pravastatin, and ramipril, for sale and use throughout the United States, including in this judicial district.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. (hereinafter "LPI"), is a corporation organized under the laws of Virginia and a wholly-owned subsidiary of Defendant Lupin Ltd., having an office and place of business at Harborplace Tower, 111 South Calvert Street, 21st floor, Baltimore, MD 21202. Defendants Lupin Ltd. and LPI are hereinafter collectively referred to as "Lupin."

6. On information and belief, LPI is the United States agent for Lupin 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, LPI also is the United States marketing and sales agent for Lupin Ltd. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Lupin Ltd. manufactures and supplies the approved generic drug product to LPI, 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, Lupin Ltd. will sell the generic product accused of infringement in this action through LPI 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. 6,417,191 ("the '191 patent") and 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. §§ 100 *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 Lupin because, *inter alia*, it has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with the State. Lupin also does business and sells its products in this judicial district as well as throughout the United States. In particular, Lupin markets and sells its generic pharmaceuticals in this judicial district. Furthermore, Lupin Ltd. and LPI have previously submitted to the jurisdiction of this Court. For example, on September 20, 2011, Lupin Ltd. filed counterclaims in *ViiV Healthcare UK Ltd. et al v. Lupin Ltd. et al*, 1:11-cv-00576-RGA (D. Del. filed June 29, 2011, closed Jan. 24, 2014). *See also Eisai Co. Ltd. et al. v. Lupin Ltd., et al.*, 1:13-cv-01281-LPS, Docket No. 12, Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc.'s Answer, Defenses and Counterclaims (D. Del. filed July 24, 2013) (asserting counterclaims by Lupin Ltd.); *Novartis Pharms. Corp. v. Lupin Ltd. et al*, 1:12-cv-00595-SLR, Docket No. 8, Answer, Defenses and Counterclaims of Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (D. Del. filed May 14, 2012, terminated Nov. 6, 2012) (asserting counterclaims by Lupin Ltd. and LPI).

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

## THE PATENTS

13. 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) as well as a method of treating Human Immunodeficiency Virus (“HIV”) infection in humans by administering the combination.

14. ViiV Healthcare UK Ltd. is the owner of the entire right, title and interest in the ’191 patent. ViiV Healthcare Co. is the exclusive licensee of the ’191 patent and has 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.

15. 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).

16. ViiV Healthcare UK Ltd. is the owner of the entire right, title and interest in the ’540 patent. ViiV Healthcare Co. is the exclusive licensee of the ’540 patent 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 B.

## ACTS GIVING RISE TO THIS ACTION

17. 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.

18. 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®.

19. The ’540 patent is listed in the Orange Book for Epzicom®.

20. On information and belief, on or before February 5, 2014, Lupin Ltd., through its subsidiary and agent LPI, submitted ANDA No. 204-990 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

21. ANDA 204-990 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 expirations of the ’191 patent and the ’540 patent.

22. ANDA 204-990 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 and the ’540 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 204-990 and its § 505(j)(2)(A)(vii)(IV) allegations on February 6, 2014.

23. On information and belief, and consistent with its practice with respect to other generic products, Lupin Ltd. has designated LPI as its agent in the United States for purposes of filing ANDA 204-990 and for marketing and selling the Generic Product in the United States, including in this judicial district, upon approval of ANDA 204-990.

24. Lupin Ltd.’s submission of ANDA 204-990 with its § 505(j)(2)(A)(vii)(IV) allegations to the FDA through its subsidiary and agent LPI constitutes infringement of the ’191 patent and the ’540 patent under 35 U.S.C. § 271(e)(2)(A).

25. LPI is jointly and severally liable for the infringement of the ’191 patent and the ’540 patent. On information and belief, LPI participated in, contributed to, aided, abetted and/or

induced the submission of ANDA 204-990 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

26. LPI's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 204-990 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitute infringement of the '191 patent and the '540 patent under 35 U.S.C. § 271(e)(2)(A).

27. ViiV is entitled to full relief from Lupin'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 Lupin's ANDA be a date that is not earlier than the later expiration date for the '191 patent or the '540 patent, or any other expiration of exclusivity to which ViiV is or becomes entitled.

28. Lupin had actual and constructive notice of the '191 patent and the '540 patent prior to filing ANDA 204-990 and, on information and belief, was aware that the filing of ANDA 204-990 with its § 505(j)(2)(A)(vii)(IV) allegations with the FDA constituted an act of infringement of the '191 patent and the '540 patent.

29. ViiV will be irreparably harmed by Lupin'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 Lupin;

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

C. A judgment under 35 U.S.C. § 271(e)(4)(A) declaring that the effective date of any FDA approval of Lupin's ANDA No. 204-990, or any product or compound that infringes the '191 and '540 patents, shall not be earlier than the later expiration of the '191 and '540 patents, including any extensions and additional periods of exclusivity;

D. An order under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Lupin, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, have made, using, offering to sell, selling, marketing, distributing, or importing the Generic Product, or any product or compound that infringes the ’191 and ’540 patents, or inducing the infringement of the ’191 and ’540 patents, until the expiration of the ’191 and ’540 patents.

E. 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

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

Dated: March 21, 2014

Respectfully submitted,

FARNAN LLP

By: /s/ Brian E. Farnan

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