IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE UK LTD. and VIIV HEALTHCARE CO., Plaintiffs, v. LUPIN LTD., et al. Defendants.	C.A. No. 11-cv-00576-RGA (CONSOLIDATED) **HIGHLY CONFIDENTIAL FILED UNDER SEAL**

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF EMERGENCY MOTION FOR PRELIMINARY INJUNCTION AGAINST LUPIN'S GENERIC LAUNCH, PENDING THE COURT'S DECISION ON THE MERITS, AND TEMPORARY RESTRAINING ORDER

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Pursuant to Federal Rule of Civil Procedure 65(a)-(b), 35 U.S.C. § 283, and the Court's inherent power to issue stays, ViiV Healthcare UK Ltd. and ViiV Healthcare Co. (collectively "ViiV") respectfully request that the Court preserve the status quo pending its decision in this matter by **(a)** enjoining Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") from launching their proposed generic version of Trizivir while the Court completes its decision on the merits, and **(b)** ***immediately*** issuing a temporary restraining order to prevent Lupin's potentially imminent generic launch while the Court considers this motion. *See, e.g.*, *AstraZeneca LP v. Breath Ltd.*, No. 13-1312, Docket No. 17, at 2 (Fed. Cir. Apr. 10, 2013) (appellees "temporarily enjoined from launching their accused generic products pending the court's receipt of the response and the court's consideration of the papers submitted.").

As ViiV explained in its November 14, 2013 letter to the Court, the 30-month stay under the Hatch-Waxman Act expired November 19, 2013 as to Lupin. Lupin received FDA approval ***yesterday, December 5, 2013***, *see* http://www.fda.gov/Drugs/NewsEvents/ucm130961.htm (screen image below, accessed December 5, 2013), and has refused ViiV's requests to provide ***any*** advance notice of an at-risk launch.

New and Generic Drug Approvals

December 5, 2013

Drug Name	Active Ingredient	Dosage Form/Route	Sponsor	Submission Type
Abacavir Sulfate, Lamivudine and Zidovudine	abacavir sulfate; lamivudine; zidovudine	Tablet;Oral	Lupin Ltd	Approval

ViiV has contacted Lupin several times to attempt to reach agreement that would avoid the need for this motion. ViiV has requested that Lupin agree not to launch at risk while the Court's decision is pending, or to provide ViiV 30-days notice—or even any notice at all—of any

planned at-risk launch. At a minimum, ViiV has requested that Lupin agree not to launch over the weekend of December 7-8 so that the parties can attempt to reach a mutually agreeable arrangement that would avoid the need for further motion practice while the Court completes its decision on the merits. Even though the Court has made clear that it expects to issue its decision by December 23, 2013—little more than two weeks from today—Lupin has not agreed to any such arrangement. ViiV contacted Lupin on December 5 and December 6 regarding this motion, but did not reach agreement with Lupin. ViiV must therefore seek relief from the Court.[1]

As set forth in greater detail below, ViiV will suffer extreme, irreversible harm if Lupin launches its generic product for even a few days. While the phenomenon of irreversible price erosion from a generic is well-known in the pharmaceutical industry generally, a generic launch here would be particularly catastrophic to ViiV. ViiV is a small, relatively new company focused exclusively on anti-HIV drugs. [redacted] Even a short generic launch would deform the market irreparably, as industry experience has shown. In *Sanofi-Synthelabo v. Apotex, Inc.*, for example, Apotex was permitted to launch its generic for 23 days before the district court entered an injunction. 470 F.3d 1368, 1373 (Fed. Cir. 2006). During that time, Apotex shipped a ***six-month supply*** of its product to distributors in the United States, causing havoc in the market for Sanofi's Plavix product. *Id.* at 1382-83. Within ***ten days***, Apotex had captured 78% of new prescriptions, and 65% of the entire market. R. Pierson, *Deal Allows Sales, Apotex Tells Court: Generic Plavix*, NAT'L POST

[1] The 30-month stay expires on December 27, 2013, as to Teva, and Teva has already received tentative approval. ViiV has contacted Teva to request that Teva agree not to launch at risk while the Court's decision is pending and to agree to provide ViiV 30-days notice of any at-risk launch, but Teva has refused both requests. ViiV does not seek relief with respect to Teva at this time because the Court has indicated that it expects to issue its opinion on the merits no later than December 23, 2013. (Oral Order of November 18, 2013).

(CANADA) 6 (Aug. 22, 2006), *available at* 2006 WLNR 26269097; *See also* T. Agovino, *Generic Version Eating Into Plavix Sales*, GLOBE & MAIL (TORONTO) B2 (Aug. 22, 2006), *available at* 2006 WLNR 14494313 (16.6% of new prescriptions by the end of the first week of generic launch). Thus, Lupin should be enjoined from launching pending the Court's decision on the merits.

ARGUMENT

I. THE COURT HAS AUTHORITY TO ENJOIN LUPIN FROM LAUNCHING WHILE THE COURT'S DECISION IS PENDING WITHOUT APPLYING THE TRADITIONAL TEST FOR A PRELIMINARY INJUNCTION

As described in ViiV's November 14, 2013, letter, in other cases where it has appeared that the 30-month Hatch-Waxman Act stay could expire before the Court reached a decision on the merits, this Court has issued *sua sponte* stays to preserve the status quo and allow the Court sufficient time to complete its decision. In *Galderma Labs., LP v. Tolmar, Inc.*, No. 10-CV-45-LPS [D.I. No. 334] (D. Del. June 4, 2012), for example, Judge Stark issued an order *sua sponte*, three months after trial ordering that "Defendant Tolmar Inc. is enjoined from launching its generic drug product that was the subject of the trial until the Court issues its opinion in the above-captioned matter." The stay remained in effect for approximately three months beyond the end of the 30-month stay, until the Court's opinion issued on September 11, 2012.

Similarly, in *OSI Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 09-CV-185-SLR [D.I. No. 231] (D. Del. June 30, 2011), Judge Robinson issued an order *sua sponte*, six weeks after trial that, "in the absence of a stipulated briefing schedule that gives the court sufficient time to issue a decision prior to the expiration of the 30-month stay, defendant is enjoined from launching its generic drug until the court's decision issues."[2] Neither party

[2] Defendant Mylan's Opening Post-Trial Brief at 1, *OSI Pharms., Inc. v. Mylan Pharm. Inc.*, No. 09-185-SLR [D.I. No. 232] (D. Del. filed July 7, 2011) ("Plaintiffs' infringement action

expedited the briefing schedule, and the Court's opinion issued ten months later, on May 1, 2012. Lupin suggested that *OSI* made an implicit finding that the defendant failed to cooperate in expediting the briefing schedule, but that is not a fair reading of the *OSI* order. The Court simply alerted the parties that it may not have sufficient time to decide the case before the stay expired, and enjoined defendant from launching its generic drug in the event that the stay expired without a decision from the Court. In *OSI*, the parties' briefing schedule gave the Court seven months between the filing of the last post-trial brief (October 7, 2011) and the expiration of the 30-month stay (May 18, 2012). Here, the parties' expedited briefing schedule gave the Court four months between the filing of the last post-trial brief (July 17, 2013) and the expiration of the 30-months stay for Lupin (November 19, 2013). As the Court has determined, as Judge Robinson did in *OSI* and as Judge Stark did in *Galderma*, that the timing between the conclusion of post-trial briefing and the expiration of the 30-months stay is an insufficient amount of time, the Court should issue an order preserving the status quo until the court issues its decision.

Most notably, the Court issued its orders *sua sponte* in *Galderma* and *OSI*, to permit sufficient time to complete its decision, and without requesting briefing on considerations of likelihood of success on the merits, irreparable harm, or considerations of public interest. This belies the notion that ViiV must demonstrate its entitlement to a preliminary injunction under the traditional four-part test and Lupin offers no explanation for the orders in *Galderma* and *OSI*, and no basis for distinguishing them.

Regardless, because Lupin has received FDA approval, it can apparently launch at risk at any time, and has refused ViiV's requests for notice, ViiV demonstrates its entitlement to a preliminary injunction in the sections that follow. Further, although ViiV strongly believes it is

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triggered a thirty-month stay for Mylan and Teva … which expires on or about May 18, 2012.") (footnote omitted).

not necessary under these conditions, ViiV is capable of posting an appropriate security to ensure its ability to satisfy a monetary judgment, if the Court were to require it.[3]

II. VIIV IS ENTITLED TO A PRELIMINARY INJUNCTION UNDER THE TRADITIONAL FOUR-PART TEST

The decision whether to grant temporary injunctive relief depends on four factors: (1) likelihood of success, (2) irreparable harm to ViiV in the absence of an injunction, (3) relative harm to Defendants if an injunction is granted and (4) where the public interest lies. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006). The movant "must establish a strong likelihood of success on the merits or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor." *Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2010 WL 3374123 (Fed. Cir. Aug. 26, 2010) (granting injunction). In ANDA cases, district courts and the Federal Circuit have frequently granted injunctions in recognition of the irreversible damage that a generic launch can cause to the market, and of the comparatively lesser burden on the generic of having to wait a bit longer before launching its product. *See Astrazeneca LP v. Breath Ltd.*, No. 13-1312, Docket No. 70, slip op. at 2 (Fed. Cir. May 24, 2013) (granting injunction pending appeal); *Eli Lilly*, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010) (same); *Sanofi-Synthelabo*, 470 F.3d at 1382-83 (similar, affirming grant of preliminary injunction). In this case, the standard for a preliminary injunction is readily satisfied: ViiV has a substantial case on the merits, and—as described below and attested to in the attached declarations of ViiV's Senior Vice President and Head of North America William Collier and expert economist Dr. Henry Grabowski—ViiV will plainly suffer irreparable harm in the event of a generic launch.

[3] ViiV respectfully submits that, if the Court were to require a bond, that it first order the parties to reach agreement on a bonding arrangement, or request separate briefing on the issue.

Balancing the relative harms and, after considering the public interest, the Court should enjoin Lupin from launching its generic product pending resolution on the merits.

A. ViiV Is Likely to Succeed on the Merits

The Court has received substantial briefing on the merits of this case, and ViiV's arguments on the merits need not be repeated here. Suffice it to say however, that ViiV is likely to succeed on the merits. Lupin's non-infringement argument principally depends on the assertion that the abacavir sulfate in its generic product *and in ViiV's own Trizivir® product* is not the abacavir claimed in the '191 patent. Turning to validity, Lupin does not contend that any of the claims are anticipated. Lupin's arguments that the asserted claims are obvious are inconsistent with Teva's arguments and, more importantly, do not satisfy the clear-and-convincing evidence standard. Indeed, Lupin simply has no answer at all to the objective indicia of non-obviousness. And Lupin's strained assertion that the asserted claims are not enabled (which Teva does not join) is contrary to the weight of the evidence. Thus, for the reasons provided in ViiV's post-trial briefing, ViiV is likely to succeed on the merits.

B. ViiV Will be Irreparably Harmed in the Absence of an Injunction

ViiV will be irreparably harmed in the event of a generic launch from Lupin. The Federal Circuit and district courts have long recognized that the effects of a generic launch are often irreversible. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (affirming injunction; branded company "could not be made whole" because "erosion of markets, customers, and prices, is rarely reversible"); *Sanofi-Synthelabo*, 470 F.3d at 1382-83 (upholding district court's findings of irreparable harm, including price erosion); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003) ("generic competition would likely drive down the brand name's price and market share, causing permanent loss of customers and users of plaintiffs' patented product"); *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, 821

F. Supp. 2d 681, 695 (D.N.J. 2011) (similar, granting injunction).

"Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis In Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) (same, reversing denial of preliminary injunction). As described below and in the attached declarations of Mr. Collier and Dr. Grabowski, ViiV will suffer all of these harms and more in the event of a generic launch.

The nexus between Lupin's infringement and ViiV's irreparable harm is straightforward. Lupin sought and obtained FDA approval to market a generic version of ViiV's Trizivir®. Lupin will infringe the asserted claims because its proposed generic contains and provides the claimed combinations for the treatment of HIV infection. *See* D.I. 203, 223 (ViiV's post-trial briefs explaining Lupin's infringement); *see also* Grabowski Decl. ¶ 25.

[redacted]

Lupin has offered no contrary evidence, and has asked the Court to assume that ViiV's harm would be purely monetary and reparable (D.I. 210, Lupin Post-Trial Br., at 19-20), but the Federal Circuit has explicitly held that such an assumption is "not sufficient," and if accepted, "patents would lose their character as an exclusive right as articulated by the Constitution and become at best a judicially imposed and monitored compulsory license." *Aria*, 726 F.3d at 1304.

1. Premature Generic Entry By Lupin Would Cause Significant and Irreversible Loss In Market Share and Price Erosion

a. Loss of Sales, Profits, and Market Share

ViiV is a pharmaceutical company focused on generating life-saving HIV/AIDS drugs.

Collier Decl. ¶ 8; Grabowski Decl. ¶ 17. [redacted] As explained below, any launch by Lupin will cause immediate and irreparable harm to ViiV. *Id.* ¶¶ 7, 20-37; *see also* Grabowski Decl. ¶¶ 9-13, 21-44.

If Lupin were allowed to prematurely introduce a generic version of Trizivir®, such an introduction would cause significant, irreversible losses in market share, as courts have frequently recognized in directly analogous situations. *See Hoffmann-La Roche Inc. v. Cobalt Pharms. Inc.*, No. 07–4539, 2010 WL 4687839, at *11-*13 (D.N.J. Nov. 10, 2010) (granting preliminary injunction in light of showing of price erosion and 50-90% projected loss in market share); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. 1:06–cv–1017–SEB–JMS, 2009 WL 1080432, at *21-22 (S.D. Ind. Apr. 22, 2009) (granting preliminary injunction where loss of market exclusivity and share would be difficult to recover even if Court later rules in favor of patentee). [redacted] Because generic drugs are required to be bioequivalent to the branded drugs, Lupin's generic would compete directly with Trizivir®. Collier Decl. ¶ 21. [redacted]

[redacted]

At a minimum, these generic market penetration rates should be expected for Trizivir®. *Id.* ¶ 26; *see also* Grabowski Decl. ¶¶ 21, 26, 28 (describing rapid and severe erosion of branded pharmaceutical sales and prescriptions by generic entry, including other HIV/AIDS drugs).

[redacted]

Sanofi-Synthelabo, 470 F.3d at 1382 (finding irreparable harm based on price erosion where patentee offered price concessions to third-party payors, and unfavorable tier placement). [redacted]

[redacted]

Second, there are third-party payors, such as managed care organizations, that use a tier system—also known as formularies—to decide the amount of co-pay for a drug. *Id.* ¶ 24; Grabowski Decl. ¶¶ 22-23. [redacted].

Third, many retail pharmacies will push a generic product over a branded product because retail pharmacies receive a higher profit from the generic drug than the branded drug. *Id.* ¶ 25; Grabowski Decl. ¶ 21. [redacted]

[redacted]

b. Price Erosion

Trizivir® would suffer irreversible price erosion from a generic launch. "The phenomenon of price erosion in the pharmaceutical industry is well known." *Hoffmann-La Roche*, 2010 WL 4687839, at *12. And price erosion is recognized as irreparable harm. *Celsis*, 664 F.3d at 930; *Aria*, 726 F.3d at 1304 (same); *Sanofi-Synthelabo*, 470 F.3d at 1382 (finding irreparable harm based on irreversible price erosion from presence of infringing generic drug in the market). [redacted]

[redacted] The irreparable harm factor thus counsels in favor of an injunction. *See Aria*, 726 F.3d at 1304; *Celsis*, 664 F.3d at 930; *Sanofi-Synthelabo*, 470 F.3d at 1382.

2. Loss of Goodwill and Harm To ViiV's Reputation

If Lupin enters the market before the expiration of the '191 patent, ViiV will suffer permanent loss of goodwill. *See Sanofi-Synthelabo*, 470 F.3d at 1382-83 (loss of goodwill is irreparable harm); *Aria*, 726 F.3d at 1304 (same); *Celsis*, 664 F.3d at 930 (same). [redacted]; *Baker Hughes Inc. v. Nalco Co.*, 676 F. Supp. 2d 547, 554 (S.D. Tex. 2009) (finding irreparable harm to patentee's reputation where patentee could not resume elevated pricing without suffering harm to its good name and ability to conduct business). [redacted] *Sanofi-Synthelabo*, 470 F.3d at 1382-1383 (discontinuation of clinical trials shows irreparable harm). [redacted]

[redacted] *Eisai Co. v. Teva Pharms. USA, Inc.*, Nos. 05-5727 (HAA)(ES), 07-5489(HAA)(ES), 2008 WL 1722098, at *11 (D.N.J. Mar. 28, 2008) ("In that regard, Teva's argument that any damage is easily compensated with money is not accurate. Indeed, if there is a reasonable likelihood that research on future drugs—drugs that Teva no doubt will covet in the future and then argue that they are so important that a generic launch should not be prevented lest the poor be denied access to available remedies—will be eliminated, or even reduced or delayed, then the harm is irreparable."). [redacted]

C. The Balance of Hardships Favors an Injunction

"[T]he 'balance of hardships' assesses the relative effect of granting or denying an injunction on the parties." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010), *aff'd* 131 S. Ct. 2238 (2011). As explained above, ViiV would suffer significant, irreversible harm if this Court does not enjoin Lupin's generic launch.

Lupin, by contrast, will merely have to endure the status quo for less than three weeks while it awaits the Court's decision on the merits. If the Court rules in ViiV's favor, Lupin will have suffered no harm at all as it will merely be required to continue to respect ViiV's patent. If

the Court rules in Lupin's favor, Lupin will have suffered minimal harm from the postponement of market entry.[4] *See Impax Labs., Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (finding preliminary injunction would "cause Impax only minimal hardship since doing so will leave Impax in the same position as it was in before the injunction was granted, i.e., excluded from the riluzole market"). While Lupin may prefer to launch sooner, any such preference pales in comparison to the irreparable harm ViiV would suffer in the event of a launch. In sum, this factor strongly favors an injunction pending the Court's decision on the merits.

D. The Public Interest Favors an Injunction

The public interest in the enforcement of patent rights and in the provision of incentives to invent lifesaving drugs favors granting the injunction ViiV seeks. Moreover, ViiV has the capacity to meet demand in the United States for Trizivir® as it has done all along, so there is no countervailing public health interest that would be served by allowing an irreversible generic launch before ViiV can pursue its appeal rights.

The public interest in enforcing patent rights is longstanding and undisputed. *See, e.g., Sanofi–Synthelabo*, 470 F.3d at 1383 ("We have long acknowledged the importance of the patent system in encouraging innovation."); *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1567 (Fed. Cir. 1996) (recognizing "the strong public policy favoring the enforcement of patent rights."). The enforcement of valid patents encourages crucial investment in drug research and development. As the Federal Circuit has stated: "[I]nvestment in drug research and development must be encouraged and protected by the exclusionary rights conveyed in valid patents. That incentive would be adversely affected by taking market benefits away from the

[4] If the Court rules in Lupin's favor, ViiV reserves the right to seek an injunction pending appeal.

patentee and giving them to the accused infringer. . . ." *Celsis*, 664 F.3d at 931-932 (citations omitted); *Abbott**Error! Bookmark not defined.** Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362-63 (Fed. Cir. 2008) (similar).

There is no countervailing public interest sufficient to tip the scales in Lupin's favor. *See The Research Found. of State Univ. of New York v. Mylan Pharms, Inc.*, 723 F. Supp. 2d 638, 663 (D. Del. 2010) (the public interest in enforcing patents and encouraging innovation, outweighs interest in low-cost generics). There is nothing unique about Lupin's products as compared to ViiV's patented, branded, and readily-available Trizivir®. And as it has since the launch of Trizivir® in December 2000, ViiV is able to fill the market demand for this product. *See PPG Indus., Inc.*, 75 F.3d at 1567. Under those circumstances, the public interest favors the enforcement of ViiV's presumptively valid patent. "Selling a lower priced product does not justify infringing a patent." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005), (citation omitted); *see also Impax Labs.*, 235 F. Supp. 2d at 396-97 (the public interest in enforcing valid patents is not outweighed by interest in obtaining cheaper generic drugs). Moreover, the public interest would not be best served by setting aside the rights of ViiV to permit access to a low cost alternative to a beneficial product. "To approach this issue that way, however, would be to eviscerate patent law. The public interest in creating incentives to invent useful or desirable products is captured in the patent law. The *paramount incentive* is exclusivity." *Abbott Labs. v. Andrx Pharms., Inc.*, No. 05C1490, 2005 WL 1273105, at *5, (N.D. Ill. May 20, 2005) (emphasis added); *see also Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) ("[W]hile the statutory framework under which [the generic company] filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical

patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents."). The public interest favors the requested relief.

E. ViiV is Willing to Provide Appropriate Security

Federal Rule of Civil Procedure 65(c) requires the movant for a preliminary injunction to "give security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." The "determination that rests within the sound discretion of a trial court." *Sanofi-Synthelabo*, 470 F.3d at 1385. Should the Court require security, ViiV will comply, "in such sum as the court deems proper," Fed. R. Civ. P. 65(c). Lupin has thus far not suggested any amount to ViiV or to the Court. ViiV respectfully submits that if the parties cannot agree on the amount and parameters, then that should be the subject of separate briefing.

III. THE COURT SHOULD IMMEDIATELY ENJOIN LUPIN'S LAUNCH WHILE IT CONSIDERS THE MERITS OF THIS MOTION

Finally, ViiV requests a temporary restraining order to preserve the status quo at least while the Court considers the merits of this motion. Lupin's 30-month stay has expired, the FDA has given Lupin approval, and Lupin refuses to give ViiV notice of any at-risk launch. ViiV thus has no choice but to seek relief now or to wait until after a launch to do so. As described above, however, ViiV would be irreparably harmed by a launch of even a few days.

To avoid the possibility that Lupin may launch a generic product before the Court can even consider the merits of this motion, ViiV respectfully requests that the Court preliminarily, or at least temporarily, enjoin Lupin from launching at-risk at least pending a decision on this motion. The power of courts is well-established to issue such injunctions to preserve the status quo while they consider the merits of motions for injunctive relief. *See, e.g.*, *AstraZeneca LP v. Breath Ltd.*, No. 13-1312, Docket No. 17, at 2 (Fed. Cir. Apr. 10, 2013) (appellees "temporarily

enjoined from launching their accused generic products pending the court's receipt of the response and the court's consideration of the papers submitted [regarding an injunction pending appeal]."); *Brady v. NFL*, 638 F.3d 1004, 1005 (8th Cir. 2011) ("The purpose of this administrative stay is to give the court sufficient opportunity to consider the merits of the motion for a stay..." (collecting cases)).

CONCLUSION

For the foregoing reasons, ViiV respectfully requests that the Court immediately enjoin Lupin from launching at-risk pending its decision on the merits.

Dated: December 6, 2013

Respectfully submitted,

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