Alan M. Mansfield, SBN: 125998
WHATLEY KALLAS LLP
amansfield@whatleykallas.com
1 Sansome Street, 35th Floor PMB #131
San Francisco, CA 94104
Tel: (619) 308-5034
Fax: (888) 341-5048

Henry C. Quillen
(Admitted *Pro Hac Vice*)
hquillen@whatleykallas.com
WHATLEY KALLAS, LLP
159 Middle Street, Suite 2C
Portsmouth, NH 03801
Tel: (603) 294-1591
Fax: (800) 922-4851

Attorneys for Plaintiffs

[additional counsel appear on signature page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

JACKSONVILLE POLICE OFFICERS AND FIRE FIGHTERS HEALTH INSURANCE TRUST and JOHN DOE, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

GILEAD SCIENCES, INC., CIPLA LTD., CIPLA USA INC., and DOES 1-10, inclusive,

Defendants.

CASE NO. 4:20-cv-06522-JSW

SECOND AMENDED CLASS ACTION COMPLAINT

(1) Violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq.*

(2) Violation of Cal. Bus. & Prof. Code §§ 17200 *et seq.* ("UCL")

(3) Restitution, Money Had and Received, Unjust Enrichment, Quasi-Contract and/or Assumpsit

(4) Violation of Fla. Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201 *et seq.*

JURY TRIAL DEMANDED ON ALL CAUSES OF ACTION SO TRIABLE

Plaintiffs, on behalf of themselves and all others similarly situated, upon personal knowledge as to their own acts and status as specifically identified herein, and otherwise upon information and belief based upon investigation as to the remaining allegations, which allegations are likely to have support after a reasonable opportunity for investigation and discovery, hereby allege as follows against Defendants:

INTRODUCTION

1. Over the years, Gilead Sciences, Inc. ("Gilead") has employed several unlawful strategies to stave off competition for its HIV medications. Many of these strategies have been the subject of various lawsuits. This lawsuit involves a strategy that has not yet been explored in depth: Gilead's large, unexplained payment to the generic drug manufacturer Cipla Ltd. and Cipla USA Inc. (collectively "Cipla") in return for Cipla's agreement not to compete against the drug Truvada by selling a copackaged drug containing the active ingredients in Truvada. This payment likely came in the form of a license to produce another drug (Atripla), the right to provide the ingredients for another company's generic competitor to Truvada, and/or a license to produce drugs for Hepatitis C in India. Such a payment is unlawful. Gilead's agreement with Cipla kept the price of Truvada at anticompetitive levels and harmed the health plans that pay for this drug on behalf of their members.

PARTIES

2. On personal knowledge, Plaintiff Jacksonville Police Officers and Fire Fighters Health Insurance Trust ("Jacksonville") is a health insurance trust organized under the laws of the State of Florida, with its principal place of business at 625 Stockton Street, Jacksonville, Florida 32204. During the Damages Period, Plaintiff has spent approximately $15,000 or more on Truvada for the benefit of its members in Florida.

3. On personal knowledge, Plaintiff John Doe[1] is an individual who resides in the State of California. He had prescription insurance through Anthem during the relevant class period, which charged him co-insurance for his medications on a percentage basis. He has been prescribed Truvada since at least 2015. Plaintiff has spent thousands of dollars on Truvada prescriptions, which as a result of the conduct at issue herein was paid for by him based on inflated rates and artificially inflated and supra-competitive prices.

4. Defendant Gilead is a Delaware corporation with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

5. Defendant Cipla Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

6. Defendant Cipla USA Inc. is a Delaware corporation with its principal place of business at 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, Florida 33323. Cipla USA Inc. is a subsidiary of Cipla Ltd.

7. The true names, roles and/or capacities of Defendants named as Does 1 through 10, inclusive, are currently unknown to Plaintiffs and, therefore, are named as Defendants under fictitious names as permitted by the rules of this Court. Plaintiffs will identify their true identities and their involvement in the wrongdoing at issue if and when they become known.

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[1] Due to the sensitive nature of this action, Plaintiff John Doe has chosen to file under a fictitious name. *Doe v. City & Cnty. of San Francisco*, 2017 WL 1508982, at *2 (N.D. Cal. Apr. 27, 2017) (plaintiff's HIV status justified use of a pseudonym); *Doe v. Metro. Life Ins. Co.*, 2016 U.S. Dist. LEXIS 64387, at *2 (N.D. Cal. May 13, 2016) (same); *Doe v. Kaweah Delta Hosp.*, 2010 U.S. Dist. LEXIS 135808 (E.D. Cal., Dec. 22, 2010) (same); *Does I thru XXIII v. Advanced Textile Corp*. 214 F.3d 1058, 1068 (9th Cir. 2000) (holding that one of the grounds for proceeding anonymously was that anonymity was necessary "to preserve privacy in a matter of sensitive and highly personal nature"). Plaintiff John Doe will disclose his identity to Defendants pursuant to a protective order or other agreement that protects his identify from public disclosure.

8. Defendants' conduct described herein was undertaken or authorized by Defendants' officers or managing agents who were responsible for supervision and operations decisions. The described conduct of said managing agents and individuals was therefore undertaken on behalf of Defendants. Defendants had advance knowledge of the actions and conduct of said individuals whose actions and conduct were ratified, authorized, and approved by such managing agents. By engaging in the conduct described herein, Defendants have agreed with each other to not compete against the drug Truvada by selling a copackaged drug containing the active ingredients in Truvada. This payment likely came in the form of a license to produce another drug (Atripla), the right to provide the ingredients for another company's generic competitor to Truvada, and/or a license to produce drugs for Hepatitis C in India. Such a payment is unlawful. Gilead's agreement with Cipla kept the price of Truvada at anticompetitive levels and harmed individuals who take Truvada and health plans that pay for this drug on behalf of their members.

JURISDICTION

9. This Court has jurisdiction over this Complaint pursuant to 28 U.S.C. § 1332(d) because the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs; a member of a class of plaintiffs is a citizen of a state different from any defendant; and the number of members of all proposed plaintiff classes in the aggregate is greater than 100.

10. This Court has general personal jurisdiction over Defendant Gilead because its headquarters are located in this District.

11. This Court has specific personal jurisdiction over Defendants Cipla Ltd. and its agent Cipla USA Inc. because they have participated in an unlawful conspiracy with Defendant Gilead, and they have committed acts in furtherance of the conspiracy in California, namely the sale of Atripla to California residents pursuant to the unlawful License Agreement at issue in this case.

VENUE

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant Gilead resides in this District, is an inhabitant of this district and may be found here, and because it transacts substantial business in this District. Defendants Cipla Ltd. and Cipla USA Inc. transact substantial business in this District relevant to this case, and Cipla USA Inc. has acted as an agent for Cipla Ltd. with respect to some of the allegations of this complaint, as described below. Moreover, a substantial part of the events or omissions giving rise to the claim occurred in this District.

INTRADISTRICT ASSIGNMENT

13. This action was originally filed in the San Francisco Division. Assignment to that Division is proper because Defendant Gilead resides in that Division and because a substantial part of the events or omissions giving rise to the claim occurred in that Division. The Clerk assigned this action to the Oakland Division pursuant to Local Rule 3-2(c).

FACTUAL ALLEGATIONS

I. Regulatory Background

14. The Food and Drug Administration ("FDA") must approve all new drugs before a company can begin sales in the United States. 21 U.S.C. § 355(a). To obtain FDA approval, the company must file a New Drug Application (NDA), which contains information about the safety and efficacy of the drug, the components of the drug, and any patents issued on the composition of the drug or methods for its use. *Id.* § 355(b)(1). The FDA publishes this information in the directory of *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book."

15. As generic drugs offer significant cost savings, Congress passed the Hatch–Waxman Act in order to provide an additional streamlined FDA approval process. See Pub. L. No. 98–417, 98 Stat. 1585 (1984). Under the Hatch–Waxman

Act, a generic manufacturer can file an Abbreviated New Drug Application (ANDA), and show that the generic drug is biologically and pharmaceutically equivalent to an FDA-approved brand-name drug. 21 U.S.C. § 355(j)(2)(A). The generic manufacturer does not need to conduct time-consuming and costly clinical trials anew, but can rely on the scientific findings of safety and effectiveness included in the brand-name drug's NDA. That said, the generic manufacturer must invest significant resources in developing a drug that is biologically and pharmaceutically equivalent.

16. In order to protect the brand-name drug manufacturer's patent rights, the generic manufacturer must make one of four "paragraph" certifications: (i) that no patent for the brand-name drug has been filed with the FDA (Paragraph I); (ii) that the patent for the brand-name drug has expired (Paragraph II); (iii) that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (Paragraph III); or (iv) that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (Paragraph IV). 21 U.S.C. § 355(g)(2)(A)(vii).

17. After filing an ANDA with a Paragraph IV certification, the generic manufacturer must send notice to the patent holder. 21 U.S.C. § 355(j)(2)(B). This notice is treated as actual infringement, and it triggers a forty-five day period during which the patent holder may file a patent infringement lawsuit before the generic reaches the market. Id. § 355(j)(5)(B)(iii). If the patentee files suit, the FDA stays the ANDA for the lesser of thirty months or entry of final judgment of non-infringement or invalidity. *Id.* During this stay, the FDA can grant tentative approval. § 355(j)(5)(B)(iv)(II)(dd).

18. The first party to file a Paragraph IV ANDA receives a special benefit: a period of 180 days where the FDA will not grant any competing ANDA. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period can be "worth several hundred million

dollars" to the generic drug manufacturer, who typically earns most of the profits on the generic drug during this time. *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013). However, this only excludes other generic manufacturers, not the brand-name drug manufacturer, who can always release a generic. See 21 U.S.C. § 355(j)(5)(B)(iv)(I). Generic drugs that are released by the brand-name drug manufacturer are called "authorized generics," which allow the brand-name drug manufacturer to recover some of the sales and profits it would otherwise lose when an ANDA applicant begins to sell the generic drug.

19. There are circumstances, however, in which the first party to file a Paragraph IV ANDA can forfeit its 180-day exclusivity period. These include failing to market the drug within a certain period of time, entering into an agreement with the patent holder that violates the antitrust laws, and expiration of the patents that are the subject of the Paragraph IV certification. 21 U.S.C. § 355(j)(5)(D)(i).

II. HIV Prevention and Treatment

20. The human immunodeficiency virus (HIV) causes HIV infection and acquired immunodeficiency syndrome (AIDS). HIV comes in two types, HIV-1 and HIV-2. In the United States, HIV-1 is far more common, and this complaint will use the term "HIV" to refer to HIV-1. Scientists have developed various drugs to treat HIV infection, prevent it, or both. Among these drugs are tenofovir disproxil fumarate (TDF), emtricitabine, and efavirenz. These drugs are typically prescribed in combination with each other or with other drugs.

21. Gilead is the holder of NDAs for multiple drugs that include TDF, emtricitabine, efavirenz, or a combination of them. Among them are:

a. Viread® tablets, which contain 300 mg of TDF.

b. Emtriva® tablets, which contain 200 mg of emtricitabine. Gilead did not invent emtricitabine. It was patented by researchers at Emory University, who assigned the patents to Gilead.

c. Truvada® tablets, which contain 200 mg of emtricitabine and

300 mg of TDF (the same dosages of these drugs as Emtriva® and Viread® contain).

d. Atripla® tablets, which contain 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of TDF (the same dosages of the latter two drugs as Emtriva® and Viread® contain). Gilead does not own the patents to efavirenz, which are licensed by their owner, Merck Sharp & Dohme (Merck) to Bristol-Myers Squibb Company (Bristol-Myers). Atripla® was formulated by a joint venture between Gilead and Bristol-Myers.[2]

22. On July 16, 2012, the FDA approved Truvada for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired HIV infection in adults at high risk. Studies have shown that Truvada significantly reduces the risk of contracting HIV. Until October 3, 2019, Truvada was the only drug approved for PrEP in the United States.

23. On March 10, 2016, the FDA approved Truvada in the following emtricitabine/TDF dosage strengths for the treatment of HIV infection in pediatric patients: 167mg/250mg, 133mg/200mg, and 100mg/150mg.

24. Truvada is very profitable for Gilead. In 2018, the price for a month's supply was about $2,000, and this price has not changed significantly since. According to the group ACT UP New York, a month's supply of Truvada costs Gilead about $6 to produce. Gilead's sales of Truvada totaled more than $2.6 billion in the United States in 2018. These figures include Truvada used for treatment of HIV and PrEP.

25. Atripla is also very profitable. In 2018, the retail price for a month's supply of Atripla was about $3,400, and this price has not changed significantly since. Like Truvada, Atripla is relatively inexpensive to manufacture. In the

[2] For readability, this Complaint will omit the registered trademark symbol when referring to the names of drugs.

developing world, the wholesale cost for a month's supply was less than $11 in 2015. Gilead's sales of Atripla totaled $967 million in the United States in 2018.

III. Patents on Emtricitabine, Truvada, and Atripla

26. To understand the allegations of this case, one must understand the concept of enantiomers of chemical compounds. As Gilead has explained in other litigation, "when a compound's 3-dimensional structure is not superimposable upon a compound that is its mirror image (like our left and right hands), these two compounds are referred to as 'enantiomers.'" Such a compound is called "chiral," a word that derives from the Greek word for "hand."

27. Often, when a chiral compound is synthesized, both of its enantiomers are present in equal proportions. This is called a "racemic mixture" or a "racemate." Through various techniques, often one can treat a racemic mixture so that one enantiomer exists in a larger proportion than the other. This process is called "enantioenrichment." If only one enantiomer of the compound is present, the compound is "enantiomerically pure."

28. Emtricitabine is one of two enantiomers of a compound whose name is abbreviated as β-FTC, specifically the enantiomer called "(–)-β-FTC." (The other enantiomer is called "(+)-β-FTC.")

29. Gilead had rights in a patent that claims β-FTC (Patent No. 5,814,639, or the '639 Patent) and another that claims the use of β-FTC to treat HIV (Patent No. 5,210,085, or the '085 Patent). These patents covered β-FTC broadly; they did not limit their claims to a particular enantiomer. The '085 Patent expired in 2010, and the '639 Patent expired on September 29, 2015.

30. Gilead also has rights in two other patents relating to emtricitabine: Patent No. 6,703,396 (the '396 Patent) and Patent No. 6,642,245 (the '245 Patent). The '396 Patent claims (–)-β-FTC (that is, emtricitabine), and the '245 Patent claims the use of (–)-β-FTC to treat HIV. The '396 Patent expired on March 9, 2021, and is also subject to a pediatric exclusivity period of six months beyond its statutory

expiration date, which ended on September 9, 2021. (A drug manufacturer who undertakes pediatric studies for a drug can be entitled to an additional six months of exclusive marketing beyond the expiration of any patents covering the drug.) The '245 Patent expired on November 4, 2020. The '245 patent is also subject to a pediatric exclusivity period of six months beyond its statutory expiration date, which ended on May 4, 2021.

31. Gilead also has rights in patents that cover the combination of TDF and emtricitabine in a single dosage form, which Gilead markets as Truvada. In litigation in Canada, a similar patent was held to be invalid because it was anticipated and obvious. Additionally, Gilead has rights in patents that cover the combination of TDF, emtricitabine, and efavirenz in a single dosage form, which Gilead markets as Atripla.

IV. Gilead Has Settled Litigation over Drugs Containing Emtricitabine with Large, Unjustified Reverse Settlement Payments.

32. Gilead's patents covering emtricitabine, which is a component of Truvada, Atripla, and other drugs, have been under attack in the courts for a decade. While the patents suffer from glaring weaknesses, no case has ever been fully litigated. The reason why, as explained below, is that Gilead has given the defendants in these cases agreements of such great value that they amount to large, unjustified reverse settlement payments.

A. Litigation with Teva Exposes the Weakness of the Emtricitabine Patents.

33. In 2008, Teva Pharmaceuticals USA, Inc. or Teva Pharmaceutical Industries Ltd. (collectively, "Teva") filed an ANDA seeking approval to manufacture and sell tablets containing 200 mg of emtricitabine and 300 mg of TDF—a generic version of Truvada. In late 2009 or early 2010, Teva filed two more ANDAs: one seeking approval to manufacture and sell tablets containing 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of TDF (a generic version of Atripla)

and one seeking approval to manufacture and sell tablets containing 300 mg of TDF (a generic version of Viread). These ANDAs contained Paragraph IV certifications with respect to patents covering efavirenz, emtricitabine, and TDF.

34. The holders of the patents at issue sued Teva for infringement. These claims for infringement eventually proceeded in three suits, all in the United States District Court for the Southern District of New York:

a. *Merck, Sharp & Dohme Corp. & Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 10-cv-1851 (the "Teva efavirenz suit"). The plaintiffs alleged that Teva's manufacture and sale of generic Atripla would infringe their patents on efavirenz.

b. *Gilead Sciences, Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., & Cipla Ltd.*, No. 10-cv-1796 (the "Teva TDF suit"). The plaintiff, Gilead, alleged that Teva's manufacture and sale of generic Viread would infringe its patents on TDF.

c. *Gilead Sciences, Inc. & Emory University v. Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries, Ltd.*, No. 08-cv-10838 (the "Teva emtricitabine suit"). The plaintiffs, including Gilead, alleged that Teva's manufacture and sale of generic Truvada would infringe their patents on emtricitabine.

35. The Teva efavirenz suit proceeded as far as pretrial briefing before being settled. The terms of the settlement were confidential, but Teva never made any drugs containing efavirenz in the United States before the last of the patents at issue expired in 2018. Mylan, N.V. was the first company to launch generic efavirenz, on February 1, 2018, and the FDA has now approved multiple ANDAs for the manufacture and sale of 600 mg efavirenz tablets.

36. The Teva TDF suit also proceeded as far as pretrial briefing before being settled. Most of the terms of the settlement were confidential, but Teva announced an exclusive launch of 300 mg TDF tablets (generic Viread) on December 15, 2017—shortly before expiration of the last relevant patents (and exclusivity periods) on TDF on January 25, 2018. The value of this roughly six-week period of exclusivity has been alleged in other litigation to have been worth $106 million to Teva, based on Teva's sales of TDF and profit margins during that time. Gilead would not rationally have given such a benefit to Teva (and incurred the reciprocal costs associated with competing with a generic version of Viread for six weeks) unless it believed that Teva could have prevailed in the Teva TDF suit.

37. The Teva emtricitabine suit was tried to a judge. It settled before closing statements.

38. As described above, the issue in the Teva emtricitabine suit was this: given that β-FTC and its use to treat HIV were already patented, could Gilead obtain further patent protection for (–)-β-FTC and its use to treat HIV?

39. Teva asserted throughout the litigation that Gilead had engaged in "obviousness-type double patenting," which "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). According to Teva, the '396 and '245 Patents (for (–)-β-FTC and its use) were not distinct enough from the '639 and '085 Patents (for β-FTC and its use) to merit additional patent protection. Obviousness-type double patenting can mean that claims in a later patent are "obvious over" claims in an earlier patent. It can also mean that claims in a later patent are "anticipated by" claims in an earlier patent. *Id.* at 968. The Court in the Teva emtricitabine suit referred to the latter as the "anticipation sub-theory of obviousness-type double patenting." Teva pursued both sub-theories—obviousness and anticipation—in its pretrial briefing.

40. The anticipation sub-theory gave Teva a clear path to a verdict in its favor. To prevail on the anticipation sub-theory, Teva needed to show at most that a person of ordinary skill in the art would visualize the (–)-β-FTC enantiomer when presented with the chemical structure of β-FTC, and that such a person could obtain (–)-β-FTC without undue experimentation. The first requirement was undisputedly met (although Gilead argued that this was not dispositive). And Teva conclusively proved the second requirement at trial.

41. On the first element, whether a person of ordinary skill in the art would visualize (–)-β-FTC, the Court was deeply skeptical of Gilead's main argument. Gilead did not dispute that a person of ordinary skill in the art would visualize (–)-β-FTC when presented with the chemical structure of β-FTC, but argued that pure (–)-β-FTC was one of an infinite number of potential ratios of (–)-β-FTC and its enantiomer (+)-β-FTC. Therefore, Gilead contended, a person of ordinary skill in the art would see (–)-β-FTC as one member of an infinite universe, rather than something readily identified. When Gilead made this argument in its opening statement at trial, the Court (which did not challenge any part of Teva's opening statement) said,

> That's just a mathematical proposition, right? I mean if there's billions or millions, hundreds of millions of molecules, then I guess you might have one or two and then the balance all one and then everything in between. It's hard for me to see why that's a compelling argument, but we'll come to that.

Gilead's counsel tried to explain further, but the Court interrupted again:

> That's a mathematical proposition that basically there is infinity between point A and point B, so there will be an infinite number of stops along that chain. But I don't think -- it seems to me that's not really scientific argument that there are an infinite number of ratios that a scientist of ordinary skill in the art would be looking to experiment to

> see whether a ratio of 49.6 percent was better than a ratio of 49.7 percent, which might be better or worse than 47.2 percent. That just strikes me as illogical.

Gilead's counsel tried again, stating that "a person of ordinary skill in the art would not understand what ratio would be the ratio that might make the best compound." But the Court remained unconvinced:

> It would seem a person of ordinary skill in the art even in 1990 would look to separate into the pure forms to see what the efficacy of each was. And, presumably, that would be the starting point rather than start at points in the middle and then start, you know, bit by bit going to either end. So maybe in 1990 they weren't that smart, but it seems to me that that's what a person would logically do.

Gilead's counsel tried yet again, responding that "one of ordinary skill in the art would have to envisage all of the mixtures at once in his or her head. They would have to be able to envisage the full claim scope in their head, which is not possible for a person to do." The Court did not buy it: "All right. I guess we'll see. I'm not convinced, but we'll see."

42. This exchange was a disaster for Gilead because it showed that the Court would not agree with Gilead's "infinite mixtures" theory unless trial testimony showed that a person of ordinary skill in the art in 1990 would have been overwhelmed with that infinity of mixtures, rather than simply looking to separate β-FTC into its enantiomers, (–)-β-FTC and (+)-β-FTC. After a full trial, no testimony remotely supported such a proposition. In fact, witnesses for Gilead and Teva both testified that a person of ordinary skill in the art would have readily visualized (–)-β-FTC after seeing the structure of β-FTC, and that separating and testing enantiomers was common practice. The Court also admitted evidence that the FDA encouraged scientists to separate and test enantiomers of chiral compounds, and that the inventors of β-FTC separated the enantiomers of analogous drugs at the request

of the drug company Glaxo. Had the case gone to a verdict, Teva likely would have prevailed on this element of its anticipation sub-theory.

43. On the other element of its anticipation sub-theory—whether a person of skill in the art could obtain (–)-β-FTC without undue experimentation—Teva elicited powerful evidence that put the lie to a narrative Gilead had promoted throughout the case. Before trial, Gilead claimed that real-world experience had shown that separating the enantiomers of β-FTC required a very high amount of time and ingenuity. Gilead's pretrial brief asserted that "the inventors themselves attempted five of those methods [of separation] during their research (all but one of which failed) before settling on enzymatic resolution." But one of the inventors admitted at trial that enzymatic resolution was the first method he tried, and he was able to separate the enantiomers with the very first enzyme he tried, pig liver esterase. This was not just an amazing coincidence; the evidence showed that enzymatic resolution was a commonly used method at the time, and the inventor was sure enough that it would work that in the patent application for β-FTC, he listed it as a method for separation even before trying it. Gilead also claimed before trial that the company BioChem took more than a year to separate the enantiomers of BCH-189, a compound similar to β-FTC. That was incorrect. In fact, a technician at BioChem, who had never before attempted to separate enantiomers, testified that she successfully did so with BCH-189 in "less than 15 days of laboratory time." Based on the evidence at trial, and the judge's view of Gilead's "infinite mixtures" argument, Gilead was very likely to lose.

44. Gilead's arguments against the obviousness sub-theory fared no better. Here, the parties contested whether in light of the patents for β-FTC and its use, it would be obvious to a person of ordinary skill in the art to try to obtain (–)-β-FTC, and whether doing so would involve undue experimentation. As described above, Teva would have prevailed on the second element, as the inventors of β-FTC obtained (–)-β-FTC on their first try, using well-known methods, and a technician at

BioChem did the same with a β-FTC analogue in less than 15 days. Gilead claimed, however, that the person of ordinary skill in the art would not have been motivated to obtain (–)-β-FTC for various reasons. This was highly implausible because in 1987, three years before (–)-β-FTC was obtained, the FDA issued guidance stating that enantiomers should be separated and may need to be tested:

> When the NDS [i.e., new drug substance] is asymmetric (e.g., contains one or more chiral centers, or has cis-trans or other types of isomers), the sponsor should ideally (and prior to the submission of an IND [i.e., investigational new drug]) have either separated the various potential stereoisomers of the NDS or synthesized them independently. Physical/chemical information about each stereoisomer should be provided (in detail), or may be requested. Individual stereoisomers may need to be studied for pharmacological and toxicological properties (and/or for safety and efficacy).

(Stereoisomers are molecules that have the same sequence of atoms but differ in their three-dimensional structure. Enantiomers are a type of stereoisomer.) Gilead had no real response to this evidence. Moreover, the evidence at trial showed that the separation and study of enantiomers was a regular practice as early as the 1970s, and the development of single-enantiomer drugs was standard practice in the pharmaceutical industry by 1990. And while Gilead had claimed that a person of ordinary skill in the art would have viewed (+)-β-FTC, not (–)-β-FTC, as the more obvious candidate for development, Gilead's own expert and fact witnesses agreed that such a person would have tested both before rejecting either of them.

45. The presentation of evidence in the Teva emtricitabine suit ended on October 28, 2013. At that time, Teva had a strong likelihood of succeeding on both sub-theories of obviousness-type double patenting. On December 19, 2013, the Court ordered the parties to give summations on February 14, 2014. The day before summations, the parties informed the Court that they had reached a settlement in

principle. Summations were canceled, and a stipulated dismissal was entered on April 30, 2014. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

46. On May 8, 2019, more than five years after the case was dismissed, Gilead announced that Teva would be able to launch generic versions of Truvada and Atripla on September 30, 2020, with six months of exclusivity. Teva did in fact launch these generic drugs on that date.

B. Gilead Settles Emtricitabine Litigation with Cipla Shortly After the Teva Settlement.

47. In 2007, Cipla Ltd. submitted an ANDA in which it sought to market a generic version of Viread. The ANDA contained a Paragraph III certification, indicating that Cipla Ltd. would wait until the expiration of the patents on Viread before marketing a generic version. The ANDA was tentatively approved in April 2009. In 2009, Cipla Ltd., through its agent Cipla USA, Inc., submitted ANDAs in which it sought to market generic versions of Emtriva, Truvada, and Atripla. All three ANDAs contained Paragraph III certifications. The ANDAs for Emtriva, Truvada, and Atripla were tentatively approved in March 2011, February 2014, and February 2012, respectively.

48. On July 18, 2012, Cipla informed Gilead that it had amended its ANDA for Emtriva to include a Paragraph IV certification for the '245 and '396 Patents, the same patents on emtricitabine at issue in the Teva emtricitabine suit. Twelve days later, Cipla informed Gilead that it had amended its ANDA for Viread to include a Paragraph IV certification for four patents relating to TDF, the only active ingredient in Viread. On August 20, 2012, Gilead filed two suits against Cipla Ltd., one for infringing the emtricitabine patents, and one for infringing the TDF patents. The cases, *Gilead Sciences, Inc. v. Cipla Ltd.*, No. 1:12-cv-6350 (S.D.N.Y.) (the "Cipla emtricitabine suit") and *Gilead Sciences, Inc. v. Cipla Ltd.*, No. 1:12-cv-6351

(S.D.N.Y.) (the "Cipla TDF suit") were filed in the same court and assigned to the same judge as the Teva emtricitabine suit.

49. Gilead and Cipla had completed all or nearly all discovery in both cases by June 26, 2014, when they asked the Court to stay the litigation so that the parties could discuss settlement. This was less than two months after the dismissal of the Teva emtricitabine suit. On July 28, 2014, the parties informed the Court that they had reached a settlement, and the cases were dismissed the next day. As in the Teva emtricitabine suit, no terms of the settlements were disclosed to the public, although the dismissals did state that each party would bear its own costs, expenses, and attorneys' fees. The letters requesting dismissal, which were substantially identical, did not disclose details of the settlements but did refer to a "Settlement and License Agreement."

50. After the settlements, Cipla amended its ANDA for Atripla to include a Paragraph IV certification for patents covering emtricitabine (including the '245 and '396 Patents) as well as patents covering the combinations of TDF, emtricitabine, and efavirenz in Atripla. Cipla notified Gilead of its Paragraph IV certification, and Gilead did not file suit for infringement. Cipla received tentative approval of its ANDA for Atripla on March 22, 2016. As of August 14, 2018, all of the remaining patents subject to Paragraph III certification expired, including periods of pediatric exclusivity. Cipla received final approval of its ANDA for Atripla on June 3, 2019, but it did not market a generic version of Atripla in the United States until March 30, 2021. At that point, Cipla marketed a generic version of Atripla nationwide, including in California.

51. Cipla received approval for its ANDA for Emtriva on July 2, 2018. Cipla did not market a generic version of Emtriva in the United States until August 31, 2020.

52. Several facts lead to the conclusion that Gilead made a large, unexplained reverse payment to Cipla as part of its settlement of its cases against

Cipla, consisting of valuable consideration in exchange for Cipla's agreement not to compete with Gilead except on terms that Gilead dictated. By keeping all terms of its settlement agreements confidential, Gilead has prevented the public from knowing exactly what form this consideration took, but the facts of the case suggest that it at least included a license to manufacture a generic version of Atripla, a license to manufacture drugs for hepatitis C, and/or the right to supply Teva with the active pharmaceutical ingredients (APIs) for Truvada and Atripla. Gilead decided in California, its headquarters state, to enter into the anticompetitive agreements, and it is more likely than not that it entered into the Settlement and License Agreement in California, as the executives with authority to enter into such an agreement work at Gilead's headquarters in California. Thus, Gilead engaged in anticompetitive activity in California.

53. First, the parties had completed or substantially completed discovery when they settled. Given that Cipla had not agreed to settle for Gilead's anticipated future litigation expenses before discovery, when those expenses were higher and Cipla's path to victory was less clear (because the Teva emtricitabine suit had not been tried yet), it would have been irrational for Cipla to settle after discovery for consideration equal to Gilead's anticipated future litigation expenses, when those expenses were lower and Cipla had seen from the Teva suit that it could likely prevail on its challenge to the patents on emtricitabine. Between the obvious strength of Cipla's claims and the limited expense of continuing to litigate, Cipla would have behaved irrationally to settle for anything other than a large reverse payment.

54. Second, the parties requested a stay in order to discuss settlement on June 26, 2014, less than two months after the stipulated dismissal of the Teva emtricitabine suit. The timing suggests that the weakness of the emtricitabine patents, which was revealed in the Teva emtricitabine suit, influenced Gilead's decision to settle the Cipla emtricitabine suit.

55. Third, when the Cipla emtricitabine suit settled, the FDA had

tentatively approved ANDAs for Emtriva from Aurobindo and Matrix. Because Cipla was the first to submit an ANDA for Emtriva with a Paragraph IV certification, the FDA could not issue final approval for any other ANDA until 180 days after Cipla had begun marketing a generic version of Emtriva. Thus, Gilead had additional incentive to compensate Cipla to delay its marketing of a generic version of Emtriva because doing so would automatically delay the entry of a generic version of Emtriva from at least two other manufacturers.

56. Fourth, the sale of generic Emtriva would have been valuable to Cipla. When the case settled, Gilead's most recent Form 10-K indicated that it had sold $27.4 million of Emtriva in the previous year. Had Cipla prevailed at trial, it could have taken a significant portion of those sales for the 180 days that it would have FDA exclusivity. This would have been worth millions of dollars to Cipla, and it would have been irrational for Cipla to give up the prospect of this benefit without receiving significant consideration in return.

57. Fifth, Cipla's ANDAs for Viread and Emtriva threatened not only the sales of those two drugs, but also the sales of Truvada. Cipla's decision to challenge the patents on Viread and Emtriva almost simultaneously, without challenging the separate patents on Truvada, would have indicated to Gilead that Cipla intended to sell copackaged TDF and emtricitabine to compete with Truvada. (See Paragraphs 90–100 below for a discussion of copackaged drugs and their competitive threat to Truvada.) Thus, Gilead's incentive to compensate Cipla for dropping its challenge to the TDF and emtricitabine patents would have gone beyond the desire to preserve its profits from Viread and Emtriva. Moreover, even if the Viread patents were ultimately held to be valid, Cipla could still have marketed a copackaged TDF/emtricitabine product as early as January 2018 if it could successfully challenge the patents on emtricitabine, because that is the month when the last patents on TDF expired. Such a scenario would have been extremely damaging to Gilead because of the terms of its settlement of its claims against Teva. In that

settlement, Gilead granted Teva a future license to produce a generic version of Truvada, with exclusivity for six months. If any other company were to enter the market before Teva's agreed entry date, Teva's permitted entry would be moved up accordingly. If Cipla were to produce its own generic copackaged drug, Teva's right to immediately sell generic Truvada likely would have been triggered, costing Gilead significant revenue, potentially in the billions of dollars.

58. Sixth, Cipla stood to gain from the sale of a copackaged TDF/emtricitabine product, even in a competitive market. Had Cipla succeeded in challenging Gilead's patents on emtricitabine, it could have marketed such a product beginning in January 2018. While Cipla could have faced competition from Teva's generic product, and copackaged products from other manufacturers, the potential revenue and profits from the sale of the copackaged product would have been worth pursuing. Even if competition from generics and copackaged products reduced the price of Truvada from $2,000 per month to $56.40 (see Paragraph 96 for an explanation of this figure), there would still be a reasonable opportunity to profit from a product that costs $6 to make. And at such low prices, it is reasonable to assume that Truvada would be used more widely. But even if Truvada were not used more widely, and even if its price dropped this much, Truvada would have represented about a $75 million opportunity in 2018 alone, and a similar opportunity at least through 2021, when the last patents on Truvada's ingredients would expire. Cipla could have reasonably expected to capture a proportional share of that opportunity. While it is not possible to calculate the exact value of that opportunity at this time, the figures above indicate that it would have likely been as high as $10–20 million. It would have been irrational for Cipla to forgo this opportunity in its settlement with Gilead unless it received significant consideration in return.

59. Seventh, Cipla apparently agreed not to market a competitor to Truvada in exchange for a license to market a generic version of Atripla before its patents would expire, a license to manufacture drugs for hepatitis C, and/or the right to

supply Teva with the active pharmaceutical ingredients (APIs) for Truvada and Atripla. This conclusion is based on nine facts:

a. Cipla's ANDA for a generic version of Emtriva was approved on July 2, 2018, but Cipla did not begin to market such a drug until August 31, 2020.

b. Cipla never sought approval from the FDA to sell a copackaged emtricitabine/TDF drug (which would compete with Truvada), despite strong indications from the FDA that such an application would be approved. (*See* ¶¶ 90–100 below.)

c. By staying out of the market with emtricitabine or an emtricitabine/TDF drug, Cipla gave up the period of time in which such a drug would be most valuable. That value began to decrease in September 2020, when Gilead allowed Teva to market a generic version of Truvada, and it decreased further when other manufacturers introduced generic versions of Truvada in 2021. Cipla would be behaving irrationally to forgo sales of a copackaged emtricitabine/TDF drug in the period from 2018 to 2021, when doing so would be most profitable, unless it received significant consideration in return.

d. When Cipla amended its ANDA for Atripla to include Paragraph IV certifications for patents covering emtricitabine (including the '245 and '396 Patents), as well as patents covering the combinations of TDF, emtricitabine, and efavirenz in Atripla, Gilead did not sue for infringement. This strongly implies that the settlement agreement in the Cipla emtricitabine suit included an agreement that Gilead would not sue for infringement of those patents, and instead, Cipla would be allowed to market Atripla on terms agreed to by Gilead and Cipla. The patents covering the

combinations of TDF, emtricitabine, and efavirenz in Atripla were not at issue in the Cipla emtricitabine suit, so any agreement to allow Cipla to market a generic version of Atripla, or escape an infringement suit relating to those patents, represents compensation that Cipla could not have obtained in its emtricitabine suit even if it had prevailed.

e. When it settled with Teva over the emtricitabine patents, Gilead gave Teva a 180-day period in which it could sell generic Atripla exclusively, with the right to accelerate its entry if other competitors came to the market. Gilead's very next settlement over emtricitabine patents was with Cipla. A similar agreement for Cipla to enter the market immediately after, with only limited competition for a certain period of time, and the right to accelerate its entry under certain conditions, would have been valuable to Cipla and would have represented a significant sacrifice to Gilead. The last of Gilead's patents on Atripla will not expire until 2026, meaning that Gilead can still dictate the terms of competition for about five years after Teva's period of exclusivity is over. In the last full year before Gilead's settlement with Cipla, Gilead earned $3.6 billion in revenue from Atripla, or about $70 million per week. According to a study by the Food and Drug Administration, for products with a single generic producer, the median generic price is 39% lower than the price of the branded drug before generic competition. With two generic producers, the median generic price is 54% lower, and with three generic producers, it is 68% lower. As it turns out, Cipla and Aurobindo (which Gilead sued for infringement of the same patents that Cipla challenged, as described below) were

allowed to compete against only Gilead's branded Atripla and Teva's generic for nearly 24 weeks, from March 30, 2021 to September 13, 2021, when the next competitor arrived. With 24 weeks of semi-exclusivity among three generic producers, Cipla could have reasonably expected to receive about third of the total revenue of generic Atripla, which itself would have been priced about 68% lower than branded Atripla due to competition. Moreover, Cipla could reasonably have expected that generic Atripla would take the majority of prescriptions away from branded Atripla, as is common when a branded drug begins to face generic competition. Thus, even assuming conservatively that branded Atripla retained half of its market share, Cipla could reasonably have expected to earn around $90 million in revenue, which is much more than it could have obtained by prevailing on its challenge to the emtricitabine patents. At the same time, Gilead would have sacrificed profits by accelerating the erosion of Atripla's price by allowing Cipla to enter the market for a product for which Cipla had not even sought FDA approval.

f. Gilead's pattern of behavior indicates that its decision not to sue Cipla after Cipla amended its ANDA for Atripla was tied to the Settlement and License Agreement. Four generic pharmaceutical manufacturers have submitted ANDAs for Atripla with Paragraph IV certifications. Two of those, Teva and Macleods, had not settled any litigation relating to HIV medications when they submitted their ANDAs. Gilead sued them both. The other two, Cipla and Aurobindo, had settled litigation relating to HIV medications (but not the combination patents that cover Atripla) when they submitted their ANDAs. Gilead sued neither of them.

This pattern strongly implies that the right to file an ANDA with a Paragraph IV certification, without a challenge from Gilead, was part of its settlements with Cipla and Aurobindo.

g. Gilead's letters requesting dismissal of the case refer to a "Settlement and License Agreement," indicating that Cipla was allowed to compete on terms dictated by agreement between Gilead and Cipla.

h. In September 2014, less than two months after the Cipla emtricitabine suit was settled, Gilead announced that it was licensing seven Indian generics manufacturers, including Cipla, to sell generic versions of Gilead's hepatitis C drugs sofosbuvir and ledipasvir in 91 developing countries, including India. At the time, a news article reported, "Estimates suggest that ledipasvir could potentially be worth US$300–US$500m, and offer a $110–$185m formulation and active pharmaceutical ingredient (API) opportunity. Cipla is expected to earn API rights to the drug, though this could not be immediately confirmed." Manufacturing Chemist, Gilead announces generic licensing agreements with Indian companies (Sept. 16, 2014), available at https://bit.ly/2lTQvqO. Notably, although seven companies were identified as receiving a license, only one—Cipla—was identified as earning the lucrative API rights. It is plausible that the sudden availability of a benefit worth as much as $185 million to Cipla was related to the settlement of the Cipla emtricitabine suit less than two months earlier.

i. In 2019, the Indian newspaper Financial Express reported that Cipla would have the exclusive right to supply APIs to Teva for its production of Truvada, Atripla, and Viread. On November 6,

2020, Cipla confirmed that it is providing the APIs to Teva for its manufacture of generic Truvada and Atripla. Because Teva competes with Truvada and Atripla on terms dictated by an agreement with Gilead, it is plausible that Gilead arranged for Cipla to be the exclusive API supplier to Teva for its production of the generic version of these drugs. This inference is especially plausible because many companies are capable of making the APIs for these products; according to PharmaCompass, twenty-two companies manufacture the APIs for emtricitabine, and fourteen manufacture the APIs for TDF. Yet the one with an exclusive supply relationship with Teva is the one that settled its patent litigation two months after Teva's.

C. Gilead Settles Several Other Suits Relating to Its Patents on Its HIV Drugs.

60. In addition to settling with Teva and Cipla, Gilead has established a pattern of bringing and then quickly settling patent infringement suits whenever a generic drug manufacturer files a Paragraph IV certification with respect to patents covering its HIV medications.

61. Aurobindo Pharma Limited or Aurobindo Pharma USA, Inc. (collectively "Aurobindo") submitted ANDAs in which it sought to market generic versions of Emtriva (submitted in 2007), Truvada (2008), and Atripla (2011). Initially, all three ANDAs contained Paragraph III certifications, indicating that Aurobindo would wait until the expiration of the patents on those drugs before marketing generic versions. The ANDAs for Emtriva, Truvada, and Atripla were tentatively approved in May 2008, March 2009, and April 2013, respectively.

62. In May 2016, Aurobindo informed Gilead that it had amended its ANDA for Emtriva to include a Paragraph IV certification for the '245 and '396 Patents, the same patents on emtricitabine at issue in the Teva and Cipla

emtricitabine suits. On June 23, 2016, Gilead sued Aurobindo for infringing those patents. *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd.*, No. 1:16-cv-3722 (D.N.J.). The case settled quickly and was dismissed on September 16, 2016. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

63. In May 2016, Aurobindo also informed Gilead that it had amended its ANDA for Truvada to include a Paragraph IV certification for the '245 and '396 Patents on emtricitabine, as well as two other patents that cover the combination of TDF and emtricitabine in a single dosage form: Patent Nos. 8,592,397 and 8,716,264. On July 8, 2016, Gilead sued Aurobindo for infringing those patents. The case, *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd.*, No. 1:16-cv-4178 (D.N.J.), was filed in the same court and assigned to the same judge as Aurobindo's emtricitabine suit. Like that case, this one settled quickly and was dismissed on September 16, 2016. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

64. In April 2018, Aurobindo informed Gilead that it had submitted an ANDA to market generic versions of lower-dosage forms of Truvada, and that its ANDA had a Paragraph IV certification for the '245 and '396 Patents on emtricitabine. (Aurobindo did not have to make a Paragraph IV certification for the patents that cover the combination of TDF and emtricitabine in a single dosage form because those patents do not cover the lower-dosage forms.) On May 18, 2018, Gilead sued Aurobindo for infringing the '245 and '396 Patents. *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd.*, No. 1:18-cv-765 (D. Del.). On October 3, 2018, the parties stipulated to a stay of the case "pending final documentation of a settlement agreement." The stay was granted the next day. On October 5, 2018, the parties stipulated to an order dismissing the case. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own

costs, expenses, and attorneys' fees. The court entered the dismissal order on October 10, 2018.

65. On July 13, 2012, Lupin Ltd. informed Gilead that it had submitted an ANDA in which it sought to market a generic version of Truvada. The ANDA contained a Paragraph IV certification with respect to Gilead's patents on emtricitabine and TDF. On August 16, 2012, Gilead filed two separate suits against Lupin, one claiming infringement of the patents on emtricitabine, and the other claiming infringement of the patents on TDF. *Gilead Sciences, Inc. v. Lupin Ltd.*, No. 1:12-cv-6293 (S.D.N.Y.) (the "first Lupin emtricitabine suit"); *Gilead Sciences, Inc. v. Lupin Ltd.*, No. 1:12-cv-6294 (S.D.N.Y.) (the "Lupin TDF suit"). Both cases were filed in the same court and assigned to the same judge as the Teva emtricitabine and TDF suits, and the Cipla emtricitabine and TDF suits. At least some of the discovery in the Lupin suits was coordinated with discovery in the Cipla suits.

66. The Lupin TDF suit proceeded through discovery and was dismissed on May 30, 2014. The dismissal order is almost entirely redacted, but it does provide that each party shall bear its own costs, disbursements, and attorneys' fees. Gilead stated in its 2015 Form 10-K: "In May 2014, Lupin amended its ANDAs to certify that it is no longer seeking approval to market generic versions of Truvada and Viread prior to the expiration of the four patents associated with tenofovir disoproxil fumarate in January 2018 (including pediatric exclusivity)."

67. On June 13, 2014, Lupin Ltd. informed Gilead that it had submitted an ANDA in which it sought to market a generic version of Atripla. The ANDA contained a Paragraph IV certification with respect to the '245 and '396 Patents on emtricitabine. On July 16, 2014, Gilead sued Lupin for infringing these patents. *Gilead Sciences, Inc. v. Lupin Ltd.*, No. 1:14-cv-5352 (S.D.N.Y.) (the "second Lupin emtricitabine suit"). The case was filed in the same court and assigned to the same judge as the first Lupin emtricitabine suit.

68. The parties to the first Lupin emtricitabine suit had completed all or

nearly all discovery by July 18, 2014, when the Court scheduled a trial beginning on December 8, 2014. On August 6, 2014, the Court consolidated the first and second Lupin emtricitabine suits for trial, based on the parties' agreement that doing so would not require a change in schedule. On September 16, 2014, the parties advised the Court that they had executed a settlement, and the two Lupin emtricitabine suits were dismissed the next day. In their letter to the Court about the settlement, Gilead's counsel stated, "The parties respectfully request that the Court enter the Order on Stipulation for Dismissal attached as Exhibit A to this letter pursuant to the Settlement and License Agreement." No terms of the settlement, or any license agreement, were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

69. On April 24, 2014, Mylan Inc. informed Gilead that it had submitted an ANDA in which it sought to market a generic version of Truvada. The ANDA contained a Paragraph IV certification with respect to Gilead's patents on emtricitabine, as well as a patent covering the combination of TDF and emtricitabine in a single dosage form: Patent No. 8,592,397. Gilead filed suit against Mylan in the Southern District of New York on June 2, 2014. When Mylan indicated that it would contest personal jurisdiction there, Gilead filed suit in the Northern District of West Virginia. *Gilead Sciences, Inc. v. Mylan Inc.*, No. 1:14-cv-99 (N.D. W. Va.). Gilead then dismissed the suit in New York.

70. The case proceeded through discovery, and Gilead amended its complaint twice, adding a claim of infringement of another patent covering the combination of TDF and emtricitabine in a single dosage form: Patent No. 8,716,264.

71. The last substantive development in this case was the denial of a motion to compel by Gilead. The context was a request for the production of documents from Mylan that Gilead claimed were relevant to Mylan's "enablement" defense, which claimed that the patents on Truvada did not enable a "person skilled in the

art" to make Truvada. The problem for Gilead was that Mylan had refused to produce those documents, and Gilead had missed the deadline to move to compel by months. Gilead's excuse was that it was not on notice of the enablement defense until after Mylan's refusal, but the Court pointed out filings where Mylan had explicitly invoked the defense, and stated that "Gilead's argument … strains credulity." Thus, Gilead's motion to compel was denied as untimely.

72. Less than six weeks later, the case settled. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

73. Hetero Drugs Ltd., Hetero Labs Ltd., or Hetero USA Inc. (collectively "Hetero") submitted an ANDA in which it sought to market a generic version of Truvada. The FDA tentatively approved the ANDA on December 22, 2011. The ANDA and the approval letter are not publicly available, but Hetero presumably made a Paragraph III certification regarding the patents listed in the Orange Book for Truvada, including the emtricitabine patents.

74. On June 29, 2016, Hetero informed Gilead that it had amended its ANDA to include a Paragraph IV certification for the '245 and '396 Patents on emtricitabine, as well as two other patents that cover the combination of TDF and emtricitabine in a single dosage form: Patent Nos. 8,592,397 and 8,716,264. On August 11, 2016, Gilead sued Hetero for infringing those patents. The case, *Gilead Sciences, Inc. v. Hetero Drugs Ltd.*, No. 16-cv-4938 (D.N.J.), was filed in the same court and assigned to the same judge as the Aurobindo suits.

75. The case was not litigated, and the parties stipulated to dismissal, which was granted on August 26, 2016. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

76. In or around December 2016, Amneal Pharmaceuticals, LLC submitted an ANDA in which it sought to market a generic version of Truvada. The ANDA

contained Paragraph IV certifications for at least three of the patents listed in the Orange Book for Truvada: the '245 and '396 Patents on emtricitabine, as well as one other patent that covers the combination of TDF and emtricitabine in a single dosage form: Patent No. 8,716,264. On April 6, 2017, Gilead sued Amneal for infringing those patents. *Gilead Sciences, Inc. v. Amneal Pharmaceuticals, LLC*, No. 17-cv-2335 (D.N.J.).

77. The case was not litigated, and it was dismissed without prejudice under Rule 41(a)(1)(A)(i) on April 18, 2017.

78. On May 31, 2017, Amneal informed Gilead that it had submitted an ANDA to market generic versions of lower-dosage forms of Truvada, and that its ANDA had a Paragraph IV certification for the '245 and '396 Patents on emtricitabine. (Amneal did not have to make a Paragraph IV certification for the patents that cover the combination of TDF and emtricitabine in a single dosage form because those patents do not cover the lower-dosage forms.) On July 13, 2017, Gilead sued Amneal for infringing the '245 and '396 Patents. *Gilead Sciences, Inc. v. Amneal Pharmaceuticals LLC*, No. 1:17-cv-943 (D. Del.).

79. The parties began discovery and agreed on claim construction. On June 7, 2018, they stipulated to dismissal, which was entered the next day. No terms of the settlement were disclosed to the public, although the dismissal did state that each party would bear its own costs, expenses, and attorneys' fees.

80. On March 31, 2012, Macleods Pharmaceuticals Ltd. submitted an ANDA in which it sought to market a generic version of Atripla. Initially, this ANDA contained Paragraph III certifications, indicating that Macleods would wait until the expiration of the patents on Atripla before marketing a generic version. The ANDA was tentatively approved on November 28, 2014.

81. On June 13, 2017, Macleods informed Gilead that it had submitted ANDAs to market generic versions of Truvada and Atripla. Both ANDAs contained Paragraph IV certifications. On July 27, 2017, Gilead sued Macleods for infringing

the ’245 and ’396 Patents on emtricitabine, as well as three other patents that cover the combination of TDF and emtricitabine in a single dosage form: Patent Nos. 8,592,397, 8,716,264, and 9,457,036. *Gilead Sciences, Inc. v. Macleods Pharmaceuticals, Ltd.*, No. 1:17-cv-1039 (D. Del.).

82. The parties agreed to several extensions of Macleods’ time to answer the complaint. Ultimately, no answer was filed, the case settled, and it was dismissed without prejudice under Rule 41(a)(1)(A)(i) on December 20, 2017. No terms of the settlement were disclosed to the public, although the dismissal did state that no fees or costs shall be awarded to any party.

83. On December 30, 2008, Strides Pharma, Inc. submitted an ANDA in which it sought to market a generic version of Truvada. Initially, this ANDA contained Paragraph III certifications, indicating that Strides would wait until the expiration of the patents on Truvada before marketing a generic version. The ANDA was tentatively approved on July 31, 2013.

84. On May 15, 2018, Strides informed Gilead that it had amended its ANDA to include a Paragraph IV certification for the ’245 and ’396 Patents on emtricitabine, as well as four other patents that cover the combination of TDF and emtricitabine in a single dosage form: Patent Nos. 8,592,397, 8,716,264, 9,457,036, and 9,744,181. On June 27, 2018, Gilead sued Strides for infringing those patents. *Gilead Sciences, Inc. v. Strides Pharma, Inc.*, No. 18-cv-11134 (D.N.J.).

85. Strides answered Gilead’s complaint on July 18, 2018. On September 6, 2018, the parties asked for an adjournment of the Rule 16 conference so they could discuss settlement. The request was granted the next day. On December 21, 2018, the parties asked the court to enter an order dismissing the case with prejudice. No terms of the settlement were disclosed to the public, although the stipulated dismissal order did state that each party shall bear its own costs, expenses, and attorneys’ fees. The court entered the order on January 9, 2019.

86. On December 3, 2018, Zydus Pharmaceuticals (USA) Inc. and Calida

Healthcare Ltd. (which does business as Zydus Calida) (together, "Zydus") informed Gilead that they had submitted an ANDA for various fixed-dose combinations of emtricitabine and TDF. The ANDA includes a Paragraph IV certification for the '245 and '396 Patents on emtricitabine, as well as four other patents that cover the combination of TDF and emtricitabine in a single dosage form: Patent Nos. 8,592,397, 8,716,264, 9,457,036, and 9,744,181. On January 15, 2019, Gilead sued Zydus for infringing those patents. *Gilead Sciences, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, No. 19-cv-529 (D.N.J.). Zydus filed its answer on June 14, 2019, and the parties stipulated to dismissal on August 13, 2019.

V. Additional Factors Imply That Gilead Resolved Its Litigation with Cipla with a Large, Unexplained Reverse Payment.

87. In addition to the specific circumstances of the litigations described above, the broader pattern of litigation and the market for Truvada and Atripla implies that Gilead made large, anticompetitive, unexplained reverse payments to settle its cases.

A. The Pattern of Litigation Points to the Weakness of Gilead's Patents and Gilead's Willingness to Compensate Generic Manufacturers for Not Competing.

88. The sheer number of companies that submitted Paragraph IV certifications for Emtriva, Truvada, and Atripla, combined with Gilead's settlement of every infringement litigation, implies that Gilead and the generic manufacturers it sued all saw Gilead's patents as weak.

89. Moreover, Gilead and the defendants have kept all terms of their settlement agreements confidential, except that Gilead disclosed for the first time in May 2019 that its settlement and license agreement with Teva would allow Teva to sell generic versions of Truvada and Atripla beginning on September 30, 2020. Keeping the terms of settlement agreements confidential insulates them from public scrutiny.

B. Gilead Had Every Incentive to Delay Serious Competition for Truvada Until 2021, Which Is What It Did.

90. The last patents protecting the ingredients of Truvada expired in 2021. But if the patents on emtricitabine were held to be invalid, Truvada would have faced significant competition in 2018 instead, three years earlier. This is because the patents on the TDF, the other component of Truvada expired that year, and Cipla could have introduced a copackaged version of Truvada at that time. Because Gilead expected to sell several billion dollars' worth of Truvada between 2018 and 2021, it had every incentive to prevent a court from holding the emtricitabine patents invalid.

91. A fixed-dose combination is two or more drugs contained in a single dosage form, such as a capsule or tablet. A copackaged drug is one in which multiple capsules, tablets, or some other dosage form containing different drugs are packaged together. Truvada and Atripla are fixed-dose combinations. To obtain FDA approval without having to undertake the extensive testing associated with a New Drug Application, a manufacturer of a fixed-dose combination must demonstrate that the fixed-dose combination is bioequivalent to the individual drugs taken separately. The FDA has defined bioequivalence as: "The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1. Gilead obtained approval for Truvada this way. In fact, Truvada's FDA-approved label states, "One TRUVADA tablet was bioequivalent to one EMTRIVA capsule (200 mg) plus one VIREAD tablet (300 mg) following single-dose administration to fasting healthy subjects (N=39)."

92. In 2006, the FDA published a document called, "Guidance for Industry: Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV." The FDA

explained that "[t]his guidance is intended to encourage sponsors to submit applications to the Food and Drug Administration (FDA) for approval of fixed dose combination (FDC) and copackaged versions of previously approved antiretroviral therapies for the treatment of human immunodeficiency virus (HIV)." Fixed-dose combinations and copackaged drugs, the FDA noted, both "may facilitate distribution and improve patient adherence." The guidance also stated that the "FDA believes that when adequate evidence of safety and efficacy exists for the use of combination therapy with individually approved HIV drugs, the path to regulatory approval of an FDC or co-packaged configuration of those drugs is straightforward. FDA is prepared to move swiftly to evaluate such products when applications are submitted for approval." Such products are eligible for priority review, which takes six months or less. The FDA pointed out that even if the individual drugs that make up the fixed-dose combination or copackaged configuration are covered by a patent, the FDA can still grant tentative approval so that the fixed-dose combination or copackaged configuration could be marketed as soon as the patents expire. The guidance also listed several drug combinations for which an application for a copackaged configuration would not require clinical studies. The drug combinations of Truvada and Atripla were on the list.

93. Given the FDA's guidance, the only real obstacle to the approval of copackaged equivalents of Truvada was the patent protection on the individual components of those drugs. The relevant components of Truvada are TDF and emtricitabine. The relevant components of Atripla are TDF, emtricitabine, and efavirenz. The last patent on TDF expired on January 25, 2018, although Gilead had given Teva had the right to market generic TDF beginning on December 15, 2017. The last patent on emtricitabine expired on March 9, 2021. Emtricitabine is also subject to a pediatric exclusivity period of six months beyond its statutory expiration date, which means that the FDA would not grant final approval for generic emtricitabine before September 9, 2021.

94. If the '245 and '396 Patents on emtricitabine are valid, then no copackaged equivalent of Truvada could have been approved before September 9, 2021. But if those patents are invalid, then copackaged equivalents of Truvada could have been approved much sooner. The only other patent on emtricitabine relevant to this litigation is Patent Number 5,914,331, whose protection ended on January 2, 2018 (including a period of pediatric exclusivity). Thus, Teva could have obtained approval for a copackaged equivalent of Truvada on January 2, 2018, and other manufacturers, including Cipla, could have done so on January 25, 2018.

95. Had Cipla applied for approval of a copackaged equivalent of Truvada, the granting of that application would have been a virtual certainty. The FDA's 2006 guidance strongly encouraged applications for copackaged equivalents of Truvada for the same indications for which Truvada is approved, and promised quick action on such applications. No additional scientific analysis would have been necessary, as Gilead's approval for Truvada was in fact based on a copackaged version of its components. And Cipla was perfectly capable of manufacturing a copackaged version of Truvada to the FDA's specifications: the FDA approved Cipla's applications to market both TDF and emtricitabine as separate medications.

96. The approval of copackaged equivalents of Truvada would have quickly led to their availability at substantially lower prices. For example, just before Gilead's last patent on Viread expired, the National Average Drug Acquisition Cost (NADAC) for one Viread tablet was $36.75. Less than a year later, the price of the generic version of Viread hit a low of $1.28, a decrease of 96.5%. With approval of a copackaged equivalent of Truvada, and in the absence of patent protection on emtricitabine, it would have been reasonable to expect a generic version of Emtriva to be priced at a similar discount to Emtriva, whose NADAC was $17.18 per tablet without competition. If that discount were also 96.5%, then a tablet of generic emtricitabine would cost $0.60. A month's supply of the copackaged equivalent of Truvada would cost $56.40, instead of the $2,000 that Gilead charges for brand-

name Truvada.

97. FDA approval of copackaged versions of Truvada would have decimated Gilead's profits, while benefitting consumers greatly. Something similar happened to Gilead's drug Harvoni, which is used to treat hepatitis C. Harvoni is very effective in treating hepatitis C, but it was extremely expensive when it was introduced, with a list price of $84,000 for a course of treatment. Harvoni was a huge financial success for Gilead, earning more than $13 billion in revenue its first full year on the market. But when the drug manufacturer AbbVie obtained approval for a competitor drug, Viekira Pak, the net price of Harvoni (that is, the list price minus Gilead's rebates) collapsed. Viekira Pak was a copackaged drug, with patients having to take multiple pills per day. But just three days after the approval of Viekira Pak, Express Scripts, the nation's largest pharmacy benefit manager (PBM), announced that it would make Viekira Pak its preferred treatment for hepatitis C genotype 1 (the most common genotype in the United States), and it would no longer cover Harvoni. The deal resulted in AbbVie's offer to sell Viekira Pak to Express Scripts for a net price of approximately $51,000 to $66,000, a significant discount to the $84,000 that Gilead was charging for Harvoni. Shortly after, Gilead entered into discounting agreements for Harvoni with CVS, Anthem, Humana, Aetna, Cigna and UnitedHealth Group. According to a report by the United States Senate Committee on Finance, industry sources estimated that those discounts were approximately 40% from the list price.

98. There are many reasons to believe that Truvada would have been discounted at least as severely if it had faced competition from a copackaged version. First, the individual components of Truvada, TDF and emtricitabine, are inexpensive to manufacture, as described above. Second, unlike Viekira Pak, a copackaged version of Truvada would have the exact same active ingredients as Truvada itself, making it even easier for pharmacy benefit managers and payors to justify taking Truvada off their formularies (or demoting it) in favor of the copackaged version.

Third, if a copackaged version of Truvada were to become available as a result of the invalidation of Gilead's patents on emtricitabine, several generic drug manufacturers would have been able to sell the copackaged version beginning in early 2018. By contrast, when Viekira Pak was introduced, AbbVie was the only manufacturer with the right to make it. More intense competition for a copackaged version of Truvada would have lowered the price even further.

99. The way Gilead chose to respond to these various threats of competition was to offer valuable consideration to Cipla in exchange for its agreement not to challenge the patents on emtricitabine, as described above. The result of these agreements was that Cipla declined to enter the market "at risk," dropped its challenge to the emtricitabine patents, and agreed not to compete against Truvada until much later in the future. But for the large and unjustified reverse payment that Gilead made, Cipla would have competed against Truvada during the class period by selling the components of Truvada as a copackaged version on or shortly after January 25, 2018.

100. Gilead apparently did allow Cipla to begin marketing a generic version of Truvada on or after March 30, 2021, but the benefit to consumers was minimal because this license was non-exclusive. By mid-2021, as many as a dozen manufacturers were marketing a generic version of Truvada. According to research by the FDA, the median difference between having nine generic competitors and ten generic competitors for a drug is a reduction in price equal to 0.2% of the original price of the brand-name drug. Thus, had Cipla not been given a license to market a generic version of Truvada in 2021, the effect on the price of generic Truvada would have been negligible. Moreover, the last exclusivity period associated with the ingredients of Truvada expired on September 9, 2021, after which any manufacturer could have sought approval to market a copackaged version of Truvada. Therefore, the negligible benefit of Cipla's license lasted less than six months.

VI. Relevant Markets

101. The relevant product market (the "Truvada market") in this case includes Truvada, the generic equivalent of Truvada, and the copackaged equivalent of Truvada. These drugs are not interchangeable with other drugs outside the Truvada market. A hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price above competitive levels for the drugs in the Truvada market. Within that market, the potential competitors to Truvada are the generic formulation of Truvada, and a copackaged formulation of Truvada.

102. The relevant geographic market for the Truvada market is the United States. For purposes of this complaint, "United States" includes its territories and the District of Columbia. Gilead sells Truvada across the United States, and it is unlawful for customers to import foreign versions of Truvada, or its generic or copackaged equivalents.

103. Gilead has market power in the relevant markets. Because of its patents on emtricitabine, and other manufacturers' agreements not to challenge those patents or manufacture emtricitabine themselves, Gilead was the only company authorized to manufacture Truvada, generic Truvada, or copackaged Truvada in the United States until September 30, 2020, and was one of two companies with such authorization until late March 2021.

VII. Interstate Commerce

104. Gilead's actions with respect to its drugs containing emtricitabine have restrained interstate trade. Gilead markets and sells these drugs throughout the United States. Likewise, competitive products would be sold throughout the United States.

VIII. Antitrust Impact and Damages

105. But for Gilead's unlawful agreements, the price of Truvada would have been significantly lower, and lower-priced copackaged equivalents would have been

available.

106. In that circumstance, Plaintiffs and Class members would have paid less for prescription medications in one or more of the following ways:

a. Paying less for Truvada.

b. Substituting purchases of lower-priced generic or copackaged equivalents of Truvada.

c. For health plans, moving Truvada into a higher tier on their formularies, or removing it entirely, in order to pay less of the cost of those medications.

107. To a large extent, Plaintiffs' and Class members' savings would have been accomplished through the insurers and PBMs that manage their prescription drug benefits and corresponding reductions in co-insurance payments to the extent paid by Class members. As described above, when a copackaged competitor to Gilead's drug Harvoni became available, the nation's largest insurers and PBMs either dropped Harvoni from their formularies in favor of its competitor, or significantly reduced the cost of Harvoni to their clients.

108. While an exact calculation is not yet available, damages suffered by Plaintiffs and Class members are at least in the hundreds of millions of dollars. Gilead's United States revenue from Truvada from the beginning of 2018 to March 30, 2021 was approximately $6.7 billion, and a significant portion of that amount represents overpayments by Plaintiffs and Class members. Of that figure, $6.5 billion represents sales made when Gilead faced no competition at all for Truvada.

109. Therefore, Gilead's unlawful agreements are a proximate cause of the antitrust injury to Plaintiffs and Class members.

110. Gilead's unlawful agreements likewise harmed the individual consumers who use Truvada such as Plaintiff John Doe. Group health plans typically require their members to pay a share of the cost of medications, with more expensive medications having co-insurance or higher out-of-pocket costs than less expensive

medications. By keeping the price of Truvada artificially high, Gilead's agreements harmed these consumers by the same method that they harmed the health plans.

111. Gilead's agreements were not procompetitive. To the extent that Gilead's consideration to Cipla included a period of limited exclusivity for Atripla, the benefit to consumers is minuscule compared to the nearly three years in which Gilead was able to sell $6.5 billion of Truvada without facing any competition, at gross profit margins approaching 100%. And to the extent that Gilead's consideration to Cipla included the right to supply ingredients for Truvada, Atripla, or other drugs, consumers received no benefit.

112. Moreover, Gilead cannot justify foreclosing competition in the Truvada market, even for the purpose of promoting competition in another market.

113. Given that discovery was complete or substantially complete in Gilead's litigation with Cipla, the consideration Gilead provided to Cipla in settlement exceeded any costs of litigation that Gilead may have avoided.

IX. Class Action Allegations

114. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3), Plaintiff John Doe brings this action on behalf of himself and the following class (the "Cartwright Act Class"):

> All persons or entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Truvada, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries in California, Alabama, Arizona, Connecticut, the District of Columbia, Hawaii, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, other than for resale, during the period January 25, 2018 until March 30, 2021.

115. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3), Plaintiff John Doe brings this action on behalf of himself and the following class (the "California Class"):

> All persons or entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Truvada, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries in California, other than for resale, during the period January 25, 2018 until March 30, 2021.

116. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3), Plaintiff John Doe brings this action on behalf of himself and the following class (the "Unjust Enrichment Class"):

> All persons or entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Truvada, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries in the United States (or such states the Court deems appropriate), other than for resale, during the period January 25, 2018 until March 30, 2021.

117. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3), Plaintiff Jacksonville also brings this action on behalf of themselves and the following class (the "Florida Class"):

> All persons or entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Truvada, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries in Florida, other than for resale, during the period January 25, 2018 until March 30, 2021.

118. Excluded from the Classes are Defendants and their employees; employee welfare benefit plans sponsored by Gilead, Cipla, or their affiliates; and

governmental entities, except for government-funded employee benefit plans.

119. Plaintiffs also reserve the right to request class certification with respect to particular issues under Federal Rule of Civil Procedure 23(c)(4).

120. The Classes are so numerous that joinder of all members is impracticable. According to the Department of Labor, in 2016 there were about 23,700 self-insured group health plans in the United States, and about 4,100 group health plans that mixed self-insurance with insurance ("mixed-insured"). In 2019, nearly 200,000 people were prescribed Truvada for PrEP alone, and many others were prescribed Truvada to treat HIV infection.

121. There are questions of law or fact common to the Classes. These questions include:

a. The terms of Gilead's Settlement and License Agreement with Cipla.

b. Whether Gilead and Cipla made an agreement whose effect was to forestall competition for Truvada in exchange for a large unjustified payment from Gilead to Cipla.

c. Whether any such agreement violated the laws listed below.

d. The effect of any such agreement on the net price of Truvada.

e. The definition of relevant product and geographic markets.

f. Whether Gilead's conduct substantially affected interstate commerce.

g. The total amount of damage suffered by the Classes.

122. These common questions of law and fact predominate over any issues affecting only individual Class members.

123. Plaintiffs' claims or defenses are typical of the claims or defenses of the Classes. Plaintiffs and members of the Classes were harmed by the identical conduct, and the theory of harm is the same—the price of Truvada was artificially kept high through an agreement between Gilead and Cipla.

124. Plaintiffs will fairly and adequately protect the interests of the Classes. Plaintiffs are represented by counsel who are competent and experienced in the prosecution of class-action antitrust litigation, including such litigation in the healthcare industry. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other members of the Classes.

125. The prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Gilead.

126. Gilead has acted or refused to act on grounds that apply generally to the Classes, so that relief is appropriate respecting the Classes as a whole. All Class members are affected by Gilead's agreements that forestall competition for Truvada.

127. A class action is superior to other available methods for fairly and efficiently adjudicating the controversy. The Class members have no particular interest in individually controlling the prosecution of separate actions, as their individual damages might not justify doing so, and Plaintiffs' claims are typical of Class members' claims. There is no existing litigation brought by individual Class members arising from the anticompetitive conduct described in this Complaint. Concentrating the litigation in this forum is desirable because Gilead is located here, and litigating in multiple forums would be unmanageable. This class action would not pose any particular difficulty; classes have often been certified in "pay-for-delay" cases like this one.

X. Tolling of the Statute of Limitations

128. Plaintiff John Doe is entitled to equitable tolling of the statute of limitations. "Equitable tolling will be applied in situations where, despite all due diligence, [the party requesting equitable tolling] is unable to obtain vital information bearing on the existence of the claim." *Albillo-De Leon v. Gonzales*, 410 F.3d 1090, 1099–1100 (9th Cir. 2005) (internal quotation marks omitted). To this day, Defendants have kept confidential the terms of the Settlement and License

Agreement that contains their anticompetitive agreement. They have not admitted any relationship between the settlement of their litigation and Gilead's alleged large, unjustifed reverse settlement payments. With respect to Cipla's semi-exclusive license to produce generic Atripla, a plaintiff would not even have known for sure until March 2021 if Cipla would ever market such a drug. And the Defendants denied in their motion to dismiss, filed in 2021, that the other two alleged reverse payments were even plausible. Thus, John Doe was unable to obtain vital information bearing on the existence of his claim until March 2021 at the earliest.

XI. Claims for Relief

COUNT I

VIOLATION OF THE CARTWRIGHT ACT,

CAL. BUS. & PROF. CODE §§ 16700 *et seq.*

129. Plaintiff John Doe incorporates the allegations set forth in the foregoing paragraphs as though set forth herein.[3]

130. Defendants have restricted trade or commerce, limited or reduced production, and prevented competition in the markets described above.

131. Defendants' actions thus violate the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq.*, including but not limited to Cal. Bus. & Prof. Code § 16720.

132. In *Stromberg v. Qualcomm Inc.*, 14 F.4th 1059 (9th Cir. 2021), the Ninth Circuit articulated for the first time the choice-of-law analysis required when

[3] Count I of the First Amended Class Action Complaint ("FACC") alleged a violation of Section 1 of the Sherman Act and sought injunctive relief. The Defendants' motion to dismiss was denied with respect to that Count. In mid-2021, after the filing of the FACC, competition for Truvada developed, and the price of generic Truvada decreased significantly. Because indirect purchasers cannot obtain damages under the Sherman Act, and injunctive relief is no longer necessary, the Plaintiffs do not allege a violation of the Sherman Act in this complaint. But the Court's determination that the allegations of the FACC stated a claim for a violation of the Sherman Act is still relevant because both the Cartwright Act and the Florida Deceptive and Unfair Trade Practices Act are generally violated by conduct that is found to violate the Sherman Act.

a plaintiff with a claim under the Cartwright Act seeks to represent class members from other states. The first step in that analysis is to determine whether the laws of the affected jurisdictions are the same or different. *Id.* at 1068. Only if the laws are different does the analysis need to proceed further. *Id.*

133. Here, the elements of proof under the Cartwright Act are not materially different from the laws of the other states in the Cartwright Act Class. Additionally, an indirect purchaser may bring a class action in all states in the Cartwright Act class, and treble damages are available in all such states.

134. In response to the Defendants' motion to dismiss the First Amended Class Action Complaint, Plaintiff Jacksonville conceded that it did not allege sufficient conduct in California to justify its claims against Cipla under California law. After that response was filed, Defendants Cipla Ltd. and its agent Cipla USA Inc. began selling Atripla to California residents pursuant to the unlawful License Agreement at issue in this case. Therefore, by virtue of participating in a conspiracy in California, committing acts in California in furtherance of that conspiracy, and injuring John Doe, a California resident, Cipla may be held liable for violating the Cartwright Act.

135. Therefore, Plaintiff John Doe and the Cartwright Act Class are entitled to damages, interest, and reasonable attorneys' fees and costs, pursuant to Cal. Bus. & Prof. Code § 16750.

COUNT II

VIOLATION OF UNFAIR COMPETITION LAW,

CAL. BUS. & PROF. CODE §§ 17200 *et seq.* ("UCL")

136. Plaintiff John Doe incorporates the allegations set forth in the foregoing as though set forth herein, except any allegations as to entitlement to damages.

137. Defendants have engaged and continue to engage in acts and practices of unfair competition, as that term is defined in Business & Professions Code § 17200 *et seq.* ("UCL"), by engaging in conduct that has substantial nexus to the State

of California as set forth above.

138. Business & Professions Code § 17200 defines "unfair competition" as "any unlawful, unfair or fraudulent business act or practice…." These are independent prongs of the UCL, such that Defendants can be found liable for violating the UCL under any of the separate tests of liability as set forth below.

139. The first prong of the UCL prohibits "unlawful" business acts and practices, which is defined as any practices prohibited by law, whether civil, criminal statutes or case law, either federal, state or local. No law explicitly legalized the acts and practices of Defendants. Defendants' conduct of entering into the anticompetitive agreements detailed herein constitute violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, and the Cartwright Act. Such conduct forms the predicates for committing "unlawful" business acts or practices within the meaning of the UCL.

140. The second prong of the UCL prohibits "unfair" business acts and practices. As the conduct at issue is not conduct directed as between competitors but conduct directed at purchasers and consumers of Truvada, there are several tests that determine whether a practice is "unfair," examining the practice's impact on the public balanced against the reasons, justifications and motives of Defendants:

(a) does the practice offend an established public policy, as here the practices at issue offend the policies against delaying competition by illegal agreements, as reflected in the Sherman and Cartwright Acts;

(b) balancing the utility of Defendants' conduct against the gravity of the harm created by that conduct, including whether Defendants' practice caused substantial injury to non-competitors with little to no countervailing legitimate benefit that could not reasonably have been avoided by the consumers themselves, which in this circumstance is the case as such agreements have no utility to consumers perspective and cause substantial injury to them by resulting in paying prices far higher than what they would otherwise pay for life sustaining medications that they could not

reasonably have avoided based on the patented nature of Truvada; or

(c) is the practice immoral, unethical, oppressive, unscrupulous, unconscionable or substantially injurious to consumers, which based on the facts alleged above in terms of entering into agreements that personally profit Defendants at the expense of consumers paying more for life sustaining medications than they should otherwise have to pay, would qualify under any of these standards.

141. Even if the competitor test were found to apply under these facts, under that alternative test for unfairness the question is whether the conduct in question threatens an incipient violation of antitrust laws, or violates the policy or spirit of those laws because its effects are comparable to or the same as a violation of such antitrust laws, or otherwise significantly threatens or harms competition. As Plaintiffs allege above, Defendants entered into agreements that resulted in the delay of a generic version of Truvada being permitted to enter into the stream of commerce, which caused Plaintiff John Doe and California Class members to pay supra-competitive pricing for these drugs. Even if such conduct does not result in a *per se* violation of the Sherman Act or Cartwright Act, such agreements threaten an incipient violation of such laws or violates the spirit and intent of the antitrust laws by delaying the impact of competition on the pricing of such medications and thus has the comparable effects as would a proven violation of the antitrust laws and thereby also significantly threatens or harms competition.

142. No law expressly declares the conduct at issue to be lawful and thus provides a "safe harbor" for Defendants' conduct for purposes of avoiding liability under the UCL.

143. In engaging in conduct that constitutes unfair competition, each Defendant has acquired or retained money or property to which Plaintiff John Doe and California Class members have a superior vested interest.

144. Plaintiff Joe Doe and California Class members have suffered injury in fact and a loss of money or property as a result of the Defendants' acts of unfair

competition in that they have paid more for these medications than they would have paid absent Defendants' acts or practices through the inflated price of the medications at issue due to the illegal conduct of Defendants, and thus have standing to bring this claim pursuant to Cal. Bus. & Prof. Code §§ 17203 and 17204.

145. In response to the Defendants' motion to dismiss the First Amended Class Action Complaint, Plaintiff Jacksonville conceded that it did not allege sufficient conduct in California to justify its claims against Cipla under California law. After that response was filed, Cipla began selling Atripla to California residents pursuant to the unlawful License Agreement at issue in this case. Therefore, by virtue of participating in a conspiracy in California, committing acts in California in furtherance of that conspiracy, and injuring John Doe, a California resident, Cipla may be held liable for violating the UCL.

146. Pursuant to Business & Professions Code §§ 17203 and 17204, the Court may order the Defendants restore to Plaintiff John Doe and California Class members any money or property that the Defendants may have acquired or retained, directly or indirectly, as a result of any act or practice that constitutes unfair competition. The Court may also order the Defendants to disgorge as part of its restitutionary powers any profits the Defendants may have obtained either directly or indirectly from Plaintiff John Doe and California Class members as a result of this conduct.

147. Plaintiff John Doe and California Class members also seek the payment of fees and costs pursuant to, *inter alia*, Cal. Code Civ. Proc. § 1021.5.

COUNT III

RESTITUTION, MONEY HAD AND RECEIVED, UNJUST ENRICHMENT, QUASI-CONTRACT AND/OR ASSUMPSIT

(AGAINST DEFENDANT GILEAD)

148. Plaintiff John Doe incorporates the allegations set forth in Paragraphs 1–128 as though set forth herein.

149. This Count is not derivative of the other Causes of Action asserted above, but rather is recognized as a separate and independent alternative Cause of Action that may be submitted to the jury.

150. John Doe alleges this Count on behalf of himself and the Unjust Enrichment Class, or in the alternative, the California Class. For purposes of this Count, both classes will be referred to interchangeably as the "Class."

151. Based on the allegations set forth above, Plaintiff John Doe and the Class members may properly assert an independent Count for equitable restitution and/or restitutionary damages at law derived from the principles of restitution and unjust enrichment, based on common counts such as monies had and received and mistaken receipt or retention of monies, and/or by implying an obligation at law based on principles of quasi-contract or the common-law principle of assumpsit. Under principles recognized under such common law theories of recovery, and under the circumstances alleged herein, it would be inequitable or unjust, as between the parties, for Gilead to retain such benefits based on the conduct described above.

152. By paying monies for the products at issue that Gilead charged supra-competitive prices for either directly or indirectly, Plaintiff John Doe and the Class members conferred a benefit on Gilead. Gilead owes Plaintiff John Doe and the Class members specific sums that can be measured and calculated based on the records of or that are available to Gilead.

153. Specifically, Plaintiffs seek, both for themselves and all others similarly situated, restitution at both equity and law measured as the inflated price of the medications at issue due to the illegal conduct of Gilead, either in terms of moneys expended for such medications plus any moneys or profits retained or made by Gilead on such amounts.

154. Such money or property belongs in good conscience to Plaintiff John Doe and the Class members. Gilead was unjustly conferred a benefit by obtaining money from Plaintiff John Doe and the Class members through illegal conduct as

set forth above. Having received such benefits using misleading and illegal acts, practices and/or policies and omitting material facts as set forth in detail above, Gilead is therefore required to pay monies to Plaintiff John Doe and the Class members under common law principles of restitution.

155. One who acquires a benefit may not justly retain such monies and thus must return such monies so as not to be unjustly enriched. Gilead has been unjustly enriched by Plaintiff John Doe and the Class members through payments or retention of monies it was able to retain or not pay, and the resulting profits enjoyed by Gilead. Gilead's unjust enrichment is related to and flowed from the conduct challenged in this Complaint. Such monies were not intended to be used for Plaintiff John Doe and the Class members' benefit, but rather for Gilead's own profit. Gilead is therefore required to pay such monies to Plaintiff John Doe and the Class members under common law principles of unjust enrichment.

156. An entity that has been unjustly enriched at the expense of another by the retention of a benefit wrongfully obtained or retained at another's expense is required to make restitution to the other. Gilead is required to pay over such benefits when the retention of such benefits would unjustly enrich Gilead under common law principles of common counts such as money had and received and mistaken receipt or retention of monies.

157. Gilead entered into a series of implied-at-law obligations that resulted in a sum certain as stated above being unjustly retained by Gilead, either directly or indirectly, at the expense of Plaintiff John Doe and the Class members. Gilead had knowledge of such benefits. This obligation is imposed by law, regardless of the intent of the parties. Equity and good conscience dictate that under the circumstances Gilead as the benefitted party should make restitution to Plaintiff John Doe and the Class members of such monies under common law principles of quasi-contract.

158. Plaintiff John Doe and the Class members plead just grounds for recovering money for benefits Gilead either directly or indirectly either received or

failed to pay under the above principles of common law. Gilead must restore or pay over to Plaintiff John Doe and the Class members money or benefits that Gilead received or retained, but that really should belong to Plaintiff John Doe and the Class members, as Gilead either knew or had reason to know that it was charging supra-competitive prices for these medications. Under these circumstances such monies were not properly paid to or retained by Gilead. Gilead has an obligation created by law to ensure the status quo is obtained or retained and to restore Plaintiff John Doe and the Class members to their former or rightful position by paying over monies Gilead is not lawfully entitled to retain. As Gilead is unjustly retaining such benefits at the expense of Plaintiff John Doe and the Class members, the unjustified retention of such monies entitles Plaintiff John Doe and the Class members to restitution of such monies under common law principles of assumpsit.

159. Pursuant to California Civil Code § 2224, one who gains or retains a thing (including money) by fraud, accident, mistake, undue influence, the violation of a trust, or other wrongful act, unless they have some other and better right thereto, is an involuntary trustee of the thing gained, for the benefit of the person who would otherwise have had it. Based on the facts and circumstances alleged above, in order to prevent unjust enrichment and to prevent Gilead from taking advantage of its own wrongdoing, Plaintiff John Doe and the Class members are entitled to the establishment of a constructive trust, in a sum certain, of all monies that have been improperly retained by Gilead, as well as the monies made by Gilead on such monies, from which Plaintiff John Doe and the Class members may seek restitution.

160. In addition, in light of Gilead's knowledge of the true facts as set forth above, Gilead's conduct warrants an assessment of exemplary damages under this independent cause of action in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

161. Other causes of action may not permit Plaintiff John Doe and the Class members to obtain the relief available under this Count, otherwise leaving them

without a complete and adequate remedy at law in terms of the relief sought herein.

162. All states' unjust-enrichment laws are substantially similar enough that common questions predominate over any individual differences.

163. Based on the facts set forth above, Plaintiff John Doe, both individually and on behalf of the Class, seeks appropriate restitution and/or restitutionary damages and exemplary damages as is permitted by law for such claims. Plaintiff John Doe, both individually and on behalf of the Class, also requests an order for an accounting of all such monies to which they are entitled.

COUNT IV

VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. §§ 501.201 *et seq.*

164. Plaintiff Jacksonville incorporates the allegations set forth in Paragraphs 1–128 as though set forth herein on behalf of itself and the Florida Class.

165. By virtue of their anticompetitive actions described above, Defendants have violated Fla. Stat. §§ 501.201 *et seq.*, injuring Plaintiff Jacksonville and Florida Class members.

166. The Court has held that Plaintiffs' allegations state a claim under the Sherman Act. Because the Sherman Act is a "statute … which proscribes unfair methods of competition" Defendants' conduct also constitutes a *per se* violation of the Florida Deceptive and Unfair Trade Practices Act. Fla. Stat. § 501.203(3)(c). *Jawhbs, LLC v. Arevalo*, 2017 WL 1345141, at *7 (S.D. Fla. Apr. 12, 2017); *Cross v. Point & Pay, LLC*, 2017 WL 1196676, at *5 (M.D. Fla. Mar. 31, 2017).

167. Further, the conduct described herein is deceptive and unfair in that it offends established public policy, is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers in violation of § 501.204, as it has resulted in massively inflated prices and reduced output with respect to the products at issue. Defendants' conduct therefore violates the Florida Deceptive and Unfair Trade Practices Act independent of any violation of the Sherman Act or any other law.

168. As a direct result of Defendants' unfair, unconscionable, and anticompetitive conduct, Plaintiff Jacksonville and Florida Class members have each been injured, sustained damages, and are aggrieved.

169. Therefore, Plaintiff Jacksonville and Florida Class members are entitled to damages, interest, and reasonable attorneys' fees and costs.

XII. Prayer for Relief

WHEREFORE, on behalf of themselves and the Classes, Plaintiffs request that the Court or jury as appropriate and applicable to the Counts set forth above:

A. Determine that this action may be maintained as a class action, and appoint Plaintiffs as representatives of the Class;

B. Declare that Defendants' conduct constitutes a violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq.*, and award treble damages to the members of the Cartwright Act Class under Cal. Bus. & Prof. Code § 16750;

C. Declare that Defendants' conduct constitutes a violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*, and award appropriate equitable monetary relief to the members of the California Class;

D. Declare that Defendants' conduct constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201 *et seq.*, and award damages to the members of the Florida class;

E. Award reasonable attorneys' fees and costs as allowed by law;

F. Award pre-judgment and post-judgment interest as allowed by law;

G. Award restitution and/or restitutionary disgorgement as allowed by law;

H. Award exemplary damages as allowed by law;

I. Order an accounting of monies to which Plaintiffs and the Class are entitled;

J. Grant such other relief as the Court deems just and proper.

XIII. Jury Demand

Plaintiffs demand a trial by jury on all claims so triable.

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Henry C. Quillen
(Admitted *Pro Hac Vice*)
hquillen@whatleykallas.com
WHATLEY KALLAS LLP
159 Middle Street, Suite 2C
Portsmouth, NH 03801
Tel: (603) 294-1591
Fax: (800) 922-4851

Alan M. Mansfield (SBN 125998)
WHATLEY KALLAS LLP
amansfield@whatleykallas.com
1 Sansome Street, 35th Floor PMB #131
San Francisco, CA 94104
Tel: (619) 308-5034
Fax: (888) 341-5048

Joe R. Whatley, Jr.
(Admitted *Pro Hac Vice*)
jwhatley@whatleykallas.com
Edith M. Kallas
(Admitted *Pro Hac Vice*)
ekallas@whatleykallas.com
WHATLEY KALLAS, LLP
152 W. 57th Street, 41st Floor
New York, NY 10019
Tel: (212) 447-7060
Fax: (800) 922-4851

CONSUMER WATCHDOG
Jerry Flanagan (SBN: 271272)
jerry@consumerwatchdog.org
Benjamin Powell (SBN: 311624)
ben@consumerwatchdog.org

Daniel L. Sternberg (SBN: 329799)
danny@consumerwatchdog.org
6330 San Vicente Blvd., Suite 250
Los Angeles, CA 90048
Tel: (310) 392-0522
Fax: (310) 392-8874

Attorneys for Plaintiffs