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27 **Attorneys for Plaintiff**

28 UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

JACKSONVILLE POLICE OFFICERS
AND FIRE FIGHTERS HEALTH
INSURANCE TRUST, on behalf of
itself and all others similarly situated;
Plaintiff,

v.

GILEAD SCIENCES, INC., CIPLA
LTD., CIPLA USA INC.,
Defendants.

CASE NO.

CLASS ACTION COMPLAINT

- (1) Violation of Section 1 of the Sherman Act, 15 U.S.C. § 1
- (2) Violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq.*
- (3) Violation of Cal. Bus. & Prof. Code §§ 17200 *et seq.* (“UCL”)
- (4) Restitution, Money Had and Received, Unjust Enrichment, Quasi-Contract and/or Assumpsit
- (5) Violation of State Law

JURY TRIAL DEMANDED

1 Plaintiff, on behalf of itself and all others similarly situated, upon personal
2 knowledge as to its own acts and status as specifically identified herein, and
3 otherwise upon information and belief based upon investigation as to the remaining
4 allegations, which allegations are likely to have support after a reasonable
5 opportunity for investigation and discovery, hereby alleges as follows against
6 Defendants:

7 INTRODUCTION

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

19 PARTIES

20 2. Plaintiff Jacksonville Police Officers and Fire Fighters Health
21 Insurance Trust is a health insurance trust organized under the laws of the State of
22 Florida, with its principal place of business at 625 Stockton Street, Jacksonville,
23 Florida 32204. Since the beginning of 2020, Plaintiff has spent approximately
24 \$15,000 on Truvada for the benefit of its members.

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

27 4. Defendant Cipla Ltd. is a corporation organized and existing under the
28 laws of India, with its principal place of business at Cipla House, Peninsula Business

1 Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

2 5. Defendant Cipla USA Inc. is a Delaware corporation with its principal
3 place of business at 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, Florida
4 33323. Cipla USA Inc. is a subsidiary of Cipla Ltd.

5 JURISDICTION

6 6. This Court has jurisdiction over Count I of this complaint pursuant to
7 28 U.S.C. § 1331 because it arises under the laws of the United States.

8 7. This Court has jurisdiction over Count I of this complaint pursuant to
9 28 U.S.C. § 1337 because it arises under an Act of Congress regulating commerce
10 or protecting trade and commerce against restraints and monopolies.

11 8. This court has jurisdiction over Counts II–V of this complaint pursuant
12 to 28 U.S.C. § 1367(a) because they are so related to Count I that they form part of
13 the same case or controversy under Article III of the United States Constitution.

14 9. This Court has jurisdiction over Counts II-V this complaint pursuant to
15 28 U.S.C. § 1332(d) because the matter in controversy exceeds the sum or value of
16 \$5,000,000, exclusive of interest and costs; a member of a class of plaintiffs is a
17 citizen of a state different from any defendant; and the number of members of all
18 proposed plaintiff classes in the aggregate is greater than 100.

19 VENUE

20 10. Venue is proper in this district pursuant to 15 U.S.C. § 15(a), 15 U.S.C.
21 § 22, and 28 U.S.C. § 1391 because Defendant Gilead resides in this District, is an
22 inhabitant of this district and may be found here, and because it transacts substantial
23 business in this District. Defendants Cipla Ltd. and Cipla USA Inc. transact
24 substantial business in this District, and Cipla USA Inc. has acted as an agent for
25 Cipla Ltd. with respect to some of the allegations of this complaint, as described
26 below. Moreover, a substantial part of the events or omissions giving rise to the
27 claim occurred in this District.

INTRADISTRICT ASSIGNMENT

11. Assignment to this division is proper because Defendant Gilead resides in this division and because a substantial part of the events or omissions giving rise to the claim occurred in this division. In the alternative, this antitrust case may be assigned on a district-wide basis pursuant to Local Rule 3-2(c).

FACTUAL ALLEGATIONS

I. Regulatory Background

12. 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.”

13. 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.

14. In order to protect the brand-name drug manufacturer’s patent rights, the generic manufacturer must make one of four “paragraph” certifications: (i) that

1 no patent for the brand-name drug has been filed with the FDA (Paragraph I); (ii)
2 that the patent for the brand-name drug has expired (Paragraph II); (iii) that the
3 patent for the brand-name drug will expire on a particular date and the generic
4 company does not seek to market its generic product before that date (Paragraph III);
5 or (iv) that the patent for the brand-name drug is invalid or will not be infringed by
6 the generic manufacturer's proposed product (Paragraph IV). 21 U.S.C.
7 § 355(g)(2)(A)(vii).

8 15. After filing an ANDA with a Paragraph IV certification, the generic
9 manufacturer must send notice to the patent holder. 21 U.S.C. § 355(j)(2)(B). This
10 notice is treated as actual infringement, and it triggers a forty-five day period during
11 which the patent holder may file a patent infringement lawsuit before the generic
12 reaches the market. *Id.* § 355(j)(5)(B)(iii). If the patentee files suit, the FDA stays
13 the ANDA for the lesser of thirty months or entry of final judgment of non-
14 infringement or invalidity. *Id.* During this stay, the FDA can grant tentative approval.
15 § 355(j)(5)(B)(iv)(II)(dd).

16 16. The first party to file a Paragraph IV ANDA receives a special benefit:
17 a period of 180 days where the FDA will not grant any competing ANDA. 21 U.S.C.
18 § 355(j)(5)(B)(iv). This exclusivity period can be “worth several hundred million
19 dollars” to the generic drug manufacturer, who typically earns most of the profits on
20 the generic drug during this time. *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).
21 However, this only excludes other generic manufacturers, not the brand-name drug
22 manufacturer, who can always release a generic. See 21 U.S.C. § 355(j)(5)(B)(iv)(I).
23 Generic drugs that are released by the brand-name drug manufacturer are called
24 “authorized generics,” which allow the brand-name drug manufacturer to recover
25 some of the sales and profits it would otherwise lose when an ANDA applicant
26 begins to sell the generic drug.

27 17. There are circumstances, however, in which the first party to file a
28 Paragraph IV ANDA can forfeit its 180-day exclusivity period. These include failing

1 to market the drug within a certain period of time, entering into an agreement with
2 the patent holder that violates the antitrust laws, and expiration of the patents that
3 are the subject of the Paragraph IV certification. 21 U.S.C. § 355(j)(5)(D)(i).

4 **II. HIV Prevention and Treatment**

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

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

- 14 a. Viread® tablets, which contain 300 mg of TDF.
- 15 b. Emtriva® tablets, which contain 200 mg of emtricitabine. Gilead
16 did not invent emtricitabine. It was patented by researchers at
17 Emory University, who assigned the patents to Gilead.
- 18 c. Truvada® tablets, which contain 200 mg of emtricitabine and
19 300 mg of TDF (the same dosages of these drugs as Emtriva®
20 and Viread® contain).
- 21 d. Atripla® tablets, which contain 600 mg of efavirenz, 200 mg of
22 emtricitabine, and 300 mg of TDF (the same dosages of the latter
23 two drugs as Emtriva® and Viread® contain). Gilead does not
24 own the patents to efavirenz, which are licensed by their owner,
25 Merck Sharp & Dohme (Merck) to Bristol-Myers Squibb
26 Company (Bristol-Myers). Atripla® was formulated by a joint
27
28

1 venture between Gilead and Bristol-Myers.¹

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

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

10 22. Truvada is very profitable for Gilead. In 2018, the price for a month's
11 supply was about \$2,000. According to the group ACT UP New York, a month's
12 supply of Truvada costs Gilead about \$6 to produce. Gilead's sales of Truvada
13 totaled more than \$2.6 billion in the United States in 2018. These figures include
14 Truvada used for treatment of HIV and PrEP.

15 23. Atripla is also very profitable. In 2018, the retail price for a month's
16 supply of Atripla was about \$3,400. Like Truvada, Atripla is relatively inexpensive
17 to manufacture. In the developing world, the wholesale cost for a month's supply
18 was less than \$11 in 2015. Gilead's sales of Atripla totaled \$967 million in the
19 United States in 2018.

20 **III. Patents on Emtricitabine, Truvada, and Atripla**

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

27
28 ¹ For readability, this Complaint will omit the registered trademark symbol when referring to the names of drugs.

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

7 26. Emtricitabine is one of two enantiomers of a compound whose name is
8 abbreviated as β -FTC, specifically the enantiomer called “(-)- β -FTC.” (The other
9 enantiomer is called “(+)- β -FTC.”)

10 27. Gilead had rights in a patent that claims β -FTC (Patent No. 5,814,639,
11 or the '639 Patent) and another that claims the use of β -FTC to treat HIV (Patent No.
12 5,210,085, or the '085 Patent). These patents covered β -FTC broadly; they did not
13 limit their claims to a particular enantiomer. The '085 Patent expired in 2010, and
14 the '639 Patent expired on September 29, 2015.

15 28. Gilead also has rights in two other patents relating to emtricitabine:
16 Patent No. 6,703,396 (the '396 Patent) and Patent No. 6,642,245 (the '245 Patent).
17 The '396 Patent claims (-)- β -FTC (that is, emtricitabine), and the '245 Patent claims
18 the use of (-)- β -FTC to treat HIV. The '396 Patent is scheduled to expire on March
19 9, 2021, and is also subject to a pediatric exclusivity period of six months beyond its
20 statutory expiration date, which is scheduled to end on September 9, 2021. (A drug
21 manufacturer who undertakes pediatric studies for a drug can be entitled to an
22 additional six months of exclusive marketing beyond the expiration of any patents
23 covering the drug.) The '245 Patent is scheduled to expire on November 4, 2020.
24 The '245 patent is also subject to a pediatric exclusivity period of six months beyond
25 its statutory expiration date, which is scheduled to end on May 4, 2021.

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

1 obvious. Additionally, Gilead has rights in patents that cover the combination of
2 TDF, emtricitabine, and efavirenz in a single dosage form, which Gilead markets as
3 Atripla.

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

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

12 **A. Litigation with Teva Exposes the Weakness of the**
13 **Emtricitabine Patents.**

14 31. In 2008, Teva Pharmaceuticals USA, Inc. or Teva Pharmaceutical
15 Industries Ltd. (collectively, "Teva") filed an ANDA seeking approval to
16 manufacture and sell tablets containing 200 mg of emtricitabine and 300 mg of
17 TDF—a generic version of Truvada. In late 2009 or early 2010, Teva filed two more
18 ANDAs: one seeking approval to manufacture and sell tablets containing 600 mg of
19 efavirenz, 200 mg of emtricitabine, and 300 mg of TDF (a generic version of Atripla)
20 and one seeking approval to manufacture and sell tablets containing 300 mg of TDF
21 (a generic version of Viread). These ANDAs contained Paragraph IV certifications
22 with respect to patents covering efavirenz, emtricitabine, and TDF.

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

- 26 a. *Merck, Sharp & Dohme Corp. & Bristol-Myers Squibb Co. v.*
27 *Teva Pharmaceuticals USA, Inc. & Teva Pharmaceutical*
28 *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.

- 1 b. *Gilead Sciences, Inc. v. Teva Pharmaceuticals USA, Inc., Teva*
2 *Pharmaceutical Industries, Ltd., & Cipla Ltd.*, No. 10-cv-1796
3 (the “Teva TDF suit”). The plaintiff, Gilead, alleged that Teva’s
4 manufacture and sale of generic Viread would infringe its patents
5 on TDF.
6 c. *Gilead Sciences, Inc. & Emory University v. Teva*
7 *Pharmaceuticals USA, Inc. & Teva Pharmaceutical Industries,*
8 *Ltd.*, No. 08-cv-10838 (the “Teva emtricitabine suit”). The
9 plaintiffs, including Gilead, alleged that Teva’s manufacture and
10 sale of generic Truvada would infringe their patents on
11 emtricitabine.

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

18 34. The Teva TDF suit also proceeded as far as pretrial briefing before
19 being settled. Most of the terms of the settlement were confidential, but Teva
20 announced an exclusive launch of 300 mg TDF tablets (generic Viread) on
21 December 15, 2017—shortly before expiration of the last relevant patents (and
22 exclusivity periods) on TDF on January 25, 2018.

23 35. The Teva emtricitabine suit was tried to a judge. It settled before closing
24 statements.

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

28 37. Gilead’s case started to unravel due to Gilead’s failure to prepare for
one of Teva’s main arguments. Teva had 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).

1 According to Teva, the '396 and '245 Patents (for (–)-β-FTC and its use) were not
2 distinct enough from the '639 and '085 Patents (for β-FTC and its use) to merit
3 additional patent protection. Obviousness-type double patenting can mean that
4 claims in a later patent are “obvious over” claims in an earlier patent. It can also
5 mean that claims in a later patent are “anticipated by” claims in an earlier patent. *Id.*
6 at 968. The Court in the Teva emtricitabine suit referred to the latter as the
7 “anticipation sub-theory of obviousness-type double patenting.” Teva pursued both
8 sub-theories—obviousness and anticipation—in its pretrial briefing. Gilead was
9 taken off guard; its opening pretrial brief did not address the anticipation sub-theory
10 at all. Gilead objected in a letter to the Court that Teva had not previously disclosed
11 that it would rely on the anticipation sub-theory and should not be allowed to do so.
12 The Court disagreed, stating, “Defendants’ reliance on this sub-theory cannot have
13 been unexpected to Plaintiffs.”

14 38. The Court’s decision to allow Teva to proceed on the anticipation sub-
15 theory gave Teva a clear path to a verdict in its favor. Gilead had argued in its pretrial
16 briefing that to prevail on the obviousness sub-theory, Teva would have to establish
17 that a “person of ordinary skill in the art” would have been motivated to prepare the
18 (–)-β-FTC enantiomer, that (–)-β-FTC had unexpected properties, that it felt an
19 unmet need, and many other facts. But to prevail on the anticipation sub-theory, Teva
20 needed to show at most that a person of ordinary skill in the art would visualize the
21 (–)-β-FTC enantiomer when presented with the chemical structure of β-FTC, and
22 that such a person could obtain (–)-β-FTC without undue experimentation. The first
23 requirement was undisputedly met (although Gilead argued that this was not
24 dispositive). And Teva conclusively proved the second requirement at trial.

25 39. On the first element, whether a person of ordinary skill in the art would
26 visualize (–)-β-FTC, the Court was deeply skeptical of Gilead’s main argument.
27 Gilead did not dispute that a person of ordinary skill in the art would visualize (–)-
28 β-FTC when presented with the chemical structure of β-FTC, but argued that pure

1 (-)-β-FTC was one of an infinite number of potential ratios of (-)-β-FTC and its
2 enantiomer (+)-β-FTC. Therefore, Gilead contended, a person of ordinary skill in
3 the art would see (-)-β-FTC as one member of an infinite universe, rather than
4 something readily identified. When Gilead made this argument in its opening
5 statement at trial, the Court (which did not challenge any part of Teva’s opening
6 statement) said,

7 That’s just a mathematical proposition, right? I mean if there’s billions
8 or millions, hundreds of millions of molecules, then I guess you might
9 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.

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

11 That’s a mathematical proposition that basically there is infinity
12 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
13 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
14 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.

15 Gilead’s counsel tried again, stating that “a person of ordinary skill in the art would
16 not understand what ratio would be the ratio that might make the best compound.”

17 But the Court remained unconvinced:

18 It would seem a person of ordinary skill in the art even in 1990 would
19 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
20 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
21 me that that’s what a person would logically do.

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

27 40. This exchange was a disaster for Gilead because it showed that the
28 Court would not agree with Gilead’s “infinite mixtures” theory unless trial testimony

1 showed that a person of ordinary skill in the art in 1990 would have been
2 overwhelmed with that infinity of mixtures, rather than simply looking to separate
3 β -FTC into its enantiomers, (-)- β -FTC and (+)- β -FTC. After a full trial, no testimony
4 remotely supported such a proposition. In fact, witnesses for Gilead and Teva both
5 testified that a person of ordinary skill in the art would have readily visualized (-)-
6 β -FTC after seeing the structure of β -FTC, and that separating and testing
7 enantiomers was common practice. The Court also admitted evidence that the FDA
8 encouraged scientists to separate and test enantiomers of chiral compounds, and that
9 the inventors of β -FTC separated the enantiomers of analogous drugs at the request
10 of the drug company Glaxo. Had the case gone to a verdict, Teva likely would have
11 prevailed on this element of its anticipation sub-theory.

12 41. On the other element of its anticipation sub-theory—whether a person
13 of skill in the art could obtain (-)- β -FTC without undue experimentation—Teva
14 elicited powerful evidence that put the lie to a narrative Gilead had promoted
15 throughout the case. Before trial, Gilead claimed that real-world experience had
16 shown that separating the enantiomers of β -FTC required a very high amount of time
17 and ingenuity. Gilead’s pretrial brief asserted that “the inventors themselves
18 attempted five of those methods [of separation] during their research (all but one of
19 which failed) before settling on enzymatic resolution.” But one of the inventors
20 admitted at trial that enzymatic resolution was the first method he tried, and he was
21 able to separate the enantiomers with the very first enzyme he tried, pig liver
22 esterase. This was not just an amazing coincidence; the evidence showed that
23 enzymatic resolution was a commonly used method at the time, and the inventor was
24 sure enough that it would work that in the patent application for β -FTC, he listed it
25 as a method for separation even before trying it. Gilead also claimed before trial that
26 the company BioChem took more than a year to separate the enantiomers of BCH-
27 189, a compound similar to β -FTC. That assertion turned out to be based on Gilead’s
28 misunderstanding of the evidence. In fact, a technician at BioChem, who had never

1 before attempted to separate enantiomers, testified that she successfully did so with
2 BCH-189 in “less than 15 days of laboratory time.”

3 42. Gilead tacitly recognized the severe damage the BioChem evidence did
4 to its case by attempting in its post-trial brief to supplement the record with two new
5 exhibits that supposedly put this evidence “in context.” The Court rejected this
6 attempt, stating, “The evidentiary phase of trial closed on October 28, 2013.
7 Accordingly, the Court will not consider any new exhibits introduced through post-
8 trial submissions, or any arguments or findings of fact relying on such exhibits.”
9 Following this ruling, Gilead had little hope of prevailing on the second element of
10 the anticipation sub-theory. Thus, it was likely that Gilead would lose the case, and
11 its patents on (–)-β-FTC and its use would be declared invalid.

12 43. Gilead’s arguments against the obviousness sub-theory fared no better.
13 Here, the parties contested whether in light of the patents for β-FTC and its use, it
14 would be obvious to a person of ordinary skill in the art to try to obtain (–)-β-FTC,
15 and whether doing so would involve undue experimentation. As described above,
16 Teva would have prevailed on the second element, as the inventors of β-FTC
17 obtained (–)-β-FTC on their first try, using well-known methods, and a technician at
18 BioChem did the same with a β-FTC analogue in less than 15 days. Gilead claimed,
19 however, that the person of ordinary skill in the art would not have been motivated
20 to obtain (–)-β-FTC for various reasons. This was highly implausible because in
21 1987, three years before (–)-β-FTC was obtained, the FDA issued guidance stating
22 that enantiomers should be separated and may need to be tested:

23 When the NDS [i.e., new drug substance] is asymmetric (e.g., contains
24 one or more chiral centers, or has cis-trans or other types of isomers),
25 the sponsor should ideally (and prior to the submission of an IND [i.e.,
26 investigational new drug]) have either separated the various potential
27 stereoisomers of the NDS or synthesized them independently. Physical/chemical information about each stereoisomer should be
28 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

1 their three-dimensional structure. Enantiomers are a type of stereoisomer.) Gilead
2 had no real response to this evidence. Gilead had planned to call as a witness a former
3 FDA employee who intended to testify that this guidance notwithstanding, the FDA
4 had no policy in 1990 concerning enantiomers. But her testimony was excluded
5 before trial because Gilead waited too late to disclose her. Moreover, the evidence
6 at trial showed that the separation and study of enantiomers was a regular practice
7 as early as the 1970s, and the development of single-enantiomer drugs was standard
8 practice in the pharmaceutical industry by 1990. And while Gilead had claimed that
9 a person of ordinary skill in the art would have viewed (+)- β -FTC, not (-)- β -FTC,
10 as the more obvious candidate for development, Gilead's own expert and fact
11 witnesses agreed that such a person would have tested both before rejecting either
12 of them.

13 44. The presentation of evidence in the Teva emtricitabine suit ended on
14 October 28, 2013. At that time, Teva had a strong likelihood of succeeding on both
15 sub-theories of obviousness-type double patenting. On December 19, 2013, the
16 Court ordered the parties to give summations on February 14, 2014. The day before
17 summations, the parties informed the Court that they had reached a settlement in
18 principle. Summations were canceled, and a stipulated dismissal was entered on
19 April 30, 2014. No terms of the settlement were disclosed to the public, although the
20 dismissal did state that each party would bear its own costs, expenses, and attorneys'
21 fees.

22 45. On May 8, 2019, more than five years after the case was dismissed,
23 Gilead announced that Teva will be able to launch generic versions of Truvada and
24 Atripla on September 30, 2020.

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

27 46. In 2007, Cipla Ltd. submitted an ANDA in which it sought to market a
28 generic version of Viread. The ANDA contained a Paragraph III certification,

1 indicating that Cipla Ltd. would wait until the expiration of the patents on Viread
2 before marketing a generic version. The ANDA was tentatively approved in April
3 2009. In 2009, Cipla Ltd., through its agent Cipla USA, Inc., submitted ANDAs in
4 which it sought to market generic versions of Emtriva, Truvada, and Atripla. All
5 three ANDAs contained Paragraph III certifications. The ANDAs for Emtriva,
6 Truvada, and Atripla were tentatively approved in March 2011, February 2014, and
7 February 2012, respectively.

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

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

1 49. After the settlements, Cipla amended its ANDA for Atripla to include
2 a Paragraph IV certification for patents covering emtricitabine (including the '245
3 and '396 Patents) as well as patents covering the combinations of TDF,
4 emtricitabine, and efavirenz in Atripla. Cipla notified Gilead of its Paragraph IV
5 certification, and Gilead did not file suit for infringement. Cipla received tentative
6 approval of its ANDA for Atripla on March 22, 2016. As of August 14, 2018, all of
7 the remaining patents subject to Paragraph III certification expired, including
8 periods of pediatric exclusivity. Cipla received final approval of its ANDA for
9 Atripla on June 3, 2019, but it has not marketed a generic version of Atripla in the
10 United States.

11 50. Cipla received approval for its ANDA for Emtriva on July 2, 2018.
12 Cipla has not marketed a generic version of Emtriva in the United States.

13 51. Several facts lead to the conclusion that Gilead made a large,
14 unexplained reverse payment to Cipla as part of its settlement of its cases against
15 Cipla, consisting of valuable consideration in exchange for Cipla's agreement not to
16 compete with Gilead except on terms that Gilead dictated. By keeping all terms of
17 its settlement agreements confidential, Gilead has prevented the public from
18 knowing exactly what form this consideration took, but the facts of the case suggest
19 that it at least included a license to manufacture a generic version of Atripla, a license
20 to manufacture drugs for hepatitis C, or both. Such a settlement agreement would
21 have been entered into in the State of California because Gilead's headquarters is
22 there.

23 52. First, the parties had completed or substantially completed discovery
24 when they settled. Given that Cipla had not agreed to settle for Gilead's anticipated
25 future litigation expenses before discovery, when those expenses were higher and
26 Cipla's path to victory was less clear (because the Teva emtricitabine suit had not
27 been tried yet), it would have been irrational for Cipla to settle after discovery for
28 consideration equal to Gilead's anticipated future litigation expenses, when those

1 expenses were lower and Cipla had seen from the Teva suit that it could likely prevail
2 on its challenge to the patents on emtricitabine.

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

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

16 55. Fourth, Cipla's ANDAs for Viread and Emtriva threatened not only the
17 sales of those two drugs, but also the sales of Truvada. Cipla's decision to challenge
18 the patents on Viread and Emtriva almost simultaneously, without challenging the
19 separate patents on Truvada, would have indicated to Gilead that Cipla intended to
20 sell co-packaged TDF and emtricitabine to compete with Truvada. (See Paragraphs
21 87–95 below for a discussion of co-packaged drugs and their competitive threat to
22 Truvada.) Gilead's incentive to compensate Cipla for dropping its challenge to the
23 TDF and emtricitabine patents would have gone beyond the desire to preserve its
24 profits from Viread and Emtriva. Moreover, even if the Viread patents were
25 ultimately held to be valid, Cipla could still have marketed a co-packaged
26 TDF/emtricitabine product as early as January 2018 if it could successfully
27 challenge the patents on emtricitabine, because that is the month when the last
28 patents on TDF expired.

1 56. Fifth, Cipla apparently agreed not to market a generic version of
2 Emtriva in exchange for a license to market a generic version of Atripla before its
3 patents expire, a license to manufacture drugs for hepatitis C, or both. This
4 conclusion is based on five facts:

5 a. Cipla's ANDA for a generic version of Emtriva was approved on
6 July 2, 2018, but Cipla has not begun to market such a drug or
7 announced plans to do so.

8 b. By staying out of the market with emtricitabine, Cipla is giving
9 up the period of time in which such a drug would be most
10 valuable. Emtricitabine has relatively little commercial value as
11 a stand-alone drug. For the first quarter of 2019, Gilead's United
12 States revenue from "Other HIV" drugs, a category that includes
13 Emtriva (i.e., emtricitabine) and the drug Tybost, totaled \$11
14 million. For comparison, Truvada's revenue was \$551 million.
15 But if co-packaged with TDF (generic Viread), emtricitabine
16 could compete with Truvada, opening a large market to Cipla.
17 That competition will become more difficult in September 2020,
18 when Gilead will allow Teva to market a generic version of
19 Truvada, and more difficult still when other manufacturers
20 introduce generic versions of Truvada in 2021. Cipla would be
21 behaving irrationally to forgo sales of a co-packaged
22 emtricitabine/TDF drug in the period from 2018 to 2021, when
23 doing so would be most profitable, unless it received significant
24 concessions in return.

25 c. When Cipla amended its ANDA for Atripla to include Paragraph
26 IV certifications for patents covering emtricitabine (including the
27 '245 and '396 Patents), as well as patents covering the
28 combinations of TDF, emtricitabine, and efavirenz in Atripla,

1 Gilead did not sue for infringement. This strongly implies that
2 the settlement agreement in the Cipla emtricitabine suit included
3 an agreement that Gilead would not sue for infringement of those
4 patents, and instead, Cipla would be allowed to market Atripla
5 on terms agreed to by Gilead and Cipla. The patents covering the
6 combinations of TDF, emtricitabine, and efavirenz in Atripla
7 were not at issue in the Cipla emtricitabine suit, so any agreement
8 to allow Cipla to market a generic version of Atripla, or escape
9 an infringement suit relating to those patents, represents
10 compensation that Cipla could not have obtained in its
11 emtricitabine suit even if it had prevailed.

12 d. Gilead's letters requesting dismissal of the case refer to a
13 "Settlement and License Agreement," indicating that Cipla will
14 be allowed to compete on terms dictated by agreement between
15 Gilead and Cipla.

16 e. In September 2014, less than two months after the Cipla
17 emtricitabine suit was settled, Gilead announced that it was
18 licensing seven Indian generics manufacturers, including Cipla,
19 to sell generic versions of Gilead's hepatitis C drugs sofosbuvir
20 and ledipasvir in 91 developing countries, including India. At the
21 time, a news article reported, "Estimates suggest that ledipasvir
22 could potentially be worth US\$300–US\$500m, and offer a \$110–
23 \$185m formulation and active pharmaceutical ingredient (API)
24 opportunity. Cipla is expected to earn API rights to the drug,
25 though this could not be immediately confirmed."
26 Manufacturing Chemist, Gilead announces generic licensing
27 agreements with Indian companies (Sept. 16, 2014), available at
28 <https://bit.ly/2lTQvqO>. It is plausible that the sudden availability

1 of a benefit worth as much as \$185 million to Cipla was related
2 to the settlement of the Cipla emtricitabine suit less than two
3 months earlier.

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

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

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

17 59. In May 2016, Aurobindo informed Gilead that it had amended its
18 ANDA for Emtriva to include a Paragraph IV certification for the ’245 and ’396
19 Patents, the same patents on emtricitabine at issue in the Teva and Cipla
20 emtricitabine suits. On June 23, 2016, Gilead sued Aurobindo for infringing those
21 patents. *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd.*, No. 1:16-cv-3722
22 (D.N.J.). The case settled quickly and was dismissed on September 16, 2016. No
23 terms of the settlement were disclosed to the public, although the dismissal did state
24 that each party would bear its own costs, expenses, and attorneys’ fees.

25 60. In May 2016, Aurobindo also informed Gilead that it had amended its
26 ANDA for Truvada to include a Paragraph IV certification for the ’245 and ’396
27 Patents on emtricitabine, as well as two other patents that cover the combination of
28 TDF and emtricitabine in a single dosage form: Patent Nos. 8,592,397 and

1 8,716,264. On July 8, 2016, Gilead sued Aurobindo for infringing those patents. The
2 case, *Gilead Sciences, Inc. v. Aurobindo Pharma Ltd.*, No. 1:16-cv-4178 (D.N.J.),
3 was filed in the same court and assigned to the same judge as Aurobindo's
4 emtricitabine suit. Like that case, this one settled quickly and was dismissed on
5 September 16, 2016. No terms of the settlement were disclosed to the public,
6 although the dismissal did state that each party would bear its own costs, expenses,
7 and attorneys' fees.

8 61. In April 2018, Aurobindo informed Gilead that it had submitted an
9 ANDA to market generic versions of lower-dosage forms of Truvada, and that its
10 ANDA had a Paragraph IV certification for the '245 and '396 Patents on
11 emtricitabine. (Aurobindo did not have to make a Paragraph IV certification for the
12 patents that cover the combination of TDF and emtricitabine in a single dosage form
13 because those patents do not cover the lower-dosage forms.) On May 18, 2018,
14 Gilead sued Aurobindo for infringing the '245 and '396 Patents. *Gilead Sciences,*
15 *Inc. v. Aurobindo Pharma Ltd.*, No. 1:18-cv-765 (D. Del.). On October 3, 2018, the
16 parties stipulated to a stay of the case "pending final documentation of a settlement
17 agreement." The stay was granted the next day. On October 5, 2018, the parties
18 stipulated to an order dismissing the case. No terms of the settlement were disclosed
19 to the public, although the dismissal did state that each party would bear its own
20 costs, expenses, and attorneys' fees. The court entered the dismissal order on
21 October 10, 2018.

22 62. On July 13, 2012, Lupin Ltd. informed Gilead that it had submitted an
23 ANDA in which it sought to market a generic version of Truvada. The ANDA
24 contained a Paragraph IV certification with respect to Gilead's patents on
25 emtricitabine and TDF. On August 16, 2012, Gilead filed two separate suits against
26 Lupin, one claiming infringement of the patents on emtricitabine, and the other
27 claiming infringement of the patents on TDF. *Gilead Sciences, Inc. v. Lupin Ltd.*,
28 No. 1:12-cv-6293 (S.D.N.Y.) (the "first Lupin emtricitabine suit"); *Gilead Sciences,*

1 *Inc. v. Lupin Ltd.*, No. 1:12-cv-6294 (S.D.N.Y.) (the “Lupin TDF suit”). Both cases
2 were filed in the same court and assigned to the same judge as the Teva emtricitabine
3 and TDF suits, and the Cipla emtricitabine and TDF suits. At least some of the
4 discovery in the Lupin suits was coordinated with discovery in the Cipla suits.

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

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

19 65. The parties to the first Lupin emtricitabine suit had completed all or
20 nearly all discovery by July 18, 2014, when the Court scheduled a trial beginning on
21 December 8, 2014. On August 6, 2014, the Court consolidated the first and second
22 Lupin emtricitabine suits for trial, based on the parties’ agreement that doing so
23 would not require a change in schedule. On September 16, 2014, the parties advised
24 the Court that they had executed a settlement, and the two Lupin emtricitabine suits
25 were dismissed the next day. In their letter to the Court about the settlement, Gilead’s
26 counsel stated, “The parties respectfully request that the Court enter the Order on
27 Stipulation for Dismissal attached as Exhibit A to this letter pursuant to the
28 Settlement and License Agreement.” No terms of the settlement, or any license

1 agreement, were disclosed to the public, although the dismissal did state that each
2 party would bear its own costs, expenses, and attorneys' fees.

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

12 67. The case proceeded through discovery, and Gilead amended its
13 complaint twice, adding a claim of infringement of another patent covering the
14 combination of TDF and emtricitabine in a single dosage form: Patent No.
15 8,716,264.

16 68. Gilead was on the losing end of a discovery dispute that echoed one of
17 its losses in the Teva emtricitabine suit: one in which it prejudiced itself by not
18 preparing a response to an opponent's defense, claimed that the defense was new
19 and unanticipated, and then was told by the Court that it should have seen the defense
20 coming. This time, the context was a request for the production of documents from
21 Mylan that Gilead claimed were relevant to Mylan's "enablement" defense, which
22 claimed that the patents on Truvada did not enable a "person skilled in the art" to
23 make Truvada. The problem for Gilead was that Mylan had refused to produce those
24 documents, and Gilead had missed the deadline to move to compel by months.
25 Gilead's excuse was that it was not on notice of the enablement defense until after
26 Mylan's refusal, but the Court pointed out filings where Mylan had explicitly
27 invoked the defense, and stated that "Gilead's argument ... strains credulity." Thus,
28 Gilead's motion to compel was denied as untimely.

1 69. The denial of Gilead’s motion to compel was the last substantive
2 development in the case. Less than six weeks later, the case settled. No terms of the
3 settlement were disclosed to the public, although the dismissal did state that each
4 party would bear its own costs, expenses, and attorneys’ fees.

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

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

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

22 73. In or around December 2016, Amneal Pharmaceuticals, LLC submitted
23 an ANDA in which it sought to market a generic version of Truvada. The ANDA
24 contained Paragraph IV certifications for at least three of the patents listed in the
25 Orange Book for Truvada: the ’245 and ’396 Patents on emtricitabine, as well as one
26 other patent that covers the combination of TDF and emtricitabine in a single dosage
27 form: Patent No. 8,716,264. On April 6, 2017, Gilead sued Amneal for infringing
28 those patents. *Gilead Sciences, Inc. v. Amneal Pharmaceuticals, LLC*, No. 17-cv-

1 2335 (D.N.J.).

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

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

12 76. The parties began discovery and agreed on claim construction. On June
13 7, 2018, they stipulated to dismissal, which was entered the next day. No terms of
14 the settlement were disclosed to the public, although the dismissal did state that each
15 party would bear its own costs, expenses, and attorneys' fees.

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

21 78. On June 13, 2017, Macleods informed Gilead that it had submitted
22 ANDAs to market generic versions of Truvada and Atripla. Both ANDAs contained
23 Paragraph IV certifications. On July 27, 2017, Gilead sued Macleods for infringing
24 the '245 and '396 Patents on emtricitabine, as well as three other patents that cover
25 the combination of TDF and emtricitabine in a single dosage form: Patent Nos.
26 8,592,397, 8,716,264, and 9,457,036. *Gilead Sciences, Inc. v. Macleods*
27 *Pharmaceuticals, Ltd.*, No. 1:17-cv-1039 (D. Del.).

28 79. The parties agreed to several extensions of Macleods' time to answer

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

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

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

16 82. Strides answered Gilead's complaint on July 18, 2018. On September
17 6, 2018, the parties asked for an adjournment of the Rule 16 conference so they could
18 discuss settlement. The request was granted the next day. On December 21, 2018,
19 the parties asked the court to enter an order dismissing the case with prejudice. No
20 terms of the settlement were disclosed to the public, although the stipulated dismissal
21 order did state that each party shall bear its own costs, expenses, and attorneys' fees.
22 The court entered the order on January 9, 2019.

23 83. On December 3, 2018, Zydus Pharmaceuticals (USA) Inc. and Calida
24 Healthcare Ltd. (which does business as Zydus Calida) (together, "Zydus") informed
25 Gilead that they had submitted an ANDA for various fixed-dose combinations of
26 emtricitabine and TDF. The ANDA includes a Paragraph IV certification for the
27 '245 and '396 Patents on emtricitabine, as well as four other patents that cover the
28 combination of TDF and emtricitabine in a single dosage form: Patent Nos.

1 8,592,397, 8,716,264, 9,457,036, and 9,744,181. On January 15, 2019, Gilead sued
2 Zydus for infringing those patents. *Gilead Sciences, Inc. v. Zydus Pharmaceuticals*
3 *(USA) Inc.*, No. 19-cv-529 (D.N.J.). Zydus filed its answer on June 14, 2019, and
4 the parties stipulated to dismissal on August 13, 2019.

5 **V. Additional Factors Imply That Gilead Resolved Its Litigation with**
6 **Cipla with a Large, Unexplained Reverse Payments.**

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

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

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

18 86. Moreover, Gilead and the defendants have kept all terms of their
19 settlement agreements confidential, except for the year that Truvada will face
20 generic competition. Doing so insulates the agreements from public scrutiny.

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

23 87. Even if the fixed-dose combination patents for Truvada are valid,
24 Gilead could still face competition from copackaged drugs beginning in 2021, as
25 explained below. If the patents on emtricitabine were held to be invalid, however,
26 Truvada and Atripla would face significant competition in 2018 instead, three years
27 earlier. This is because the patents on the components of Truvada other than
28 emtricitabine expire that year. 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.

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

17 89. In 2006, the FDA published a document called, “Guidance for Industry:
18 Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions
19 of Previously Approved Antiretrovirals for the Treatment of HIV.” The FDA
20 explained that “[t]his guidance is intended to encourage sponsors to submit
21 applications to the Food and Drug Administration (FDA) for approval of fixed dose
22 combination (FDC) and copackaged versions of previously approved antiretroviral
23 therapies for the treatment of human immunodeficiency virus (HIV).” Fixed-dose
24 combinations and co-packaged drugs, the FDA noted, both “may facilitate
25 distribution and improve patient adherence.” The guidance also stated that the “FDA
26 believes that when adequate evidence of safety and efficacy exists for the use of
27 combination therapy with individually approved HIV drugs, the path to regulatory
28 approval of an FDC or co-packaged configuration of those drugs is straightforward.

1 FDA is prepared to move swiftly to evaluate such products when applications are
2 submitted for approval.” Such products are eligible for priority review, which takes
3 six months or less. The FDA pointed out that even if the individual drugs that make
4 up the fixed-dose combination or copackaged configuration are covered by a patent,
5 the FDA can still grant tentative approval so that the fixed-dose combination or
6 copackaged configuration could be marketed as soon as the patents expire. The
7 guidance also listed several drug combinations for which an application for a
8 copackaged configuration would not require clinical studies. The drug combinations
9 of Truvada and Atripla were on the list.

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

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

28 92. The FDA’s 2006 guidance strongly implies that it would have approved

1 copackaged equivalents of Truvada for the same indications for which Truvada is
2 approved. The approval of copackaged equivalents of Truvada would have quickly
3 led to their availability at substantially lower prices. For example, just before
4 Gilead's last patent on Viread expired, the National Average Drug Acquisition Cost
5 (NADAC) for one Viread tablet was \$36.75. Less than a year later, the price of the
6 generic version of Viread hit a low of \$1.28, a decrease of 96.5%. With approval of
7 a copackaged equivalent of Truvada, and in the absence of patent protection on
8 emtricitabine, a generic version of Emtriva would have been priced at a similar
9 discount to Emtriva, whose NADAC is currently \$17.18 per tablet. If that discount
10 were also 96.5%, then a tablet of generic emtricitabine would cost \$0.60. A month's
11 supply of the copackaged equivalent of Truvada would cost \$56.40, instead of the
12 \$2,000 that Gilead charges for brand-name Truvada.

13 93. FDA approval of copackaged versions of Truvada would have
14 decimated Gilead's profits, while benefitting consumers greatly. Something similar
15 happened to Gilead's drug Harvoni, which is used to treat hepatitis C. Harvoni is
16 very effective in treating hepatitis C, but it was extremely expensive when it was
17 introduced, with a list price of \$84,000 for a course of treatment. Harvoni was a huge
18 financial success for Gilead, earning more than \$13 billion in revenue its first full
19 year on the market. But when the drug manufacturer AbbVie obtained approval for
20 a competitor drug, Viekira Pak, the net price of Harvoni (that is, the list price minus
21 Gilead's rebates) collapsed. Viekira Pak was a copackaged drug, with patients
22 having to take multiple pills per day. But just three days after the approval of Viekira
23 Pak, Express Scripts, the nation's largest pharmacy benefit manager (PBM),
24 announced that it would make Viekira Pak its preferred treatment for hepatitis C
25 genotype 1 (the most common genotype in the United States), and it would no longer
26 cover Harvoni. The deal resulted in AbbVie's offer to sell Viekira Pak to Express
27 Scripts for a net price of approximately \$51,000 to \$66,000, a significant discount
28 to the \$84,000 that Gilead was charging for Harvoni. Shortly after, Gilead entered

1 into discounting agreements for Harvoni with CVS, Anthem, Humana, Aetna, Cigna
2 and UnitedHealth Group. According to a report by the United States Senate
3 Committee on Finance, industry sources estimated that those discounts were
4 approximately 40% from the list price.

5 94. There are many reasons to believe that Truvada would have been
6 discounted at least as severely if it had faced competition from a copackaged version.
7 First, the individual components of Truvada, TDF and emtricitabine, are inexpensive
8 to manufacture, as described above. Second, unlike Viekira Pak, a copackaged
9 version of Truvada would have the exact same active ingredients as Truvada itself,
10 making it even easier for pharmacy benefit managers and payors to justify taking
11 Truvada off their formularies (or demoting it) in favor of the copackaged version.
12 Third, if a copackaged version of Truvada were to become available as a result of
13 the invalidation of Gilead's patents on emtricitabine, several generic drug
14 manufacturers would have been able to sell the copackaged version beginning in
15 early 2018. By contrast, when Viekira Pak was introduced, AbbVie was the only
16 manufacturer with the right to make it. More intense competition for a copackaged
17 version of Truvada would have lowered the price even further.

18 95. The way Gilead chose to respond to these various threats of competition
19 was to offer valuable consideration to Cipla in exchange for its agreement not to
20 challenge the patents on emtricitabine, as described above. The result of these
21 agreements was that Cipla declined to enter the market "at risk," dropped its
22 challenge to the emtricitabine patents, and agreed not to compete against Truvada
23 until some date in the future. But for the large and unjustified reverse payment that
24 Gilead made, Cipla would have competed against Truvada during the class period
25 by selling the components of Truvada as a copackaged version on or shortly after
26 January 2, 2018.

27 VI. Relevant Markets

28 96. The relevant product market (the "Truvada market") in this case

1 includes Truvada, the generic equivalent of Truvada, and the copackaged equivalent
2 of Truvada. These drugs are not interchangeable with other drugs outside the
3 Truvada market. A hypothetical monopolist could profitably impose a small but
4 significant and non-transitory increase in price above competitive levels for the
5 drugs in the Truvada market. Within that market, the potential competitors are the
6 generic formulation of Truvada, and a co-packaged formulation of Truvada.

7 97. The relevant geographic market for the Truvada market is the United
8 States. For purposes of this complaint, “United States” includes its territories and the
9 District of Columbia. Gilead sells Truvada across the United States, and it is
10 unlawful for customers to import foreign versions of Truvada, or its generic or
11 copackaged equivalents.

12 98. Gilead has market power the relevant markets. Because of its patents
13 on emtricitabine, and other manufacturers’ agreements not to challenge those patents
14 or manufacture emtricitabine themselves, Gilead is the only company authorized to
15 manufacture Truvada, generic Truvada, or copackaged Truvada in the United States.

16 **VII. Interstate Commerce**

17 99. Gilead’s actions with respect to its drugs containing emtricitabine have
18 restrained interstate trade. Gilead markets and sells these drugs throughout the
19 United States. Likewise, competitive products would be sold throughout the United
20 States.

21 **VIII. Antitrust Impact and Damages**

22 100. But for Gilead’s unlawful agreements, the price of Truvada would have
23 been significantly lower, and lower-priced copackaged equivalents would have been
24 available.

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

- 27 a. Paying less for Truvada.
- 28 b. Substituting purchases of lower-priced generic or co-packaged

1 equivalents of Truvada.

2 c. Moving Truvada into a higher tier on their formularies, or
3 removing it entirely, in order to pay less of the cost of those
4 medications.

5 102. To a large extent, the Plaintiff's and Class members' savings would
6 have been accomplished through the insurers and PBMs that manage their
7 prescription drug benefits. As described above, when a copackaged version of
8 Gilead's drug Harvoni became available, the nation's largest insurers and PBMs
9 either dropped Harvoni from their formularies in favor of its competitor, or
10 significantly reduced the cost of Harvoni to their clients.

11 103. While an exact calculation is not yet available, damages suffered by the
12 Plaintiff and Class members is at least in the hundreds of millions of dollars. Gilead's
13 United States revenue from Truvada from the beginning of 2018 to June 30, 2020
14 was approximately \$6 billion, and a significant portion of that amount represents
15 overpayments by Plaintiff and Class members.

16 104. Therefore, Gilead's unlawful agreements are a proximate cause of the
17 antitrust injury to the Plaintiff and Class members.

18 **IX. Class Action Allegations**

19 105. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and
20 (b)(3), the Plaintiff brings this action on behalf of itself and the following class (the
21 "Class"):

22 All self-insured or mixed-insured group health plans in the United
23 States that paid for Truvada on behalf of their members from January
24 25, 2018 to the present.

24 106. Excluded from the Class are employee welfare benefit plans sponsored
25 by Gilead, Cipla, or their affiliates, and governmental entities, except for
26 government-funded employee benefit plans.

27 107. The Plaintiff also reserves the right to request class certification with
28 respect to particular issues under Federal Rule of Civil Procedure 23(c)(4).

1 108. The Class is so numerous that joinder of all members is impracticable.
2 According to the Department of Labor, in 2016 there were about 23,700 self-insured
3 group health plans in the United States, and about 4,100 group health plans that
4 mixed self-insurance with insurance (“mixed-insured”).

5 109. There are questions of law or fact common to the class. These questions
6 include:

- 7 a. The terms of Gilead’s Settlement and License Agreement with
8 Cipla.
- 9 b. Whether Gilead and Cipla made an agreement whose effect was
10 to forestall competition for Truvada in exchange for a large
11 unjustified payment from Gilead to Cipla.
- 12 c. Whether any such agreement violated the state and federal laws
13 listed below.
- 14 d. The effect of any such agreement on the net price of Truvada.
- 15 e. The definition of relevant product and geographic markets.
- 16 f. Whether Gilead’s conduct substantially affected interstate
17 commerce.
- 18 g. The total amount of damage suffered by the Class.
- 19 h. The Class’s entitlement to injunctive relief.

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

22 111. The claims or defenses of the Plaintiff are typical of the claims or
23 defenses of the Class. The Plaintiff and members of the Class were harmed by the
24 identical conduct, and the theory of harm is the same—the price of Truvada was
25 artificially kept high through an agreement between Gilead and Cipla.

26 112. The Plaintiff will fairly and adequately protect the interests of the Class.
27 The Plaintiff is represented by counsel who are competent and experienced in the
28 prosecution of class-action antitrust litigation, including such litigation in the

1 healthcare industry. The Plaintiff's interests are coincident with, and not antagonistic
2 to, those of the other members of the Class.

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

6 114. Gilead has acted or refused to act on grounds that apply generally to the
7 Class, so that final injunctive relief or corresponding declaratory relief is appropriate
8 respecting the Class as a whole. All Class members are affected by Gilead's
9 agreements that forestall competition for Truvada.

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

20 **X. Claims for Relief**

21 **COUNT I**
22 **VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1**

23 116. The Plaintiff incorporates the allegations set forth in the foregoing
24 paragraphs as though set forth herein.

25 117. As set forth above, Gilead entered into an agreement in restraint of
26 trade, namely its agreement with Cipla that forestalled competition for Truvada. This
27 agreement constitutes a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

28 118. Gilead's unlawful conduct threatens to continue to injure the Plaintiff.

1 But for the agreement, Cipla (and potentially other manufacturers) could obtain FDA
2 approval for a co-packaged equivalent of Truvada relatively easily, and offer such a
3 product in the United States, giving the Plaintiff a lower-cost alternative to Truvada
4 and reducing the price of Truvada itself. Introducing such a product would be in
5 Cipla's interest, as Cipla could earn significant profits while still setting a price well
6 below the current price of Truvada.

7 119. Therefore, the Plaintiff and the Class are entitled to an injunction
8 against Gilead's agreement with Cipla pursuant to Section 16 of the Clayton Act,
9 15 U.S.C. § 26.

10 **COUNT II**
11 **VIOLATION OF THE CARTWRIGHT ACT,**
12 **CAL. BUS. & PROF. CODE §§ 16700 *et seq.***

13 120. The Plaintiff incorporates the allegations set forth in the foregoing
14 paragraphs as though set forth herein.

15 121. The Defendants have restricted trade or commerce, limited or reduced
16 production, and prevented competition in the markets described above.

17 122. The Defendants' actions thus violate the Cartwright Act, Cal. Bus. &
18 Prof. Code §§ 16700 *et seq.*, including but not limited to Cal. Bus. & Prof. Code
19 § 16720.

20 123. This claim is brought on behalf of all Class members nationwide for the
21 reasons articulated in *In re Qualcomm Antitrust Litigation*, 328 F.R.D. 280 (N.D.
22 Cal. 2018).

23 124. Therefore, the Plaintiff and the Class are entitled to damages, interest,
24 injunctive relief, and reasonable attorneys' fees and costs, pursuant to Cal. Bus. &
25 Prof. Code § 16750.

26 **COUNT III**
27 **VIOLATION OF UNFAIR COMPETITION LAW,**
28 **CAL. BUS. & PROF. CODE §§ 17200 *et seq.* ("UCL")**

125. The Plaintiff incorporates the allegations set forth in the foregoing
paragraphs as though set forth herein, except any allegations as to entitlement to

1 damages.

2 126. The Defendants have engaged and continue to engage in acts and
3 practices of unfair competition, as that term is defined in Business & Professions
4 Code § 17200, by engaging in conduct that has substantial nexus to the State of
5 California as set forth above. As used in this Complaint “unfair competition” means
6 an unlawful, unfair or fraudulent business act or practice. This conduct is actionable
7 pursuant to Business & Professions Code §§ 17200 and 17203.

8 127. The Defendants’ violations of the Sherman Act and Cartwright Act also
9 constitute “unlawful” business acts or practices within the meaning of the UCL.

10 128. The Defendants’ policies and practices as detailed herein causes
11 substantial injury to non-competitors with no countervailing legitimate benefit
12 and/or is immoral, unethical, oppressive, unscrupulous, and/or unconscionable, and
13 thereby constitutes “unfair” business acts or practices within the meaning of the
14 UCL.

15 129. The Defendants’ policies and practices as detailed herein and the
16 making of material statements and/or material omissions of fact relating thereto as
17 set forth in detail above, all of which is likely to mislead the Plaintiff, Class members
18 and the public, constitutes “fraudulent” business acts or practices within the meaning
19 of the UCL.

20 130. In engaging in conduct that constitutes unfair competition, each
21 Defendant has acquired or retained money or property to which Plaintiff and Class
22 members have a superior vested interest.

23 131. The Plaintiff has suffered injury in fact and a loss of money or property
24 as a result of the Defendants’ acts of unfair competition in that they have paid more
25 for these medications than they would have paid absent Defendants’ anti-
26 competitive conduct and have standing to bring this claim pursuant to Cal Bus. &
27 Prof. Code §§ 17203 and 17204.

28 132. Pursuant to Business & Professions Code §§ 17203 and 17204, the

1 Court may enjoin such conduct on behalf of the Class and for the benefit of the
2 general public, and order the Defendants to restore to the Plaintiff and Class
3 members any money or property that the Defendants may have acquired or retained,
4 directly or indirectly, as a result of any act or practice that constitutes unfair
5 competition. The Court may also order the Defendants to disgorge as part of its
6 restitutionary powers any profits the Defendants may have obtained either directly
7 or indirectly from Plaintiff and Class members as a result of this conduct.

8 133. Plaintiff also seeks the payment of fees and costs pursuant to, *inter alia*,
9 Cal. Code Civ. Proc. § 1021.5.

10 **COUNT IV**
11 **RESTITUTION, MONEY HAD AND RECEIVED, UNJUST**
12 **ENRICHMENT, QUASI-CONTRACT AND/OR ASSUMPSIT**
13 **(AGAINST DEFENDANT GILEAD)**

14 134. The Plaintiff incorporates the allegations set forth in the foregoing
15 paragraphs as though set forth herein.

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

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

28 137. By either paying monies for the products at issue that Gilead charged
supracompetitive prices for, Plaintiff and Class members conferred a benefit on
Gilead. Gilead owes Plaintiffs and Class members specific sums that can be

1 measured and calculated based on the records of or that are available to Gilead.

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

7 139. Such money or property belongs in good conscience to Plaintiff and
8 Class members. Gilead was unjustly conferred a benefit by Plaintiff and Class
9 members through illegal conduct or acts of mistake or fraud as set forth above.
10 Having received such benefits using misleading and illegal acts, practices and/or
11 policies and omitting material facts as set forth in detail above, Gilead is therefore
12 required to pay monies to Plaintiffs and Class members under common law
13 principles of restitution.

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

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

28 142. Gilead entered into a series of implied-at-law obligations that resulted

1 in a sum certain as stated above being unjustly retained by Gilead, either directly or
2 indirectly, at the expense of Plaintiff and Class members. Gilead had knowledge of
3 such benefits. This obligation is imposed by law, regardless of the intent of the
4 parties. Equity and good conscience dictate that under the circumstances Gilead as
5 the benefitted party should make restitution to Plaintiffs and Class members of such
6 monies under common law principles of quasi-contract.

7 143. Plaintiff and Class members plead just grounds for recovering money
8 for benefits Gilead either directly or indirectly either received or failed to pay under
9 the above principles of common law. Gilead must restore or pay over to Plaintiff and
10 Class members money or benefits that Gilead received or retained, but that really
11 should belong to Plaintiff and Class members, as Gilead either knew or had reason
12 to know that it was charging supracompetitive prices for these medications. Under
13 these circumstances such monies were not properly paid to or retained by Gilead.
14 Gilead has an obligation created by law to ensure the status quo is obtained or
15 retained and to restore Plaintiff and Class members to their former or rightful
16 position by paying over monies Gilead is not lawfully entitled to retain. As Gilead
17 is unjustly retaining such benefits at the expense of Plaintiff and Class members, the
18 unjustified retention of such monies entitles Plaintiff and Class members to
19 restitution of such monies under common law principles of assumpsit.

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

1 Plaintiff and Class members may seek restitution.

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

6 146. Other causes of action may not permit Plaintiff and Class members to
7 obtain the relief available under this Cause of Action, otherwise leaving them
8 without a complete and adequate remedy at law in terms of the relief sought herein.

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

14 **COUNT V**
15 **VIOLATION OF STATE LAW**

16 148. The Plaintiff incorporates the allegations set forth in the foregoing
17 paragraphs as though set forth herein.

18 149. To the extent the Cartwright Act is found to not apply to the claims of
19 Class members not located outside the State of California, by virtue of their
20 anticompetitive actions described above, the Defendants have violated the state laws
21 listed below, injuring the Plaintiff and Class members located in those states:

- 22 a. Ariz. Rev. Stat. § 44-1401 et seq.
23 b. Conn. Gen. Stat. § 35-24 et seq.
24 c. D.C. Code § 28-4501 et seq.
25 d. Fla. Stat. § 501.201 et seq.
26 e. Haw. Rev. Stat. § 480-1 et seq.
27 f. Iowa Code § 553.1 et seq.
28 g. Kan. Stat. Ann. § 50-101 et seq.

- 1 h. Md. Code Ann., Com. Law § 11-201 et seq.
- 2 i. Me. Rev. Stat. tit. 10, § 1101 et seq.
- 3 j. Mass. Gen. L. Ch. 93A
- 4 k. Mich. Comp. Laws § 445.771 et seq.
- 5 l. Minn. Stat. § 325D.49 et seq.
- 6 m. Miss. Code Ann. § 75-21-1 et seq.
- 7 n. Neb. Rev. Stat. § 59-801 et seq.
- 8 o. Nev. Rev. Stat § 598A.010 et seq.
- 9 p. N.H. Rev. Stat. Ann. § 356:1 et seq.
- 10 q. N.M. Stat. Ann. § 57-1-1 et seq.
- 11 r. N.Y. Gen. Bus. Law § 340 et seq.
- 12 s. N.C. Gen. Stat. § 75-1 et seq.
- 13 t. N.D. Cent. Code § 51-08.1-01 et seq.
- 14 u. Or. Rev. Stat. § 646.705 et seq.
- 15 v. L.P.R.A. tit. 10, § 260 et seq.
- 16 w. R.I. Gen. Laws § 6-36-1 et seq.
- 17 x. S.D. Codified Laws § 37-1-3.1 et seq.
- 18 y. Tenn. Code Ann. § 47-25-101 et seq.
- 19 z. Utah Code Ann. § 76-10-3101 et seq.
- 20 aa. Vt. Stat. Ann. tit. 9, § 2453 et seq.
- 21 bb. W. Va. Code § 47-18-1 et seq.
- 22 cc. Wis. Stat. § 133.01 et seq.

23 150. There are no material differences between the elements of proof under
24 these state unfair competition laws and the Sherman and Cartwright Acts.

25 151. Therefore, the Plaintiff and Class members who reside in one of these
26 states are entitled to monetary and injunctive relief.

1 **XI. Prayer for Relief**

2 WHEREFORE, on behalf of themselves and the Class and to the extent
3 appropriate for the benefit of the general public, the Plaintiff requests that the Court
4 or jury as appropriate:

- 5 A. Determine that this action may be maintained as a class action, and
6 appoint the Plaintiff as representatives of the Class;
- 7 B. Declare that the Defendants' conduct constitutes a violation of the
8 Sherman Act, 15 U.S.C. § 1, and award treble damages to the Class
9 under Sections 4 and 16 of the of the Clayton Act., 15 U.S.C. § § 15,
10 26;
- 11 C. Declare that the Defendants' conduct constitutes a violation of the
12 Cartwright Act, Cal. Bus. & Prof. Code §§ 16700 *et seq.*, and award
13 treble damages to the proposed Class under Cal. Bus. & Prof. Code §
14 16750;
- 15 D. Declare that the Defendants' conduct constitutes a violation of
16 California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200
17 *et seq.*, and appropriate injunctive and equitable monetary relief to the
18 Class and for the benefit of the general public;
- 19 E. To the extent found to be applicable, declare that the Defendants'
20 conduct constitutes a violation of the state laws listed in Count V, and
21 award the damages available under each state law to the members of
22 the Class who reside in each state;
- 23 F. Enjoin the Defendants from enforcing any agreement found to be
24 anticompetitive, and from entering into any agreement that would
25 restrict competition in the markets identified above;
- 26 G. Award reasonable attorneys' fees and costs as allowed by law;
- 27 H. Award pre-judgment and post-judgment interest as allowed by law;
- 28 I. Award restitution and exemplary damages as allowed by law;

1 J. Order an accounting of monies to which Plaintiff and the Class are
2 entitled;

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

4 **XII. Jury Demand**

5 The Plaintiff demands a trial by jury on all claims so triable.

6
7 DATED: September 17, 2020



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