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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

PETER STALEY, et al.,

Plaintiffs,

v.

GILEAD SCIENCES, INC., et al.,

Defendants.

Case No. 3:19-cv-02573-EMC

FIRST AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Plaintiffs, on behalf of themselves and all others similarly situated (the "Class," as defined below), on personal knowledge with respect to facts pertaining to them and upon information and belief as to other matters, bring this class action complaint against Defendants Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, Gilead Sciences Ireland UC (together, "Gilead"), Bristol-Myers Squibb Company, E. R. Squibb & Sons, L.L.C. (together, "BMS"), Janssen R&D Ireland, Janssen Products LP, and Johnson & Johnson (together, "Janssen") (collectively, "Defendants") for damages, injunctive relief, and other relief pursuant to the federal antitrust laws and state antitrust and consumer protection laws.

I. INTRODUCTION

1. Gilead and its coconspirators have engaged in a long-running scheme to restrain competition with respect to some of the most important drugs used to treat Human Immunodeficiency Virus ("HIV") infection—a disease which, if left untreated, destroys the immune system, leading to Acquired Immunodeficiency Syndrome ("AIDS") and eventual death. Through an array of anticompetitive practices—including horizontal agreements constituting per se violations of the antitrust laws—Gilead has acquired and maintained a monopoly in the market for drugs that comprise the modern HIV treatment regimen known as "combination antiretroviral therapy" ("cART"). The scheme has enabled Gilead and its coconspirators to unlawfully extend patent protection for their drugs, impair entry by would-be generic competitors, and charge exorbitant, supracompetitive prices for the drugs that people living with HIV need to survive.

2. Gilead dominates the class of drugs that target HIV known as "antiretrovirals," which are essential to effective HIV therapy. Modern antiretroviral drug regimens comprise a combination or "cocktail" of drugs, most often consisting of two nucleotide/nucleoside analogue reverse transcriptase inhibitors ("NRTIs") taken with at least one antiretroviral drug of another class, such as an integrase inhibitor, commonly referred to as "third agents." These antiretroviral cocktails are known as cART regimens. During most of the relevant time, Gilead was the exclusive maker (and is still the dominant maker) of one of the principal NRTIs used in cART regimens: Tenofovir. By controlling the market for Tenofovir, and through its collusive agreements with its coconspirators, Gilead now dominates the

market for cART. Today more than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead's sales of these products in the United States alone are more than $13 billion annually.

3. Gilead maintains a stranglehold on the cART market even though Tenofovir was discovered more than 30 years ago by researchers in the Czech Republic. In 2001, Gilead began marketing its patented formulation of the compound known as tenofovir disoproxil ("TDF"), quickly reaching sales in the hundreds of millions of dollars. Gilead expected that generic manufacturers would challenge the validity of its Tenofovir patents and potentially enter the market as early as 2009. So, in order to head off the threat of generic competition, Gilead and each of its coconspirators, BMS and Janssen, entered into a series of collusive and illegal horizontal agreements providing that each coconspirator would not compete against Gilead's Tenofovir, and would effectively block other companies from competing against Tenofovir, *even after Gilead's Tenofovir patents expired.*

4. Gilead and its coconspirators coformulated TDF with the coconspirators' third agents into single pills known as fixed-dose-combination drugs ("FDCs"). Each of the joint development agreements prevented the coconspirator from creating or marketing a competing version of the FDC formulated with generic versions of Gilead's TDF even after Gilead's patents expired (hereinafter a "No-Generics Restraint"). This gave Gilead an enormous financial incentive to move prescriptions from its standalone version of TDF to the FDCs, which would be insulated from generic competition even after TDF's patents expired. And it meant that Gilead's most likely competitors—the companies that could formulate FDCs with generic alternatives to TDF—had instead promised not to compete with Gilead. In exchange, the No-Generics Restraints and joint development agreements enabled Gilead and the coconspirator to share the artificially inflated profits from each other's sales.

5. As part of the unlawful scheme's quid pro quo, Gilead also agreed to shield BMS and Janssen's HIV drugs from imminent generic competition by allowing them to coformulate FDCs that combined their vulnerable products with a Gilead booster drug, Cobicistat, which enjoyed much longer patent protection. Just as BMS and Janssen agreed not to market a competing FDC even after Gilead's patents expired, Gilead returned the favor by agreeing not to market a competing FDC after the BMS and Janssen patents expired.

6. Collectively, the unlawful agreements between Gilead and each of its coconspirators effectively foreclosed competition for drugs essential to cART regimens. In 2018, the agreements covered more than 75% of all sales of NRTIs, more than 75% of all sales of booster drugs, and a substantial percentage of all sales of third agents for use in a cART regimen in the United States.

7. In a relentless effort to reap ever-more monopoly profits, Gilead engaged in further anticompetitive conduct to reinforce the exclusionary effects of these illegal exclusion agreements. When generic competition to TDF became imminent, Gilead amended the No-Generics pacts to preclude its coconspirators from competing not only against Gilead's then-marketed TDF but also against a new formulation of the compound, tenofovir alafenamide ("TAF"), and further extended the term of the No-Generics Restraints. Gilead had been holding TAF in reserve for more than a decade to roll out later as part of its scheme to impair competition once generic entry was imminent. With the extended No-Generics Restraints in place, Gilead reformulated the original TDF-based FDCs with TAF and then used anticompetitive tactics to drive patients towards the reformulated FDCs, which are shielded from competition in some instances until at least 2032.

8. Gilead drove patients into treatment with TAF-based FDCs by intentionally degrading some of its key products. Gilead knew before seeking FDA approval of its TDF-based FDC marketed as Stribild that the dosage of TDF in it was much higher than needed and would subject patients to increased risk of significant adverse side effects. But Gilead was already planning to eventually replace that product with a TAF-based version. Refusing to reduce the dosage in the TDF version artificially magnified the safety differences between it and the TAF-based version, helping Gilead to drive patients to the TAF version.

9. Gilead also pressed patients to TAF-based FDCs by intentionally delaying and degrading the standalone version of TAF. TAF has a substantially lower incidence than TDF of significant adverse side effects. Beginning in 2015, Gilead intentionally steered patients to the TAF-based FDCs by degrading standalone TAF in at least three ways:

(a) Gilead intentionally delayed applying for FDA approval of standalone TAF by a year, ensuring that the new, safer version of Tenofovir was available during that time only through purchase of a Gilead TAF-based FDC;

(b) When Gilead finally did make TAF available as a standalone product, Gilead intentionally degraded its safety by making it available only in a much greater dose—with consequent greater risk of side effects—than the dose that Gilead used in its FDCs; and

(c) Gilead did not seek FDA approval for the use of standalone TAF to treat HIV (getting it approved instead only for treatment of Hepatitis B), even while seeking and obtaining FDA approval for its use in treating HIV when used as a component of a Gilead FDC.

10. Gilead's refusal to get an HIV indication for standalone TAF also imposed a regulatory barrier to generic competition. Gilead did not seek that indication for standalone TAF despite designing and intending the drug as an HIV treatment and submitting data to the FDA showing its safety and efficacy in treating HIV. Gilead's decision to forgo the HIV indication for standalone TAF forced would-be competitors to re-perform time-consuming and expensive clinical trials that Gilead had already performed. Forgoing this HIV indication costs Gilead hundreds of millions of dollars in sales of standalone TAF every year, but blocking competitors' entry into the market was even more valuable.

11. Timely competition from generic manufacturers could have complicated Gilead and its coconspirators' schemes. The world's largest generic-pharmaceutical manufacturer, Teva Pharmaceuticals, started challenging the validity of Gilead's vulnerable patents covering its NRTIs in 2009. Instead of defending its portfolio, however, Gilead settled with Teva, inducing it to withdraw its challenges and significantly delay entering the market with its generic version of the Gilead NRTIs. Gilead induced Teva's delay by including anticompetitive "Most Favored Entry" clauses in settlement agreements with Teva and other generic manufacturers. Those pacts assured Teva that it would have an exclusivity period with the only generic on the market, in exchange for which Teva agreed to delay marketing its generic products.

12. This delay bought Gilead the time it needed to move its customers from TDF-based FDCs (about to face generic competition) to TAF-based FDCs. By 2017, when TDF finally faced generic competition, Gilead had switched more than 60% of its HIV product sales to the reformulated, TAF-based FDCs protected from competition by its unlawful agreements with Janssen.

13. Starting in 2004, Gilead intentionally delayed the development and regulatory approval of TAF in order to use it in the anticompetitive scheme only once generic competition to TDF was imminent. Despite that intentional delay, Gilead recently obtained from the Patent and Trademark Office ("PTO") a patent-term extension on its principal patent on TAF, extending its termination from May 2023 to April 2025. Congress intended such extensions to benefit pharmaceutical manufacturers who encounter delays in getting their products to market as a result of government-imposed regulatory hurdles, through no fault of their own. But Gilead intentionally delayed bringing TAF to market in order to impair generic competition later. Nevertheless, the PTO was powerless to deny the patent-term extension to Gilead because the statute permits such denial only if the manufacturer's delay occurs after the patent has issued. Gilead's conduct in intentionally delaying TAF and then getting a patent-term extension on it is both a perversion of the patent-extension statute and unlawfully exclusionary conduct under the antitrust laws.

14. The consequences of Gilead and its coconspirators' unlawful conduct have been, and continue to be, burdensome to the government and catastrophic for many patients. The United States federal government alone spends over $20 billion annually on HIV treatment, most of it on these Defendants' dramatically overpriced drugs. Even more of the costs of these unlawfully monopolized drugs are borne by union health and welfare funds, other third-party payors, state and local governments, and the patients themselves. Worse, the high cost of these life-saving medications prevents many patients from gaining access to the drugs at all. Half of those in this country living with HIV are not accessing the required medications, and fully 400,000 more Americans should be on HIV treatment. The high prices of cART regimens contribute to that problem.

15. Defendants' anticompetitive conduct has also stifled innovation, causing tens of thousands of people living with HIV to needlessly suffer debilitating side effects from inferior products. Gilead delayed getting FDA approval of TAF for more than a decade while it used the illegal No-Generics Restraints, rather than product innovations, to protect its market share. The unlawful restraints also prohibited competing manufacturers from gaining access to the pharmaceutical compounds needed to formulate new, innovative, superior, and substantially less expensive treatments—precluding the development and marketing of more than two dozen specifically identifiable HIV treatments. Gilead's

unlawful scheme also altogether foreclosed the availability of an affordable method of pre-exposure prophylaxis (PrEP) that would prevent HIV infection in the first place, crippling this nation's ability to stop new HIV infections.

16. To remedy these and the other devastating effects of Defendants' anticompetitive conduct set forth in detail below, Plaintiffs seek nationwide injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, because, unless enjoined, the Defendants' unlawful conduct will continue unchecked and Plaintiffs and those similarly situated will continue to suffer. Plaintiffs also assert claims for damages for Defendants' continuing violations of state antitrust and consumer protection laws.

II. JURISDICTION AND VENUE

17. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants. The Court further has jurisdiction over this action pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2. The Court also has supplemental jurisdiction over the pendent state-law claims pursuant to 28 U.S.C. § 1367.

18. Defendants transact business within this district. Venue is appropriate within this district under 28 U.S.C. §1391(b) and (c), and section 12 of the Clayton Act (15 U.S.C. § 22).

III. INTRADISTRICT ASSIGNMENT

Pursuant to Local Rule 3-2(c), this is an Antitrust Class Action to be assigned on a district-wide basis.

IV. THE PARTIES

19. Plaintiff Peter Staley is an adult, individual consumer, residing in Shohola, Pennsylvania. Mr. Staley purchased and/or paid for some or all of the purchase price for one or more of brand Viread,

Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in Pennsylvania and New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Staley will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

20. Plaintiff Ivy Kwan Arce is an adult, individual consumer, residing in New York, New York. Ms. Arce purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Ms. Arce will in the future purchase one or more of these products manufactured by the Defendants, and she has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

21. Plaintiff Steve Fuller is an adult, individual consumer, residing in Cheverly, Maryland. Mr. Fuller purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in Maryland, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Fuller will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

22. Plaintiff Gregg S. Gonsalves, PhD is an adult, individual consumer, residing in New Haven, Connecticut. Dr. Gonsalves purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in Connecticut, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Dr. Gonsalves will in the future purchase one or

more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

23. Plaintiff Brenda Emily Goodrow is an adult, individual consumer, residing in Milford, Pennsylvania. Ms. Goodrow purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York and Pennsylvania, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Ms. Goodrow will in the future purchase one or more of these products manufactured by the Defendants, and she has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

24. Plaintiff Andrew R. Spieldenner, PhD is an adult, individual consumer, residing in San Diego, California. Dr. Spieldenner purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York and California, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Dr. Spieldenner will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

25. Plaintiff Robert J. Vazquez is an adult, individual consumer, residing in Brooklyn, New York. Mr. Vazquez purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Vazquez will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

26. Plaintiff Jason Walker is an adult, individual consumer, residing in Brooklyn, New York. Mr. Walker purchased and/or paid for some or all of the purchase price for one or more of brand Viread,

Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Walker will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

27. Plaintiff Michael Warner is an adult, individual consumer, residing in East Point, Georgia. Mr. Warner purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in Georgia, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Warner will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

28. Plaintiff Jacob Zydonis is an adult, individual consumer, residing in Grass Valley, California. Mr. Zydonis purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in California, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Zydonis will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

29. Plaintiff Michael Snipe is an adult, individual consumer, residing in New York, New York. Mr. Snipe purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Snipe will in the future purchase one or more of these products

manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

30. Plaintiff John Carroll is an adult, individual consumer, residing in New York, New York. Mr. Carroll purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Carroll will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

31. Plaintiff Josh McDonald is an adult, individual consumer, residing in New York, New York. Mr. McDonald purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for resale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. McDonald will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

32. Plaintiff John Doe is an adult, individual consumer, residing in Wayne, Pennsylvania. Mr. Doe purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in Pennsylvania, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Doe will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

33. Plaintiff Gabriel Molina is an adult, individual consumer, residing in Woodlynne, New Jersey. Mr. Molina purchased and/or paid for some or all of the purchase price for one or more of brand

Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New Jersey, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Molina will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

34. Plaintiff Troy Vazquez-Cain is an adult, individual consumer, residing in New York, New York. Mr. Vazquez-Cain purchased and/or paid for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for resale, in New York, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Mr. Vazquez-Cain will in the future purchase one or more of these products manufactured by the Defendants, and he has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

35. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund ("FOP") is a governmental plan established and funded through contributions from the City of Miami and the plan's members, who are current and retired sworn officers from the City of Miami Police Department and their dependents. FOP was established pursuant to a Trust Agreement for the purpose of providing medical, surgical, and hospital care or benefits, including prescription drug benefits, to its members. FOP maintains its principal place of Miami, Florida. The FOP purchased and/or provided reimbursement for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, and other cART drugs other than for re-sale, in Florida, North Carolina, Pennsylvania, and Tennessee, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that FOP will in the future purchase one or more of these products manufactured by the Defendants, and it has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

36. Plaintiff Local No. 1 Health Fund is Taft Hartley multi-employer plan, affiliated with

Service Employees International Union Local 1, and is operated primarily for the benefit of the union's members and their families who are covered by a collective bargaining agreement between the union and its contributing employer. Local No. 1 Health Fund maintains its principal place of business in Downers Grove, Illinois. Local No. 1 Health Fund purchased and/or provided reimbursement for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, and other cART drugs other than for re-sale, in Illinois, Indiana, Michigan, and Wisconsin, at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Local No. 1 Health Fund will in the future purchase one or more of these products manufactured by the Defendants, and it has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

37. Plaintiffs Teamsters Local 237 Welfare Fund and Teamsters Local 237 Retirees' Benefit Fund (collectively "Local 237") are two related health and welfare benefit plans headquartered and with a principal place of business in New, York, New York. Local 237 administers the assets of defined contribution plans formed to provide certain benefits including prescription drug benefits. Local 237 provides health and welfare benefits to active and retired members and participants who reside in numerous locations in the United States. Local 237 purchased and/or provided reimbursement for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in New York, Florida, North Carolina, Maryland, New Jersey, Pennsylvania, Tennessee, and Virginia at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Local 237 will in the future purchase one or more of these products manufactured by the Defendants, and it has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

38. Plaintiff Pipe Trades Services MN Welfare Fund ("Pipe Trades Fund") is a Taft-Hartley fund authorized under Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in White Bear Lake, Minnesota, and an employee welfare benefit plan as defined in Section 3(1)

of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq. Pipe Trades Fund is the sponsor of a plan of benefits which provides health benefits, including prescription-drug benefits, to approximately 16,000 active participants and retirees, plus their spouses and dependents. Pipe Trades Fund purchased and/or provided reimbursement for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, or other cART drugs other than for re-sale, in Minnesota, among other locations at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that Pipe Trades Fund will in the future purchase one or more of these products manufactured by the Defendants, and it has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

39. Defendant Gilead Sciences, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

40. Defendant Gilead Holdings, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Holdings, LLC is a wholly-owned subsidiary of Gilead Sciences, Inc.

41. Defendant Gilead Sciences, LLC (formerly known as Bristol-Myers Squibb & Gilead Sciences, LLC) is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Sciences, LLC is a wholly-owned subsidiary of Gilead Sciences, Inc.

42. Defendant Gilead Sciences Ireland UC (formerly known as Gilead Sciences Limited) is an unlimited liability company organized and existing under the laws of Ireland, with a principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland. Gilead Sciences Ireland UC is a wholly-owned subsidiary of Gilead Sciences, Inc.

43. Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC are collectively referred to herein as "Gilead."

44. Defendant Bristol-Myers Squibb Company is a corporation organized and existing under

the laws of the State of Delaware, with a principal place of business at 430 East 29th Street, 14th Floor, New York, NY 10016.

45. Defendant E. R. Squibb & Sons, L.L.C. is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 430 East 29th Street, 14th Floor, New York, NY 10016. E. R. Squibb & Sons, L.L.C. is a wholly-owned subsidiary of Bristol-Myers Squibb Company.

46. Bristol-Myers Squibb Company and E. R. Squibb & Sons, L.L.C. are collectively referred to herein as "BMS."

47. Defendant Johnson & Johnson is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is the parent of the corporate entities that fall within the umbrella name of Janssen Pharmaceutical Companies. Janssen Pharmaceutical Companies, including Janssen Products LP and Janssen R&D Ireland, sell, develop, and/or license drugs, including Complera, Odefsey, Edurant, Prezista, Prezcobix, and Symtuza, whose profits inure to the benefit of Johnson & Johnson. Johnson & Johnson oversaw, directed, and/or approved the negotiation and/or execution of the agreements regarding Complera, Odefsey, Prezcobix, and Symtuza subject to this Complaint. Johnson & Johnson's employees were and continue to be active participants in the performance of the Complera, Odefsey, Prezcobix, and Symtuza agreements. Johnson & Johnson receives a financial benefit as a result of the unlawful conspiracy alleged herein, and it actively promotes itself as a leader in HIV treatment.

48. Defendant Janssen Products LP is a Pennsylvania company with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560. Janssen Products LP's employees participated in the negotiation and/or execution of the agreements regarding Complera, Odefsey, Prezista, and/or Symtuza. Janssen Products LP is the owner of the New Drug Applications for Edurant, Prezista, Prezcobix, and Symtuza. Janssen Therapeutics (formerly known as Tibotec Therapeutics), a division of Janssen Products LP, sells and promotes Edurant, Prezista, Prezcobix, and Symtuza in the United States.

49. Defendant Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals) is a private unlimited company organized and existing under the laws of Ireland, with a principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland. Janssen R&D Ireland is a subsidiary of

Johnson & Johnson.

50. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Janssen Products LP, and Janssen R&D Ireland are collectively referred to herein as "Janssen."

51. All of the Defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraints of trade alleged herein, and were authorized, ordered, and undertaken by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and ostensible authority of the Defendants.

V. SCIENCE BACKGROUND

52. HIV is one of the deadliest human pandemics in history. Since the first cases were reported in the summer of 1981, more than 35 million people across the world, and more than 700,000 in the United States, have perished from the disease. In the United States, the HIV epidemic is still ongoing. The Centers for Disease Control and Prevention ("CDC") reported that in 2017, the last year for which data is available, an estimated 1.1 million people in the United States were living with HIV, nearly 40,000 people were newly diagnosed with it, and more than 5,000 Americans perished from it.

53. If left untreated, HIV infection severely weakens a patient's immune system, leading to a condition known as Acquired Immunodeficiency Syndrome ("AIDS"). AIDS prevents the immune system from fighting diseases against which the body is normally able to protect itself. These AIDS-defining illnesses are generally the direct cause of death in people who die from untreated AIDS.

54. Over time, untreated HIV infection almost always leads to AIDS, and untreated AIDS almost always results in death. The FDA approved azidothymidine ("AZT"), the first drug to treat HIV infection, in 1987, but effective therapy to treat the disease was not available until 1996.

55. Two innovations led to the introduction of effective therapy for HIV. The first innovation was the development of novel classes of powerful drugs that target the HIV virus, known as "third agents" or "core agents." Protease inhibitors, introduced in 1996, were the original type of third agent. The second innovation was the discovery that an effective HIV treatment must include a combination or

"cocktail" of at least two drugs (initially three or more drugs) that inhibit the viral life cycle through at least two different mechanisms of action, an approach known as "combination antiretroviral therapy" or "cART."

56. Effective cART reduces HIV viral replication to such an extent that the concentration of virus (known as the "viral load") in treated patients drops to "undetectable" levels, generally defined as less than 50 RNA copies of HIV per milliliter of blood or plasma. This protects the immune system, and, in most cases, significantly restores immunologic function in people with advanced HIV infection or AIDS. People on effective cART can live healthy lives with relatively manageable side effects and normal life expectancy. Furthermore, access to cART is vital for public health efforts to reduce the number of new HIV infections. A person living with HIV who maintains an undetectable viral load durably cannot transmit the virus to others.

57. However, cART does not cure an individual living with HIV. People living with HIV must continually take the drugs that make up a cART regimen for the rest of their lives. If a person stops taking a cART regimen, viral replication will soon restart, resulting in viral rebound and the resumed destruction of a patient's immune system.

58. A modern cART regimen most often consists of two drugs of the nucleotide/nucleoside analogue reverse transcriptase inhibitor ("NRTI") class—often referred to as an "NRTI backbone"—taken with a third agent of another class. For example, all "first line" regimens that the United States government recommends for treatment-naïve patients, i.e. those not previously treated for HIV, consist of two NRTIs (either (i) Tenofovir with emtricitabine or lamivudine or (ii) abacavir with emtricitabine or lamivudine) taken with a third agent of the integrase strand transfer inhibitor ("INSTI") class, specifically dolutegravir, bictegravir, or raltegravir. The use of abacavir is recommended for only a select patient population and only with a particular third agent, dolutegravir (see Section VIII below).

59. Tenofovir is the most common NRTI used in cART regimens in the United States. Tenofovir is unique among NRTIs approved to treat HIV infection, in that it is a nucleotide analogue, rather than a nucleoside analogue. All NRTIs must be "activated" by the patient's cells for the drug to inhibit viral replication. This activation process is known as phosphorylation, and it comprises the chemical addition of a phosphate group to a drug molecule through specific human enzymes known as

kinases. As shown in detail below (see Sections VII and VIII), Tenofovir's dominance among NRTIs, and the need to use NRTIs in almost all cART regimens, allowed Gilead and its coconspirators to monopolize the market for cART regimens.

60. With the exception of Tenofovir, all NRTIs approved to treat HIV need to be triple phosphorylated, i.e. three phosphate groups need to be sequentially added to the drug molecule for the drug to be activated. Tenofovir, however, already has a single phosphate group analogue, a phosphonate moiety, attached to the drug molecule. Thus, Tenofovir needs to be phosphorylated only twice by host enzymes to be converted into its activated form, tenofovir-diphosphate ("TFV-DP"). This allows Tenofovir to skip the slowest or "rate limiting" step in the NRTI activation process, the addition of the first phosphate group to the drug, allowing Tenofovir to have superior intracellular pharmacokinetics (fundamentally, allowing a higher concentration and longer half-life of the activated molecule (TFV-DP) in the cell).

61. But the presence of a phosphonate group also comes with a distinct disadvantage: it prevents Tenofovir, by itself, from being developed as an orally administered drug. To combat this problem, Gilead developed two different "prodrugs" of Tenofovir to allow it to be swallowed. Prodrugs are pharmacologically inactive compounds that can be more efficiently absorbed and then converted into the active form of the drug within the body. Gilead markets two different Tenofovir prodrugs: tenofovir disoproxil fumarate ("TDF") and tenofovir alafenamide fumarate ("TAF").

62. Tenofovir is almost always used alongside another NRTI, specifically either lamivudine ("3TC") or emtricitabine ("FTC"). When an HIV virus becomes resistant to either 3TC or FTC, the virus's susceptibility to Tenofovir *increases*. Thus, the combination of Tenofovir with either 3TC or FTC makes it more difficult for the virus to develop resistance to a cART regimen.

63. 3TC and FTC are remarkably similar, varying by the substitution of only a single hydrogen atom in 3TC, with a fluorine atom in FTC in the 5-prime position of the cytosine ring. Both the United States Department of Health and Human Services ("HHS") and the World Health Organization ("WHO") guidelines stipulate that the drugs, when used for HIV treatment, can be used interchangeably. Any cART regimen using FTC can use 3TC instead, and vice versa, with no reduction in therapeutic efficacy.

64. The ability to use 3TC instead of FTC is important to the antitrust claims here. Gilead owns and currently still has patent protection for FTC, but generic 3TC has been available in the United States since 2012. Thus, when generic Tenofovir (specifically, generic TDF) became available in December 2017, the price of cART regimens should have dropped precipitously because two generic NRTIs—3TC and TDF—were available in the marketplace. This complaint outlines how Gilead and its coconspirators prevented those price drops from occurring.

65. The need to use multiple drugs in cART regimens can be a barrier to patient compliance. To reduce this possible burden, multiple antiretroviral drugs are often coformulated together into a single pill. These are known as "fixed-dose combinations" or "FDCs." An FDC that has all of the components of a complete cART regimen in a single pill is known as a "single tablet regimen" or "STR."

66. In addition to NRTIs and third agents, another class of drugs is sometimes used in cART regimens. Pharmacokinetic enhancers, commonly referred to as "boosters," are drugs that are not taken for their anti-HIV properties, but rather for their ability to inhibit the breakdown of some third agents. Boosters work by inhibiting enzymes of the Cytochrome P450 class, which break down some antiretroviral drugs. All modern protease inhibitors, as well as one integrase inhibitor, elvitegravir, are commonly used with boosters.

67. Two drugs are used as boosters—ritonavir ("RTV") and cobicistat ("COBI"). Ritonavir is an antiretroviral drug of the protease inhibitor class that can be used in lower doses as a booster alongside third agents to inhibit their breakdown. Cobicistat has no anti-HIV properties itself, but rather works just to inhibit the breakdown of other antiretroviral drugs. Gilead owns and currently still has patent protection on COBI.

68. Eleven distinct active pharmaceutical ingredients ("APIs") are most pertinent to this case.

API	Abbreviation	Class of Drug
Lamivudine	3TC	NRTI
Tenofovir Disoproxil Fumarate	TDF	NRTI
Emtricitabine	FTC	NRTI
Tenofovir Alafenamide Fumarate	TAF	NRTI

API	Abbreviation	Class of Drug
Efavirenz	EFV	Third Agent—Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)
Rilpivirine	RPV	Third Agent—NNRTI
Elvitegravir	EVG	Third Agent—INSTI
Atazanavir Sulfate	ATV	Third Agent—Protease Inhibitor
Darunavir Ethanolate	DRV	Third Agent—Protease Inhibitor
Ritonavir	RTV	Booster
Cobicistat	COBI	Booster

69. The following table describes seventeen of the drug products discussed in this complaint:

Drug Name/ **NDA Holder/ Approval Date**	**1st NRTI**	**2nd NRTI**	**Third Agent**	**Booster**	**Type**
Viread Gilead Oct 26, 2001	TDF	--	--	--	Standalone
Emtriva Gilead Jul 2, 2003	--	FTC	--	--	Standalone
Truvada Gilead Aug 2, 2004	TDF	FTC	--	--	FDC
Atripla Gilead Jul 12, 2006	TDF	FTC	EFV	--	STR
Complera Gilead Aug 10, 2011	TDF	FTC	RPV	--	STR
Stribild Gilead Aug 27, 2012	TDF	FTC	EVG	COBI	STR

Drug Name/ NDA Holder/ Approval Date	**1st NRTI**	**2nd NRTI**	**Third Agent**	**Booster**	**Type**
Genvoya Gilead Nov 5, 2015	TAF	FTC	EVG	COBI	STR
Odefsey Gilead Mar 1, 2016	TAF	FTC	RPV	--	STR
Descovy Gilead Apr 4, 2016	TAF	FTC	--	--	FDC
Vemlidy Gilead Nov 10, 2016	TAF	--	--	--	Standalone
Prezista Janssen Jun 23, 2006	--	--	DRV	--	Standalone
Reyataz BMS Jun 20, 2003	--	--	ATV	--	Standalone
Evotaz BMS Jan 29, 2015	--	--	ATV	COBI	FDC
Prezcobix Janssen Jan 29, 2015	--	--	DRV	COBI	FDC
Edurant Janssen May 20, 2011	--	--	RPV	--	Standalone

Drug Name/ NDA Holder/ Approval Date	**1st NRTI**	**2nd NRTI**	**Third Agent**	**Booster**	**Type**
Symtuza Janssen July 17, 2018	TAF	FTC	DRV	COBI	STR
Tybost Gilead Sep 24, 2014	--	--	--	COBI	Standalone

VI. REGULATORY BACKGROUND

A. Approval of Generic Drugs and Substitution of Generics for Branded Drugs

70. Under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), manufacturers that want to sell a new drug product must file a New Drug Application ("NDA") in order to obtain approval from the Food and Drug Administration ("FDA"). 21 U.S.C. §§ 301–392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a) & (b).

71. When the FDA approves a brand manufacturer's NDA, that manufacturer may list in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") any patents that the manufacturer believes it could reasonably assert against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the listed patents expire. The manufacturer may list in the Orange Book within 30 days of issuance any such patents issued after NDA approval. 21 U.S.C. §§ 355 (b)(1) & (c)(2).

72. The FDA relies completely on the brand manufacturer's truthfulness about a patent's validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

B. The Hatch-Waxman Amendments

73. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug—that is, that the generic drug is the pharmaceutical equivalent of the brand drug. The FDA assigns generic drugs that are pharmaceutical equivalents of branded drugs an "AB" rating.

74. The FD&C Act and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the patient's blood to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

75. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs into the marketplace, thereby reducing healthcare expenses nationwide. Congress also wanted to maintain and refine pharmaceutical manufacturers' incentives to create new and innovative products.

76. The Hatch-Waxman Amendments achieved both goals, substantially increasing the rate of generic entry into the marketplace and ushering in an era of historic high profits for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998 nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion and generic drugs accounted for 75% of all

prescriptions.

C. Paragraph IV Certifications

77. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications, that:

i. no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. the patent for the brand drug has expired (a "Paragraph II certification");

iii. the patent for the brand drug will expire on a particular date and the generic manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

78. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer brings a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA product.

79. As an incentive for manufacturers to seek approval of generic alternatives to brand drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition from other generic versions of the drug approved through the ANDA process ("ANDA Exclusivity"). The first generic applicant is entitled to 180 days of ANDA Exclusivity, i.e., subject to certain limitations the FDA is precluded from approving any other generic version of the product through the ANDA process until 180 days after the first-filer enters the market.

80. An applicant that is otherwise eligible for the 180-day ANDA Exclusivity forfeits it by failing to obtain tentative FDA approval for the product within 30 months of filing the application. 21 U.S.C. 355 § (j)(5)(D)(i)(I)(aa)(BB). And under the "failure to market" provision, a first-filer forfeits its

180-day ANDA Exclusivity if (among other grounds for forfeiture) it fails to market its generic drug within 75 days after another manufacturer obtains a final decision that the brand manufacturer's patents are invalid or not infringed. 21 U.S.C. 355 § (j)(5)(D)(i)(I)(bb).

81. Moreover, as noted in detail below (see Section VII(H)), the 180-day ANDA Exclusivity does not prevent a brand manufacturer from marketing as an "authorized generic" the product for which it got approval through the NDA process.

82. The high profit margins on brand drugs and the predictable effects of generic entry—sales switch quickly from the brand to the generic—create powerful financial incentives for brand manufacturers to sue any generic competitor that files an ANDA with a Paragraph IV certification, even if the competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. Simply by listing the patents in the Orange Book and filing the lawsuit the brand manufacturer can delay final FDA approval of an ANDA for up to 30 months.

83. By creating a statutory mechanism to enable early infringement litigation following Paragraph IV certifications, the Hatch-Waxman Amendments encourage generic manufacturers to test the validity of pharmaceutical patents and invent around them. The notion is that *bona fide* litigation will result in rulings that either confirm legitimate patent protection or ferret out invalid, unenforceable, or narrow drug patents.

D. Approvals Under 21 U.S.C. § 355(b)(2)

84. In addition to allowing drug manufacturers to seek expedited FDA approval under the ANDA process, the Hatch-Waxman Amendments permit streamlined approval under Section 505(b)(2) of the FD&C Act, 21 U.S.C. § 355(b)(2). In contrast to an ANDA, a Section 505(b)(2) application allows greater flexibility as to the characteristics of the proposed product, relaxing the otherwise applicable requirements that the product be in the same route of administration, dosage form, and strength as the referenced brand drug.

85. Consequently, a drug approved through the Section 505(b)(2) process will not necessarily be rated therapeutically equivalent to the referenced brand drug, and thus might not be automatically substitutable for it at the pharmacy counter. In some circumstances, however, the FDA will designate a

drug approved through the Section 505(b)(2) process as AB-rated to the brand drug.

86. Like an NDA, an application under Section 505(b)(2) contains full reports of investigations of the drug's safety and effectiveness. Unlike in an NDA, however, some of the required information to establish safety and effectiveness in a Section 505(b)(2) application may come from studies not conducted by the applicant. Instead, that information may come, for example, from the FDA's finding of safety and effectiveness of the referenced brand drug or from published literature. This can result in a much less expensive and much faster route to FDA approval, compared with submitting a full NDA. In essence, an application under Section 505(b)(2) is a hybrid between an NDA and an ANDA.

87. In addition to new indications and different dosage forms, routes of administration, or salts of chemical compositions, Section 505(b)(2) can be used to seek approval of new combinations of existing drugs. On a case-by-case basis, the FDA determines which clinical trials or other data the applicant will need to submit in order to get approval to market the drug.

E. New Chemical Entity Exclusivity

88. The Hatch-Waxman Amendments provide periods of exclusivity that benefit branded pharmaceutical manufacturers, one of which is a 5-year new chemical entity ("NCE") exclusivity. The NCE exclusivity provision states that, where the FDA has approved a new chemical entity (a drug substance that the FDA had not previously approved), no other manufacturer may seek FDA approval for a product containing that drug substance until five years after the FDA first approved it. 21 U.S.C. § 355 (j)(5)(F)(ii) & (c)(3)(E)(ii).

89. Under the FDA's implementing regulations, if a drug product contains a new chemical entity, the FDA is precluded from accepting any ANDA or application under 21 U.S.C. § 355(b)(2), for a drug product that contains the same chemical entity until the 5-year NCE exclusivity period has expired. 21 C.F.R. § 314.108(b)(2).

90. Pursuant to the FDA's "umbrella policy," after a drug substance becomes eligible for 5-year NCE exclusivity, products subsequently developed that contain the same drug substance also benefit from the original 5-year NCE exclusivity until the original exclusivity period has expired. For example, the FDA might in year 1 approve standalone drug X, which contains new drug substance A, and grant it

NCE exclusivity that expires in year 6. If the FDA later, in year 4, approves an FDC that contains composition A, then the existing NCE exclusivity also applies to the FDC and also runs until year 6.

91. An NCE exclusivity has a profound impact on the timing of generic approvals, generally precluding an applicant from even filing an ANDA for the entire 5-year NCE exclusivity life span. As an exception, the applicant may file an ANDA after the first four years of the 5-year exclusivity if the ANDA contains a Paragraph IV certification. But filing a Paragraph IV certification also subjects the ANDA to a 30-month stay of FDA approval, which does not commence until the 5-year NCE exclusivity expires. Thus, obtaining NCE exclusivity over a patent-protected drug may prevent the FDA from approving a generic applicant for as long as 7.5 years from the start the of NCE exclusivity.

F. Effects of AB-Rated Generic Competition

92. Typically, AB-rated generics cost much less than their branded counterparts. Over time, as more generic equivalents enter the marketplace for a drug and compete with each other, prices decline rapidly. Because generic products are commodities that cannot be differentiated, the primary basis for generic competition is price.

93. Since passage of the Hatch-Waxman Amendments, every State has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing doctor has specifically ordered otherwise). As a result of substitution laws and other institutional features of the pharmaceutical marketplace, the marketing of AB-rated generics results both in rapid price decline and rapid sales shift from the brand to the generic product. Once a generic equivalent enters the marketplace, the generic quickly captures sales of the branded drug, often garnering 80% or more of unit sales within the first six months. The Federal Trade Commission ("Commission") found that on average, within a year of generic entry, generics had captured 90% of brand unit sales and (with multiple generics in the marketplace) prices had dropped 85%. *See* Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, January 2010 at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

94. Brand manufacturers are well aware of the generics' rapid erosion of their sales. Brand manufacturers thus seek to extend their exclusivity for as long as possible, sometimes resorting to

unlawful means.

VII. DEFENDANTS' ANTICOMPETITIVE CONDUCT

95. FDCs can reduce the number of pills that patients must take, thereby possibly improving patients' compliance with their drug regimens. Plaintiffs do not contend that creating or marketing FDCs, as such, is anticompetitive. Nor do Plaintiffs contend that any statutory or regulatory exclusivity that FDCs may enjoy is anticompetitive; Plaintiffs' claims take those exclusivities as a given.

96. But Gilead and its coconspirators entered into a series of agreements that preclude the use of generic components instead of Gilead's products *even after its patents and regulatory exclusivities have expired*. The coconspirators created a private hiatus from competition that the public law does not provide. Those agreements are illegal per se.

97. Anticipating the possibility of imminent generic competition to its NRTIs—Viread (TDF), Emtriva (FTC), and Truvada (TDF/FTC)—Gilead agreed with each of BMS and Janssen to create and market FDCs that combined their third agents with Gilead's NRTIs. Each agreement included a No-Generics Restraint by which BMS and Janssen agreed not to create or market a competing FDC made with generic or comparable versions of Gilead's NRTIs even after the patents on them expired.

98. Gilead's patents on TDF, FTC, and TDF/FTC were weak, and as of 2004 Gilead expected to encounter generic competition to Viread (TDF), Emtriva (FTC), and Truvada (TDF/FTC) as early as 2009, 2011, and 2011, respectively, if generic manufacturers successfully challenged the patents. The Viread NCE exclusivity expired on October 26, 2006, so any 30-month stay blocking FDA approval of competing generics could have expired as early as April 26, 2009. The Emtriva and Truvada NCE exclusivities expired on July 2, 2008, so any 30-month stay blocking FDA approval of competing generics could have expired as early as January 2, 2011. Even in the best of circumstances for Gilead, the Orange-Book-listed patents would expire by their own terms in January 2018 as to Viread, September 2021 as to Emtriva, and January 2024 as to Truvada.

99. Absent the unlawful No-Generics Restraints, untainted competitors in the position of BMS and Janssen would have competed against Gilead by making competing, generic-containing versions of the FDCs as soon as generic TDF was available, regardless of whether generic FTC was also

available. The HHS and the WHO have concluded that a very closely related drug, lamuvidine (3TC), may be substituted for FTC, and vice-versa, when used for HIV treatment. *See, e.g.*, HHS, "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV" at F-1, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf; WHO, "Technical Update on Treatment Optimization -- Pharmacological Equivalence and Clinical Interchangeability of Lamivudine and Emtricitabine: A Review of Current Literature," https://apps.who.int/iris/bitstream/handle/10665/70936/9789241503815_eng.pdf?sequence=1.

100. Generic 3TC became available in 2012. As described in detail below, generic TDF became available in December 2017 and, absent Defendants' unlawful conduct, would have become available much earlier than that. Thus, untainted competitors in the position of BMS and Janssen would have begun making competing versions of the FDCs in December 2017 at the latest.

101. Instead of competing, each of BMS and Janssen helped Gilead protect its drugs from generic competition. In exchange, they each shared in the supracompetitive profits that the impairment of competition made possible.

102. Recognizing these anticompetitive schemes, an industry analyst invoked the term "life-cycle management," a euphemism for a scheme designed to extend an older product's market exclusivity beyond its patent term. In impairing generic competition, the schemes provided Gilead "a very neat get-out-of-jail card." Seeking Alpha, "Johnson & Johnson / Gilead Deal Could Yield More Combinations in HIV," https://seekingalpha.com/article/277464-johnson-and-johnson-gilead-deal-could-yield-more-combinations-in-hiv.

103. Gilead and Janssen renewed and extended the unlawful No-Generics Restraints when Gilead reformulated many of the FDCs to include TAF rather than TDF. And when Janssen and BMS had standalone products that faced imminent generic competition, Gilead assisted them by creating more FDCs, this time with Gilead providing No-Generics Restraints.

A. Unlawful No-Generics Restraints: Gilead and BMS

104. In December 2004 Gilead and BMS entered into an agreement to develop and commercialize a three-active-pharmaceutical-ingredient FDC comprising Gilead's TDF and FTC, and

BMS's efavirenz ("EFV"). BMS marketed EFV as a standalone product under the brand name Sustiva. At that time, Gilead expected to encounter generic competition to Viread (TDF) as early as 2009, and to Emtriva (FTC) and Truvada (TDF/FTC) as early as 2011.

105. Gilead and BMS structured the collaboration as a joint venture that operated as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC. Gilead and BMS granted royalty-free sublicenses to the joint venture for the use of the companies' respective technologies and, in return, were granted a license by the joint venture to use intellectual property that results from the collaboration. In 2006, the FDA approved the FDC, which Gilead and BMS marketed under the brand name Atripla.

106. Gilead and BMS initially shared marketing and sales efforts, jointly marketing the product in the United States from July 2006 through 2010. In 2011, except for a limited number of activities that were jointly managed, the parties stopped coordinating detailing and promotional activities.

107. A Joint Pricing Committee, comprising representatives of Gilead and BMS, determined the selling price of Atripla. In 2017 (before generic entry for Sustiva), the price for a 30-day supply of Truvada was approximately $1,600; the price of Sustiva was approximately $1,010; and the price of Atripla was approximately $2,600.

108. The economic interests of the joint venture held by Gilead and BMS (including share of revenues and out-of-pocket expenses) were based on the portion of the net selling price of Atripla attributable to Sustiva and Truvada.

109. The Gilead/BMS agreement provided that BMS would supply its EFV exclusively to the Gilead/BMS joint venture for use in an FDC with Gilead's TDF and FTC. Under the agreement, BMS was only permitted to develop, manufacture and commercialize FDCs "other than the Combination Product," that is, an FDC comprising brand or generic TDF, FTC, and EFV. The agreement thus prevented BMS and every other manufacturer from competing against Atripla with an FDC comprising EFV and generic TDF and/or FTC, even after Gilead's patents expired. Moreover, the agreement provided that the only way for BMS to avoid this exclusivity was to terminate Gilead's participation in the joint venture and thereby have BMS become the sole entity in the venture.

110. The conspirators provided that BMS could terminate Gilead's participation in the joint

venture if generic versions of both TDF and FTC became available. The agreement further provided, however, that if BMS elected to terminate Gilead's interest on that ground, BMS would be required to pay a substantial penalty to Gilead, comprising three years of additional royalty payments even after Gilead's patents had expired or were invalidated. The purpose and effect of the penalty provision was to dissuade BMS from terminating Gilead's participation in the joint venture even after its patents on TDF and/or FTC expired.

111. The coconspirators provided to Gilead a similar right of termination, with a similar termination-penalty provision, permitting it to terminate the joint venture if a generic version of Sustiva became available.

112. In addition, either party's terminating the joint venture would terminate the other's ability to continue making and selling Atripla. Gilead and BMS thus conspired to arrange that, regardless of whether or not one of the coconspirators terminated the agreement once generic versions of the other's composition(s) became available, purchasers would never benefit from a marketplace in which two versions of the Atripla FDC compete against each other. If neither party terminated the agreement, both would continue to be bound by the exclusivity provision and could not make a competing *generic*-composition-based version of the FDC; if a party did terminate, then the other would no longer have access to the continuing party's composition(s) and could no longer make a version of Atripla.

113. When Gilead and BMS entered into their No-Generics Restraint in 2004, Gilead expected to encounter competition from generic TDF and generic TDF/FTC as early as 2009 and 2011, respectively. The principal patents that protected BMS's EFV, however, were not scheduled to expire until 2018. Although it was possible that EFV would also encounter generic competition before its patents' scheduled expiration dates, Gilead's combining its TDF/FTC with EFV substantially increased the probability that it could shield those products from generic competition.

114. As contemplated by the coconspirators' No-Generics scheme, Gilead cannibalized TDF and/or FTC sales, encouraging doctors to switch their prescribing from those products to Atripla. As described in detail below (see Section VII(D)(1)), this cannibalizing had significant anticompetitive effects.

115. When generic TDF became available, purchasers and patients should have benefitted

because an untainted competitor in BMS's position would market a competing version of the FDC, with Gilead selling the original version of Atripla, and the untainted competitor selling an FDC comprising generic TDF, generic FTC (once it becomes available), and EFV. The combined price of those three products would plummet due to competition that should have ensued with the availability of generic TDF. The Gilead/BMS noncompete scheme prevents purchasers from obtaining those competitive benefits.

116. Absent the No-Generics Restraint, moreover, an untainted competitor in BMS's position would have challenged Gilead's patents and entered the market with a competing FDC even before the expiration of the FTC patents in 2021. The NCE exclusivity protecting Atripla expired on July 2, 2008. Assuming that BMS were subject to that exclusivity, an untainted competitor in its position would have challenged Gilead's patents one year before expiration of the NCE exclusivity. If Gilead timely sued BMS for patent infringement, an untainted competitor in its position would have entered the market as early as the expiration of the 30-month stay in January 2011, on a date to be determined by the jury.

117. Gilead and BMS broadened the scope of their unlawful collusion to include protecting from imminent generic competition a BMS product, atazanavir sulfate ("ATV"). ATV is a third agent—a protease inhibitor—that BMS markets as Reyataz. Just as the scheme used some of BMS's patents to protect Gilead's products from generic competition, so the conspirators also used some Gilead patents to protect BMS's ATV from generic competition. Gilead provided an exclusive license to BMS—exclusive even as to Gilead—to use Gilead's then-investigational new drug cobicistat (COBI) in combination with BMS's ATV.

118. On February 17, 2010, BMS received notice that generic manufacturer Teva Pharmaceuticals had submitted an ANDA with a Paragraph IV certification that the patents purportedly covering BMS's ATV were invalid and not infringed. BMS could expect to encounter generic competition to ATV (Reyataz) as early as August 17, 2012.

119. After BMS received notice of that challenge to its ATV patents, but before the generic manufacturer could enter the market, BMS and Gilead announced a deal (on October 26, 2011) to jointly develop an FDC that would combine BMS's vulnerable ATV with Gilead's COBI. Gilead and BMS expected that, as a potential new drug, COBI's patents would extend far into the future; in fact, the latest

of them does not expire until September 3, 2029. On January 29, 2015, the FDA approved that FDC, which BMS markets as Evotaz.

120. This deal was meant to protect BMS's product, not Gilead's, from generic competition. So, the parties provided that BMS would be responsible for commercializing the FDC, and Gilead provided a No-Generics Restraint to BMS. The license from Gilead to BMS for use of COBI in the FDC is exclusive even as to Gilead, i.e., it prohibits Gilead from commercializing its own FDC that contains a generic version of ATV. Gilead also expressly agreed that it "shall not," without the prior written consent of BMS, "make, use, sell, have sold, offer for sale, or import" a generic version of Evotaz. Gilead is prohibited from marketing an FDC with ATV even after generic versions of it become available. In return, BMS agreed to pay Gilead royalties even if Gilead's patents on COBI have expired or are invalidated.

121. Under the agreement, BMS sets the price of the FDC for sales in the United States and pays a royalty to Gilead based on sales. The agreement, including the No-Generics Restraint and obligation to pay royalties, terminates after the expiration of the last of Gilead's patents providing exclusivity for COBI.

122. As with these Defendants' prior agreement regarding Atripla, their Evotaz agreement provided for post-patent-expiration royalty payments. BMS undertook to continue paying royalties to Gilead in certain circumstances even if the COBI patents were invalidated or found to be unenforceable. Such agreements to continue paying royalties after a patent is no longer effective are per se unlawful. And they are plainly anticompetitive, especially in the circumstances here. The provision dampened the incentive for BMS to compete against Gilead by trying to invalidate the COBI patents (or to partner with a generic manufacturer that would try to invalidate them) because BMS would continue to be bound to pay the royalties. It also functioned as another means for BMS to pay Gilead for granting the No-Generics Restraint.

123. As contemplated by the No-Generics scheme between BMS and Gilead with respect to ATV, BMS cannibalized the sales of Reyataz, encouraging doctors to switch their prescribing from Reyataz to Evotaz.

124. Generic ATV became available in the United States in December 2017. At that time,

purchasers and patients should have benefitted because: (1) doctors and patients could use generic ATV in combination with Gilead's COBI or another booster, such as generic RTV; and (2) an untainted competitor in Gilead's position would have competed with BMS by marketing an FDC comprising generic ATV and COBI. The combined price of those products would have plummeted due to competition that should have ensued with the availability of generic ATV. The BMS/Gilead No-Generics Restraint was intended to prevent, and did in fact prevent, purchasers from obtaining those competitive benefits.

125. Absent the No-Generics Restraint, an untainted competitor in Gilead's position would have competed with an FDC containing COBI and generic ATV as soon as possible, and it would have done so by December 2017. Under the unlawful No-Generics Restraint, however, drug purchasers will continue to be deprived of a substitutable version of Evotaz until September 2029.

126. Gilead began in August 2011 to market an FDC, Complera (see Section VII(C)) below), and began in August 2012 to market another FDC, Stribild (see Section VII(A) above), that compete against Atripla. Gilead thereafter concentrated its marketing efforts in promoting those products rather than Atripla. And when Gilead began developing its line of TAF-based FDCs to replace the TDF-based FDCs, it did not amend the joint venture agreement with BMS to provide for the parties to commercialize a TAF-based successor to Atripla. Nor did Gilead file an application for an NDA for such a TAF-based successor product to Atripla.

127. The BMS/Gilead No-Generics Restraint with respect to Atripla prohibited BMS from making a *generic* version of Atripla when generic TDF and generic FTC became available, but did *not* prohibit BMS from making a *comparable* version comprising generic TDF, 3TC (instead of Gilead's FTC), and EFV. When generic TDF became available, BMS licensed Mylan Pharmaceuticals to produce that comparable version, which the FDA approved in February 2018. Mylan sells the generic TDF/3TC/EFV version of the product at a 40% discount to the price of branded Atripla.

128. Gilead recently terminated BMS's participation in the Atripla joint venture, triggering Gilead's obligation to make the penalty payments described above.

B. Unlawful No-Generics Restraints: Gilead and Janssen

129. On July 16, 2009, Gilead and Janssen entered into a collaboration agreement to develop and commercialize an FDC whose active pharmaceutical ingredients would be those of Gilead's Truvada (TDF/FTC) and Janssen's rilpivirine ("RPV").

130. Gilead submitted an NDA for the product on February 10, 2011. On August 10, 2011, the FDA approved the NDA for Complera, the FDC containing TDF/FTC/RPV.

131. The FDA approved Janssen's Edurant, whose only active pharmaceutical ingredient is RPV, on May 20, 2011.

132. Under the parties' agreement, with amendments through 2014, Janssen granted to Gilead a No-Generics Restraint for use of RPV in an FDC comprising TDF/FTC/RPV. Janssen expressly agreed that it "shall not," without the prior written consent of Gilead, "make, use, sell, have sold, offer for sale, or import" an FDC comprising generic TDF, generic FTC, and RPV. The agreement also prohibits Janssen from selling any "Other Combination Product" comparable to TDF/FTC/RPV, which precludes Janssen from selling a product made with generic TDF, 3TC (rather than FTC), and RPV.

133. The agreement provides that Gilead is responsible for manufacturing Complera and distributing and commercializing it in the United States as well as in much of the rest of the world. Janssen has the right to distribute it in other regions, including Japan and Russia.

134. Under the agreement, Gilead sets the price of Complera and the parties share revenues based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. The coconspirators agreed that in the United States the selling price of Complera would be the combined prices of Truvada (TDF/FTC) and Edurant (RPV) when sold separately. Gilead purchases RPV from Janssen for use in Complera at approximately the market price of RPV, less a specified percentage of up to 30%.

135. Janssen could not terminate the agreement until after the expiration of the last-to-expire patent for RPV.

136. Through 2011, Gilead reimbursed Janssen approximately $100 million in research and development expenses, which was the maximum amount allowed under the agreement.

137. When Gilead and Janssen entered into their No-Generics Restraint in 2009, Gilead—

which had recently sued Teva in connection with Teva's first-to-file ANDA for Truvada—expected to encounter generic competition as early as May 2011, the end of Teva's 30-month stay. The principal patents that protected RPV, however, were not scheduled to expire until dates ranging from 2019 to 2025.

138. As contemplated by the No-Generics scheme, Gilead cannibalized TDF and/or FTC sales, encouraging doctors to switch their patients from those products to Complera. Defendants had unlawfully used the No-Generics Restraint to protect Complera from competition.

139. As with Gilead's prior agreement with BMS regarding Atripla, the Gilead/Janssen agreement provided for post-patent-expiration royalty payments in certain circumstances. Gilead undertook to continue paying royalties to Janssen under the agreement even if the RPV patents were invalidated or found to be unenforceable. For the reasons stated in detail above, such agreements to continue paying royalties after a patent is no longer effective, especially in the circumstances here, are per se unlawful and anticompetitive.

140. On December 23, 2014, Gilead and Janssen executed a restated and amended agreement. The restated agreement expanded the parties' collaboration to include another FDC, which contains TAF (instead of TDF), FTC, and Janssen's RPV. The FDA subsequently approved that product, marketed as Odefsey, on March 1, 2016.

141. The restated agreement also confirmed that the license from Janssen to Gilead was "exclusive" even as to Janssen, i.e., it prohibits Janssen from commercializing its own FDC that contains either (1) generic versions of TDF and FTC and its own RPV or (2) generic versions of TAF and FTC and its own RPV; only Gilead has the rights to FDCs with those ingredients, even after generic versions of TDF, FTC and/or TAF become available. And again, the restated agreement further prohibits Janssen from marketing any comparable product, including one made with TAF (or TDF), 3TC (rather than FTC), and RPV.

142. Gilead is responsible for manufacturing Odefsey and has the lead role in registration, distribution, and commercialization of it in the United States. Gilead sets the price of Odefsey, and the parties share revenues based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. Gilead continues to retain a specified percentage of Janssen's share

of revenues, up to 30%.

143. The agreement, including the No-Generics Restraint and the obligation to pay royalties, expires on a product-by-product basis, at the later of (1) the expiration of the last of Janssen's patents providing exclusivity for the product or (2) the ten-year anniversary of marketing the product (a post-patent-expiration royalty provision).

144. By the time the FDA approved Odefsey for sale in March 2016, the scheduled expiration of Gilead's patents on TDF was less than 22 months away. As alleged in detail below (see Section VII(F)), Gilead used anticompetitive tactics—including making standalone TAF less safe—to drive patients to Odefsey, which the unlawful No-Generics Restraint protects from competition until March 2026.

145. When generic versions of TDF became available in 2017, purchasers and patients should have benefitted because an untainted competitor in Janssen's position would have competed with Gilead by marketing a competing version of Complera comprising generic TDF, 3TC, and RPV. The combined price of those products would have plummeted due to the competition that should have ensued with the availability of generic TDF. The Gilead/Janssen No-Generics Restraint prevented purchasers from obtaining those competitive benefits.

146. Moreover, absent the No-Generics Restraint, an untainted competitor in Janssen's position would have offered a competing product long before December 2017. Such a competitor would have challenged Gilead's patents. No NCE exclusivity applicable to Complera would have barred Janssen from timely seeking FDA approval for a competing FDC because Janssen controlled the NCE exclusivity. The only NCE-protected ingredient in Complera at the time of its approval was Janssen's RPV. And Janssen, not Gilead, owns the patents covering an FDC comprising TDF/FTC/RPV.

147. Accordingly, an untainted competitor in Janssen's position would have submitted its own application for a product containing TDF/FTC/RPV as early as August 2011, and any 30-month stay would have expired in February 2014. Thus, an untainted competitor in Janssen's position would have competed against Gilead with an FDC comprising RPV and generic versions of TDF and FTC as early as February 2014, on a date to be determined by the jury.

148. But the unlawful No-Generics Restraint resulted in Janssen's agreeing not to compete

until at least December 9, 2025, when the No-Generics Restraint expires.

149. Likewise, absent the No-Generics Restraint, an untainted competitor in Janssen's position would have produced and marketed a substitutable version of Odefsey as soon as possible. The NCE exclusivity that attached to TAF, and that protects Odefsey, does not expire until November 5, 2020. But an untainted competitor in Janssen's position would have obtained from Gilead a contractual waiver of that exclusivity (Janssen's leverage to do so is illustrated by, among other things, its having obtained co-ownership of the patents on an FDC comprising TAF/FTC/RPV). Thus, an untainted competitor in Janssen's position would have submitted its own application for a product containing RPV, generic TAF, and generic FTC as soon as the FDA approved the NDA for Odefsey. After waiting out the 30-month stay, such a competitor would have entered the market as early as September 2018.

150. In addition to their unlawful No-Generics Restraint involving RPV, Gilead and Janssen entered into mutual No-Generics promises involving Janssen's product, darunavir ("DRV"), which Janssen markets as Prezista. The agreements concerning DRV amount to a mutual nonaggression pact in which both parties could have made the FDC with generic versions of the other's compositions, but both agreed not to do so even after the relevant patents expired.

151. In October 2010, a year after the announcement of the Complera deal, Janssen received notice that generic manufacturer Mylan Pharmaceuticals had submitted an ANDA with a Paragraph IV certification that the patents purportedly covering Janssen's Prezista (DRV) were invalid and not infringed. Janssen could expect to encounter generic competition to DRV as early as April 2013.

152. On June 28, 2011—less than nine months after receiving Mylan's notice of intention to challenge the Prezista patents—Janssen and Gilead announced a tentative deal to jointly develop an FDC that would combine Janssen's vulnerable Prezista (DRV) with Gilead's then-investigational new drug cobicistat (COBI). Gilead and Janssen expected that, as a potential new drug, COBI's patents would extend far into the future; in fact, the latest of them does not expire until September 3, 2029. The FDA ultimately approved the DRV/COBI FDC on January 29, 2015, and Janssen now markets the product as "Prezcobix."

153. Gilead and Janssen, however, had made a *definitive* agreement as to Prezcobix subject to reaching an even broader deal involving DRV. Their finalizing a Prezcobix deal was expressly

contingent on concluding a further agreement to coformulate Janssen's DRV with Gilead's TAF, FTC, and COBI. The FDA ultimately approved that product on July 17, 2018, and Janssen now markets it as "Symtuza."

154. Without *mutual* No-Generics Restraints with respect to Symtuza, both Gilead and Janssen were vulnerable to generic-composition-based competition from the other. Janssen's DRV patents are weak and can easily be designed around (see Section XII below). Thus, absent Gilead's giving a No-Generics Restraint to Janssen, an untainted competitor in Gilead's position would begin in 2021 (at the latest) to market a competing version of Symtuza comprising generic DRV and Gilead's TAF, FTC, and COBI.

155. On the other hand, absent Janssen's giving a No-Generics Restraint to Gilead, Janssen could have begun in July 2018 marketing an FDC that would compete with Symtuza, comprising DRV and generic RTV. Patients could take that DRV/generic RTV pill together with an FDC comprising generic TDF/3TC. Janssen could also begin competing in May 2023 with an additional comparable FDC, comprising generic TAF, generic 3TC, generic RTV, and DRV.

156. Rather than face the competition to which consumers are entitled under the antitrust laws, Gilead and Janssen entered into their mutual nonaggression pact in which each provided a No-Generics Restraint to the other. Janssen expressly agreed with respect to DRV, just as it had with respect to RPV, that it "shall not," without the prior written consent of Gilead, "make, have made, use, sell, have sold, offer for sale, or import" a competing version of the FDC with compositions that were either generic versions of, or comparable to, Gilead's compositions even after the relevant Gilead patents have expired. Likewise, Gilead agreed that it would not produce a competing FDC comprising generic DRV and Gilead's TAF, FTC, and COBI, even after Janssen's patents on DRV expired.

157. Gilead and Janssen entered into the Symtuza deal on December 29, 2014. The same day, and in the same document, Gilead and Janssen finalized their agreement regarding Prezcobix. Also, on the same day, Gilead and Janssen amended their Complera agreement to include Odefsey. All three deals—for Complera/Odefsey, Prezcobix, and Symtuza—are part of a single conspiracy in which both Janssen and Gilead unlawfully refrain from competing against the other's vulnerable-to-competition compositions, even after the relevant patents expire.

158. The agreement regarding Prezcobix and Symtuza provides that Janssen is responsible for marketing the products in the United States. The agreement also provides that: (1) Janssen sets the price of Prezcobix and Symtuza; (2) the price will be the combined price of each of the separate compositions; (3) the parties split the revenues based on the ratio of the net selling prices of the party's component(s); and (4) the agreement, including the No-Generics Restraints, terminates at the later of the expiration of the last of either party's patents providing exclusivity for the product or the ten-year anniversary of marketing the product.

159. The agreement regarding Symtuza contained a post-patent-expiration royalty provision running in favor of Janssen, and the agreement regarding Prezcobix contained one running in favor of Gilead. Both provisions required the payment of royalties in certain circumstances even if patents covering the drugs expired or were invalidated.

160. As contemplated by the No-Generics scheme, Janssen began in the first quarter of 2015 to cannibalize the sales of Prezista, encouraging doctors to switch their prescribing from Prezista to Prezcobix and, later, to Symtuza. As of 2017, Janssen had succeeded in shifting at least 40% of Prezista prescriptions to Prezcobix.

161. After generic TDF became available (December 2017), generic RTV became available (March 2018), and the FDA approved Symtuza (July 2018), purchasers and patients should have benefitted because an untainted competitor in Janssen's position would have competed with Symtuza by marketing an FDC comprising DRV and generic RTV, which patients could take together with a pill comprising generic TDF/3TC. Alternatively, patients could have taken the DRV/generic RTV pill together with Descovy (TAF/FTC). The combined price of those products would have plummeted due to competition that should have ensued with the availability of generic TDF and generic RTV. The Janssen/Gilead No-Generics Restraints have prevented purchasers from obtaining those competitive benefits.

162. Absent the No-Generics Restraint, an untainted competitor in Gilead's position would have competed with a substitutable version of Prezcobix as soon as possible. No unexpired NCE exclusivity protected Prezcobix from competition from Gilead. An untainted competitor in Gilead's position would have filed an application for such a product by January 2015, and, after waiting out the

30-month stay, would have begun marketing it by July 2017. By that date, the only non-expired Orange Book patents owned by Janssen were those covering certain pseudopolymorphic forms of DRV, which expire on February 16, 2024 and December 26, 2026 (assuming no pediatric exclusivity is later awarded). Those patents are invalid and can easily be designed around.

163. Absent this Court's intervention, drug purchasers will continue to be deprived of a substitutable version of Prezcobix until at least January 2025 when the parties' unlawful No-Generics Restraint with respect to Prezcobix expires.

164. Unless enjoined by this Court, Gilead and Janssen's unlawful No-Generics Restraints will have additional anticompetitive effects when generic versions of the following become available: FTC, DRV, TAF, or COBI. Unrestrained by the unlawful No-Generics Restraints, an untainted competitor in Janssen's position would produce and market FDCs that are substitutable for, or comparable to, Complera, Odefsey, and Symtuza. Unrestrained by the unlawful No-Generics Restraints, an untainted competitor in Gilead's position would produce and market FDCs that are substitutable for, or comparable to, Prezcobix and Symtuza. These additional anticompetitive effects, and the need for injunctive relief to avoid them, are discussed below in Section XII.

C. The No-Generics Restraints Contain Virtually Identical Terms

165. The No-Generics Restraints are central to Gilead's monopolization scheme to obtain and maintain monopoly power. Comparing the terms of Gilead's agreements with its coconspirators reveals that most of the No-Generics Restraints use virtually identical language, which is indicative of Gilead's deliberate strategy to suppress competition and maintain its monopoly. For example, the conspirators use virtually the same language to effect the No-Generics Restraints in Gilead's agreements with Janssen for Complera in July 2009, with Janssen for Prezcobix in June 2011, and with BMS for Evotaz in October 2011. The mutual non-aggression pacts between Gilead and Janssen regarding Odefsey and Symtuza signed in December 2014 also feature the very same No-Generics Restraints. While the 2004 Gilead/BMS agreement for Atripla uses different language, it is unmistakably a No-Generics Restraint.

166. Gilead's agreements with its coconspirators also feature nearly identical provisions requiring royalty payments even if the parties' patents have expired or are invalidated in a legal

proceeding. These provisions are also part of Gilead's scheme to suppress competition. The first post-patent-expiration royalty provision was included in Gilead and BMS's 2004 agreement regarding Atripla. Then another appeared in Gilead's agreement with Japan Tobacco regarding EVG in 2005. Another appeared in the 2009 Gilead/Janssen Complera agreement. Nearly identical language to that in the EVG agreement then appeared in Gilead's agreement with Janssen for Prezcobix and with BMS for Evotaz, both signed in 2011. Gilead and Janssen's agreements regarding Odefsey and Symtuza signed in December 2014 feature the same post-patent expiration royalty provisions.

167. Most of these agreements were publicly filed or described in filings by Gilead with the Securities and Exchange Commission, including the 2004 agreement with BMS, the 2005 agreement with Japan Tobacco, and the 2009 agreement with Janssen. Before entering into agreements with Gilead, BMS and Janssen scrutinized the publicly available Gilead agreements with competitors. Thus, when entering into one or more of their unlawful agreements with Gilead, both BMS and Janssen were aware that Gilead had used No-Generics Restraints and post-patent-expiration royalty provisions with other competitors, including in nearly identical language.

D. Increased Prices and Reduced Innovation

168. Gilead and its coconspirators' use of No-Generics Restraints, as alleged above, has had myriad and very substantial anticompetitive effects.

1. The No-Generics Restraints increased prices.

169. For each of BMS and Janssen, agreeing not to market a competing, generic-based FDC after Gilead's patents expired made no business sense unless: (a) the No-Generics Restraints impaired competition; and (b) Gilead allowed the coconspirators to share in the supracompetitive profits that the impairment produced. Unless the restraints generated supracompetitive profits that the coconspirators got to share in, their economic interests would have been to market generic-drug-based FDCs as soon as possible.

170. The agreements provided several means for Gilead's coconspirators to share in the supracompetitive profits that the unlawful No-Generics Restraints generated. The restraints substantially

increased Gilead's incentive to move sales from TDF and/or FTC to the TDF-based FDCs. Those switched sales resulted in the coconspirators' selling significantly more of their third agents than they otherwise would have. The restraints also significantly dampened competition in the cART Market, generating higher prices for the FDCs and therefore for the conspirators' third agents. And Gilead directly paid the coconspirators through the royalty and other provisions of the joint-development agreements. For example, Gilead paid Janssen a $100 million fee under their original agreement.

171. Likewise, the No-Generics Restraints made no economic sense for Gilead unless they impaired competition. Those restraints did not benefit Gilead in the period of time before it lost statutory exclusivity (exclusivity from its patents or from NCE exclusivity); during that time Gilead already had exclusivity and no one could make a competing FDC that contained Gilead's exclusivity-protected products. Gilead benefitted from the No-Generics Restraints *only* during the period *after* its statutory exclusivity expired. And that is precisely the period in which Gilead could not legitimately obtain private, contractual relief from competition.

172. Gilead and the coconspirators win. Drug purchasers lose, in three principal ways (even more ways are detailed below): Defendants' anticompetitive conduct (1) artificially reduced the prescription base of Gilead's Viread (TDF), Emtriva (FTC), and/or Truvada (TDF/FTC) available for automatic generic substitution, much of that prescription base having been cannibalized to the TDF-based FDCs; (2) robbed purchasers of competing FDCs made with generic or comparable versions of those products; and (3) impaired price competition in the cART Market.

173. Defendants' anticompetitive schemes exploited a substantial imperfection in the prescription pharmaceuticals marketplace. Doctors who have switched patients from one HIV product or HIV drug regimen to another are very reluctant to switch patients back to the original product or regimen, even if a generic version of the original product becomes available at a much lower price. Switching costs (e.g., the need for another visit to the doctor for a new prescription) impair a move back to the original product. And pharmaceuticals are "experience" goods that consumers and physicians are hesitant to change if they are working.

174. These and other factors make prescription pharmaceutical sales, especially of HIV drugs, "sticky"—doctors and patients are much less likely than in fully competitive markets to switch

prescriptions back to the original product. Brand manufacturers can impair imminent generic competition by using their sales force to cannibalize the sales of the brand drug—to move the prescription base from the original product to one that does not face imminent generic competition—before the generic enters the market. Once the generic becomes available, doctors might in theory begin prescribing it rather than the new brand product. But having switched the patient from the old to the new product, the "stickiness" in these markets means that doctors are unlikely to change the patient's regimen back again. The timing is critical. If the new product beats the generic onto the market, it makes as much as 10 times more sales than it otherwise would have made.

175. Gilead's No-Generics Restraint schemes exploited this market defect. Gilead and its coconspirators switched much of the prescription base from TDF and/or FTC to the TDF-based FDCs (Atripla, Stribild, and Complera). This scheme fundamentally impaired competition. Generic versions of TDF and/or FTC are not AB-rated to, and therefore not automatically substitutable for, the TDF-based FDCs. Automatic substitution at the pharmacy counter is a generic product's most efficient means of competing. Gilead and the coconspirators' switching of the prescription base from TDF and/or FTC to the TDF-based FDCs thus impaired the only effective means for standalone generic products to compete.

176. Moreover, the No-Generics Restraints—express non-competition pacts—prevent Gilead's coconspirators from making competing versions of the FDCs with generic or comparable versions of TDF and/or FTC. The restraints thus ensured that Gilead and the coconspirators would not compete their supracompetitive profits back to consumers through price competition on sales of the FDC.

177. Depending on the competing manufacturer's regulatory strategy, generic-drug-containing versions of the FDCs could be approved under the ANDA process of Section 505(j) of the FD&C Act (21 U.S.C. § 355(j)), and the resulting product would be automatically substitutable at the pharmacy counter for the original version of the FDC. Or the competing manufacturer could gain approval under Section 505(b)(2) of the FD&C Act (21 U.S.C. § 355(b)(2)). Under either regulatory strategy, the competing generic-drug-containing versions of the FDCs would sell at very substantial discounts to the price of the original FDC.

178. Absent the No-Generics Restraints' anticompetitive effects, untainted competitors in the position of BMS and Janssen would have begun making the FDC with generic or comparable versions of

TDF and/or FTC as soon as they became available. Making the FDCs with low-cost generic ingredients would have resulted in those manufacturers' lowering the price of the FDC and thereby increasing sales, while still maintaining at least the same profit margin.

179. The No-Generics Restraints thus artificially prop up the prices of those standalone components, of the FDCs, and of other products in the cART Market that Gilead and its coconspirators have unlawfully monopolized. FDCs that are originally formulated with a generic composition and a brand composition sell for about 40% - 50% less than the combined prices of the brand versions of the two compositions. As a result of the No-Generics Restraints, the Defendants' FDCs continue to sell for about 100% of the combined prices of the brand components, even after the relevant patents expire and generic components are available.

180. Similarly, when an FDC made with comparable (but not substitutable) compositions enters the market and competes against the incumbent FDC, the competitor's price is about 40% - 50% less than the incumbent's price. As a result of the No-Generics Restraints, however, comparable versions of all but one of the affected FDCs here (Atripla being the exception) are not available. For example, the Gilead/Janssen FDC Complera (TDF/FTC/RPV) sells for $35,000 for a yearly course of treatment. A comparable version made with generic or comparable versions of Gilead's components (generic TDF and generic 3TC) and Janssen's RPV would sell for half that amount.

181. Gilead, Janssen, and BMS moved sales from their standalone products to the FDCs that they had unlawfully protected with No-Generics Restraints. Those switches ensured that drug purchasers would not get the typical 80% price discounts on generic versions of the standalone products. And the No-Generics Restraints ensured that purchasers would not get those price discounts indirectly through lower pricing of generic-drug-based versions of the FDCs.

182. The No-Generics Restraints also delayed the dates that generic drugs became available. The restraints anticompetitively reduced the incentives of generic manufacturers to challenge the patents protecting the FDCs (including those protecting the individual components). Absent the No-Generics Restraints, a generic manufacturer could assemble a substitutable version of the FDC by: (1) successfully challenging the patents on one of the coconspirator's compositions and obtaining a license from the other coconspirator to use its product in the FDC; or (2) successfully challenging the patents on both of the

coconspirators' compositions. The No-Generics Restraints eliminated the first possibility, forcing generic manufacturers into an all-or-nothing venture to succeed against the patents on all of the compositions. The No-Generics Restraints thus created formidable entry barriers to those seeking to compete against the FDCs.

183. The No-Generics Restraints also incapacitated the manufacturers that were best situated to challenge Gilead's patents—its coconspirators. Absent the No-Generics Restraints, untainted competitors in the position of BMS and Janssen (either directly themselves or through a collaboration with a generic manufacturer) would have challenged Gilead's patents in order to make generic-drug-containing versions of the FDCs. The No-Generics Restraints sidelined the competitors best able to challenge the patents. The same is true when Gilead granted No-Generics Restraints covering the coconspirators' vulnerable drugs.

184. Absent the No-Generics Restraints, untainted competitors in the position of BMS and Janssen would have made competing FDCs with generic components even if these companies typically focus on branded pharmaceuticals. Making FDCs with generic components is entirely consistent with BMS and Janssen's branded business model. Janssen, for example, markets a diabetes medication, Invokamet XR, which is an FDC of Janssen's branded canagliflozin and generic metformin hydrochloride. BMS was also perfectly willing to partner with generic-drug manufacturer Mylan to make a comparable version of Atripla using generic TDF and generic 3TC.

185. Brand pharmaceutical companies also challenge their competitors' patents when necessary to pursue business opportunities, as demonstrated by a recent wave of litigation under the Biologics Price Competition and Innovation Act of 2009. Large pharmaceutical companies including Pfizer, Merck, and Amgen developed biosimilar versions of branded biologic drugs and have aggressively litigated challenges to patents keeping their biosimilars off the market. Companies like Janssen and BMS also regularly chanllenge their competitors' patents when it makes business sense to do so. For example, in May 2008, Janssen subsidiary Centocor, Inc. filed suit against Genentech, Inc. seeking to invalidate Genentech's patents in order to avoid paying royalties on sales of Remicade.

186. Absent the No-Generics Restraints, untainted competitors in the position of BMS and Janssen would have challenged Gilead's patents prior to expiration because it makes business sense. The

cost of litigating similar patent infringement actions is approximately $6 to $10 million from complaint to verdict. American Intellectual Property Lawyers Association, 2013 Report of the Economic Survey 34 (2013). These minimal costs cannot outweigh the substantial gains that Janssen would have realized by launching into a $660 million market for Complera four years before the expiration of Gilead's patents. BMS similarly could have entered the market as early as 2011, when annual Atripla sales had reached $2 billion.

187. As described in Section XII below, Defendants are repeating this anticompetitive cycle again with respect to the TAF-based FDCs. The revised No-Generic Restraints prevent Janssen from making generic-TAF-containing versions of the TAF-based FDCs. Those amended unlawful restraints extend to as late as 2032.

2. The No-Generics Restraints reduced innovation.

188. Among the most pernicious of the unlawful pacts' anticompetitive consequences are their devastating effects on innovation. In this vitally important market, where innovation is necessary to save lives and allow them to flourish, the No-Generics Restraints directly prohibit competitors from developing and marketing more than two dozen identifiable FDCs. And rather than spurring innovation, the No-Generics Restraints caused Gilead to intentionally delay developing products and deliberately degrade the safety and efficacy of the products that it did develop.

a. Reduced innovation by Gilead's competitors

189. Reducing "pill burden" is an important goal in cART regimens. Those regimens, by definition, require patients to take multiple drugs to treat HIV, and before the development of FDCs required patients to take a separate pill for each drug in their regimens. FDCs reduced this pill burden significantly, often allowing a patient to take just a single pill once a day to effectively treat HIV.

190. Gilead and its coconspirators' No-Generics Restraints, together with the additional unlawful conduct detailed further below (see Sections VII(E)-(H)), have had a disastrous effect on innovation in this vitally important market. That unlawful conduct has suppressed innovation by Gilead's competitors, directly and expressly prohibiting them from producing and marketing FDCs that would

enhance the lives of patients on cART regimens.

191. Defendants' conduct has prevented competitors from developing dozens of specifically identifiable FDCs. Absent Defendants' unlawful conduct, *the cART Market would have nearly twice as many FDCs as are now available.*

192. Defendants' unlawful conduct has delayed or prevented the development and marketing of at least the following FDCs and other HIV drugs: genericTDF/genericFTC/RPV; genericTAF/genericFTC/RPV; TAF/FTC/COBI/genericDRV; COBI/genericDRV; genericTDF/3TC/genericCOBI/DRV; genericTDF/genericFTC/genericCOBI/DRV; genericTAF/3TC/RTV/DRV; genericTAF/genericFTC/genericCOBI/RTV; genericTAF/genericFTC/genericCOBI/genericRTV; DRV/genericRTV; genericTDF/genericFTC/EFV; COBI/genericATV; genericTDF/3TC/RPV; genericTAF/3TC/RPV; genericRTV/EVG; genericTDF/3TC/EVG; genericTAF/3TC/EVG; TDF/FTC/Dolutegravir; TDF/3TC/Dolutegravir; TAF/FTC/Dolutegravir; TAF/3TC/Dolutegravir; genericTDF/genericFTC; genericTDF/genericFTC/genericATV; TAF/FTC; TAF 10mg; generic TAF 10mg; TAF indicated for HIV treatment; generic TAF indicated for HIV treatment; generic TDF; generic FTC.

193. Unleashing this competition would have spurred competitors to innovate by creating even more and better FDCs. Defendants' conduct instead stifled that competition, to the great detriment of those living with HIV.

b. Reduced innovation by Gilead

194. Gilead and its coconspirators' conduct also dampened Gilead's own incentive to innovate. The unlawful conduct substantially diminished the competitive pressures that force manufacturers to introduce better products sooner. The No-Generics Restraints shielded Gilead from those competitive pressures, with predictable consequences: Gilead produced markedly inferior products and chose to delay introducing improved products until it had wrung as much profit as possible out of the substandard ones. The No-Generics Restraints prevented the market from forcing Gilead to do what suppliers in competitive markets must do in order to thrive—market better products as soon as possible.

195. Defendants' No-Generics Restraints allowed Gilead to make profits not principally by

innovating, but by impairing competition. This reality is seen in two stark facts: (1) from 2004 through 2017 Gilead generated more than $59 billion in revenue from its HIV franchise in the United States; (2) in that same timeframe, Gilead developed exactly one new pharmaceutical compound—COBI. And even COBI did not debut until 2014, is merely a booster, and has a close substitute in RTV. Gilead has one of the worst innovation track records of any major pharmaceutical manufacturer anywhere in the world. Rather than innovate, Gilead used the No-Generics Restraints and other anticompetitive tactics to continually wring profits out of the two compositions—TDF and TAF—that it developed more than 15 years ago.

196. A few examples demonstrate that the anticompetitive schemes created perverse incentives for Gilead, with grievous consequences for cART patients.

i. Delaying TAF in 2003-2004

197. One of the most severe anticompetitive effects of the No-Generics Restraints was that they created the incentive and ability for Gilead to delay introducing the improved TAF products much earlier than 2015.

198. No later than 2003–2004 Gilead faced the decision whether to make profits by marketing an improved product—TAF—or to instead make profits by using anticompetitive No-Generics Restraints to impair competition and thereby allow Gilead to reserve TAF to use as a "line extension" in the future. The No-Generics Restraints and other anticompetitive tactics allowed Gilead to choose the latter. If Gilead could relieve the competitive pressures that it would otherwise face, it could withhold TAF from the market for use only later as the foundation for a line extension, transitioning the TDF-based prescription bases to TAF-based products. That is exactly what the No-Generics Restraints allowed Gilead to do.

199. The timeline unmistakably shows that the No-Generics Restraints caused the delay in introducing TAF.

200. Gilead knew at least by 2001 that TAF created significantly less risk of side effects. Compared to TDF, far smaller doses of TAF deliver equal or greater concentrations of Tenofovir in the cells that HIV targets. A 25mg dose of TAF has the same therapeutic effect as a 300mg dose of TDF.

TAF therefore has far less risk of toxicity and side effects, especially kidney toxicity and bone-density loss.

201. TDF and TAF are two different prodrugs of Tenofovir. Gilead scientists began research on TAF—specifically as a potential avenue for reducing kidney and bone side effects—as early as 2000. Early Gilead studies in animals showed that TAF had 1,000-fold greater activity than TDF against HIV.

202. In 2002 Gilead conducted clinical trials of TAF in humans, with the explicit goal, as articulated by Gilead's senior executive, of "deliver[ing] a more potent version of tenofovir that can be taken in lower doses, resulting in better antiviral activity and fewer side effects…."

203. In 2003 Gilead reported to investors regarding the TAF clinical trials that the "[i]nitial data look promising," and that Gilead was "excited" about TAF's prospects. In January 2004 Gilead again reported to investors that the TAF results were "promising," and that it was "continuing the clinical development of [TAF] … based on favorable Phase I/II results." In March 2004 Gilead reported that "[b]ased on data from our Phase 1/2 clinical trials of [TAF], we have begun developing a Phase 2 program for the treatment of HIV infection…."

204. In May 2004 Gilead reported that the TAF clinical studies had confirmed that TAF gets higher concentrations of Tenofovir into the blood than does TDF, thus allowing the patient to take a far smaller dose, thereby significantly reducing the risk of negative side effects. Gilead told investors that "we know that doses of [TAF], which are 1/6 or 1/2 of the [TDF] dose, can give greater antiviral response. So, the theory holds that you can target and treat HIV differently using these kinds of prodrug and targeting technologies."

205. Gilead continued to praise TAF to investors through at least June 2004.

206. On October 21, 2004, however, Gilead abruptly announced that it had changed course and decided to shelve further development of TAF. The announcement attributed the decision to "an internal business review." In fact, Gilead had concluded that it could use No-Generics Restraints in FDCs to shield TDF and TDF-based products from competition and therefore could safely shelve the TAF project to use much later as part of an anti-generic strategy once competition from generic TDF was imminent.

207. On December 17, 2004, Gilead formally entered into the unlawful No-Generics Restraint with BMS for Atripla. Gilead's December 2004 Press Release noted that Gilead and BMS's joint work

on developing the project had "been ongoing throughout most of 2004." Notably, in October 2004—the same month that Gilead announced the shelving of its TAF project—the coconspirators announced favorable results from an ongoing clinical trial of Atripla.

208. This No-Generics Restraint fundamentally altered the competitive landscape that Gilead faced. It gave Gilead the means to protect TDF from prospective generic competition, even if generic manufacturers were to successfully challenge the TDF patents. Thus, it no longer made economic sense for Gilead to do what competition would otherwise have forced it to do—to bring out TAF as soon as possible in order to take sales from its rivals in the antiretroviral class. With the No-Generics Restraint in place, the economic calculus changed: Gilead could make more profits by defeating generic competition to TDF and then rolling out TAF much later as part of a line extension.

209. Gilead itself eventually made explicit the connection between the anticompetitive BMS deal and the shelving of TAF. At an investor conference in March 2011, Kevin Young, the executive vice president of Gilead's commercial operations, admitted that in 2004 Gilead "didn't bring TAF through development because at the time we were launching Truvada, launching Atripla…."

210. Gilead's patenting strategy also reveals its anticompetitive scheme. Despite having allegedly abandoned TAF research in 2004, Gilead in fact filed seven applications for patents on TAF from 2004 to 2005. Six years later, when it was finally time to prepare for the TAF-based line extension, Gilead told investors in 2010 that "a new molecule" would replace its TDF-based sales and add "a great deal of longevity" to its HIV franchise. In fact, the "new molecule" wasn't new at all—it was the TAF molecule that had been sitting on Gilead's shelf, having been held in reserve to roll out later when needed in the line extension.

211. As part of the line extension, Gilead told investors, doctors, and patients that TAF was superior to TDF. In October 2010, Gilead told investors that "you can take a lower dose [of TAF], and actually our clinical study would indicate 1/6th to 1/10th the Viread dose and you would actually get higher efficacy with less exposure." But this was not new information: Gilead's statements were based on the 2003 clinical study, not any new study or data.

212. Similarly, in March 2011 Gilead's then-COO, John Milligan, told investors that "even at low doses of 50 milligram, [TAF] is a more potent antiviral than Viread." TAF provided "lower exposure

[of Tenofovir] to the rest of the body. So, the therapeutic index goes up by about 34, which is pretty dramatic." But again, this was not new information: Gilead's statements were based on the 2003 studies.

213. And on May 3, 2011, Milligan confirmed why Gilead had sat on TAF for more than 10 years. Holding TAF in reserve to later reformulate the TDF-based FDCs would "bring quite a bit of longevity to the Gilead portfolio," securing an "important opportunity for Gilead long-term." It allowed Gilead to "have another wave of single tablets."

214. COO Milligan admitted to analysts and others in June 2011 that the plan was to transition the TDF-based franchise to a "new" TAF-based franchise. Gilead was specifically using the switch to defeat generic competition: "our ability to develop and get [the TAF-based products] onto the market prior to patent expiration will be key to us, to maintain the longevity."

215. Gilead actively and effectively used TAF's more favorable risk profile to encourage doctors to switch their prescribing from the TDF-based to the TAF-based products. Gilead consistently and aggressively presented doctors with head-to-head comparisons of TDF versus TAF with respect to kidney function and bone density. Gilead then followed the presentations with direct appeals for doctors to switch to the TAF-based products. For example, Gilead stated at a major doctors' conference that TDF "has been associated with an increased risk of [chronic kidney disease]," whereas "[d]ue to a 91% lower plasma tenofovir level, [TAF] relative to TDF has demonstrated a significantly better renal safety profile …." At another major conference Gilead told the assembled doctors that "[s]witching from TDF to TAF may be an important treatment strategy to increase bone mineral density in those at the highest fracture risk." Gilead instructed its "detailers"—the sales force that calls on individual doctors—to make the same pitch regarding the "new" TAF.

216. Gilead also used the TAF-is-superior sales message when marketing the TAF-based products directly to patients. Gilead made the same case to clinical investigators and to the FDA itself when Gilead sought approval of the TAF-based products.

217. Advising its investors of its marketing message, Gilead neatly summed it up: "if you're a new patient, start with a TAF-based single-tablet regimen, because that's going to be highly efficacious and very safe and very tolerable for long-term usage. And if you're on a Viread-based regimen, it's a great idea to convert, switch, upgrade to a TAF-based regimen as soon as possible."

218. Mr. Milligan characterized the switch of prescriptions to its TAF-based FDC, Genvoya, as the most successful launch of an HIV product in history. And he concluded that the success resulted from the "very strong medical rationale for TAF versus [TDF]," and doctors' consequent "desire to move patients from a TDF containing regimen to a TAF containing regimen."

219. The problem is that TAF was not new. As a result of the No-Generics Restraints, Gilead had been sitting on TAF for more than a decade, at enormous human cost to many HIV patients. From 2006 to 2015 tens of thousands of HIV patients using Gilead's TDF-based products unnecessarily suffered life-impairing kidney and bone side effects. Gilead itself later sponsored research that concluded that forcing patients to take TDF-based rather than TAF-based products could result in more than 16,000 excess deaths and 150,000 excess kidney, bone, and renal injuries over a nine-year period. *See Am J Manag Care.* 2018;24 (Spec. Issue No. 8): SP322-SP328.

220. In addition to causing enormous, immediate human suffering, Defendants' unlawful conduct also caused a delay in the ability of generic manufacturers and other competitors to challenge Gilead's TAF-related patents. As noted in detail above, NCE exclusivity prohibits a generic manufacturer from even filing an ANDA with respect to the branded product until a year before the end of the NCE exclusivity. Moreover, the Hatch-Waxman automatic 30-month stay does not commence until after the five-year NCE exclusivity expires. So, a generic version of an NCE-protected drug cannot realistically launch until at least 7.5 years after the brand manufacturer first receives approval of the NCE-protected drug.

221. Accordingly, Gilead's delay in marketing its TAF-based FDCs dramatically delayed the date on which generic manufacturers can challenge those products' patents. For example, the NCE exclusivity on Genvoya prohibits a generic manufacturer from filing an ANDA until November 5, 2019, one year before the expiration of the NCE exclusivity. Gilead timely sued the generic manufacturers, with the result that the Hatch-Waxman automatic 30-month stay will prevent generic entry until May 5, 2023 at the earliest.

222. If Defendants' No-Generics Restraints had not resulted in Gilead's delay in marketing TAF, these dates would have been much earlier. If Gilead had not shelved TAF development, an untainted manufacturer in its position would have begun marketing TAF and TAF-based FDCs not later

than 2007.

223. Thus, instead of the NCE protection for the TAF-based products (Vimlidy, Descovy, Genvoya, Odefsey, and Symtuza) expiring in November 2020, and the Hatch-Waxman 30-month stays expiring in May 2023, the NCE exclusivity protecting those products would have expired in November 2011, and the Hatch-Waxman 30-month stays would have expired in May 2013. Those living with HIV would already have generic versions of the TAF-based FDCs.

ii. Degrading Products

224. Gilead's delay in marketing TAF until 2015 illustrates that the No-Generics Restraints incentivized and enabled it to intentionally delay introducing any innovations. Gilead's conduct when it finally did make TAF-based products available illustrates that the pacts incentivized and enabled Gilead to actually *degrade* the safety and efficacy of its products rather than improve them. The pacts allowed Gilead to generate profits by impairing competition rather than creating the best possible products as soon as possible.

225. As set forth in detail below (see Section VII(E)), Gilead intentionally degraded Stribild. Gilead knew when seeking FDA approval of Stribild that Tenofovir in a regimen boosted with COBI increased the probability of adverse side effects. Yet Gilead refused to reduce the strength of TDF in Stribild to account for the booster. Gilead did so in order to magnify the safety differences between TDF-based Stribild and its anticipated replacement product, TAF-based Genvoya. When formulating Genvoya, Gilead *did* reduce the strength of TAF to account for the booster.

226. Similarly, as set forth in detail below (see Section VII(F)), Gilead intentionally delayed seeking FDA approval to market standalone TAF (Vemlidy), altogether withholding it from the market from November 2015 to November 2016. In addition, Gilead intentionally did not seek FDA approval to market standalone TAF in a safer milligram strength (10mg), while seeking and receiving that approval only for TAF used in Gilead's FDCs. Gilead likewise intentionally did not seek FDA approval for use of standalone TAF in the treatment of HIV (instead getting only an indication for treatment of Hepatitis B), while seeking and obtaining an HIV indication for all of the TAF-based FDCs.

227. Intentionally and substantially degrading Stribild and standalone TAF made economic

sense for Gilead only because doing so helped it to impair competition in the cART Market. The No-Generics Restraints incentivized and enabled that anticompetitive conduct. Gilead's conduct in degrading these products is discussed further below because it not only illustrates the No-Generics Restraints' anticompetitive effects on innovation, but is also itself exclusionary conduct in furtherance of Gilead's scheme to monopolize the cART Market.

E. Gilead's Unlawful Degrading of Stribild

228. As part of its scheme to move its TDF-based FDCs to TAF-based FDCs, Gilead intentionally refused to reduce the toxicity of TDF-based Stribild. Making Stribild less safe than even the other TDF products would help Gilead to later move prescriptions from TDF-based Stribild to TAF-based Genvoya.

229. Gilead knew before it ever began marketing Viread that co-administering TDF with a pharmacokinetic "booster" such as RTV very substantially increased the concentrations of Tenofovir in the patient's blood. Gilead also knew that this increased exposure to Tenofovir concomitantly increased the patient's risk of severe side effects, including kidney disorders and bone-density loss.

230. Stribild is EVG, FTC, and TDF, plus the booster COBI. Gilead's own clinical trials on Stribild showed that it was even more toxic than unboosted TDF, resulting in more adverse events and treatment discontinuations. Gilead nevertheless formulated Stribild with 300mg of TDF together with the pharmacokinetic booster COBI. This is the same dosage in which Gilead sold TDF as a standalone product, i.e., for use *without* a booster.

231. At the same time that Gilead was formulating TDF-based Stribild, Gilead was conducting Phase I studies of TAF. Gilead knew from those studies that COBI, like RTV, significantly increased the patient's exposure to Tenofovir and thereby substantially increased the risk of significant kidney and bone side effects. A Phase I TAF dosing trial showed that TAF 25mg was the optimal dose to achieve activity similar to a 300mg dose of TDF.

232. Based on that study and others, when formulating Genvoya—the TAF-based version of Stribild—Gilead significantly reduced the dosage of TAF, from 25mg for standalone TAF to only 10mg in the COBI-boosted Genvoya. Likewise, when later formulating COBI-boosted Symtuza, Gilead again

used TAF 10mg rather than TAF 25mg.

233. Despite already having the results of the TAF studies, Gilead sought FDA approval of COBI-boosted Stribild with 300mg of TDF—the equivalent of 25mg of TAF—instead of reducing the dose of TDF. Gilead intended, when the time was ripe, to transition the Stribild prescription base to Genvoya. Making Stribild even less safe than its other TDF drugs would *help* Gilead transition the prescription base from Stribild to Genvoya, which was protected by the longer No-Generics Restraint.

234. Gilead compounded the injury to Stribild purchasers by artificially raising Stribild's price. Since first marketing Stribild in 2012, Gilead had consistently taken price increases on the drug once a year, in the range of 5% to 7%. That was the product's profit-maximizing price level. In connection with the switch to TAF-based Genvoya in 2016, however, Gilead took its usual annual price increase on Stribild *plus* another mid-year price increase of an additional 7%. That increase boosted the wholesale price of a 12-month supply of Stribild to $34,686, substantially higher than the $30,930 price of Genvoya. Having withheld TAF from the market for a decade, Gilead now punished consumers who stuck with TDF-based Stribild, making them pay even higher supracompetitive prices.

235. Gilead's intentional degradation of Stribild, and raising its price above the historical and profit-maximizing level, made economic sense for Gilead only because that conduct was part of an anticompetitive scheme to impair competition. Absent a purpose and effect of impairing competition, Gilead's economic incentive would have been to produce the best possible products as soon as possible, and to sell them at the profit-maximizing price.

F. Gilead's Unlawful Degrading of Standalone TAF

236. As part of its unlawful scheme, Gilead also intentionally degraded another product—standalone TAF. From November 2015 to November 2016 Gilead made TAF available *only* as a component of its FDCs, not as a standalone product. Thus, during that critical year, when Gilead was aggressively moving prescriptions from the TDF-based products to its new line of TAF-based products, doctors could not prescribe standalone TAF together with HIV drugs manufactured by Gilead's competitors in the cART Market. Any patient who wanted TAF could get it only by buying a Gilead FDC. Gilead thus used its control over Tenofovir to impair competition from suppliers of 3TC, RTV,

substitute third agents, and substitute FDCs.

237. Even after it belatedly made standalone TAF available, Gilead sold it only in 25mg strength while making TAF available in 10mg strength when purchased as part of a Gilead FDC. When TAF is taken concurrently with a "booster" drug (such as COBI or RTV), it is safer to take only 10mg rather than 25mg of TAF. By refusing to make TAF 10mg available as a standalone product, Gilead forced the many patients who need a booster drug to buy Gilead FDCs rather than TAF plus a competing third agent.

238. Gilead achieved the same anticompetitive result by refusing to seek from the FDA approval of standalone TAF for use in the treatment of HIV. Gilead instead sought approval of the standalone drug for use only in the treatment of chronic Hepatitis B. Thus, any patients who want to use TAF in an approved regimen for treatment of HIV can obtain it only by purchasing one of Gilead's FDCs. Gilead has deprived patients of the choice of using standalone TAF as part of an FDA-approved HIV treatment together with a competing HIV drug.

1. Gilead anticompetitively withheld standalone TAF in 2015-2016.

239. Tenofovir is an essential input in a cART regimen, and Gilead has control over Tenofovir. And as described in detail above (see Section VII(D)(2)(b)), TDF carries a substantial risk of severe side effects such as kidney toxicity and bone-density loss. TAF has a significantly better side-effects profile.

240. In 2014, Gilead began applying for FDA approval for TAF-based FDCs. On November 5, 2014, Gilead filed NDA 207561 for Genvoya (TAF/FTC/EVG/COBI); on June 1, 2015 filed NDA 208351 for Odefsey (TAF/FTC/RPV); and on April 7, 2015 filed NDA 208215 for Descovy (TAF/FTC).

241. At that time, Gilead did not, however, apply for FDA approval of a standalone TAF product. Instead, Gilead intentionally delayed filing its application for that FDA approval, withholding the application until January 11, 2016. Gilead knew and intended that in intentionally delaying the application for standalone TAF by one year, the FDA would not grant approval to market standalone TAF until about a year after approving Gilead's TAF-based FDCs.

242. The FDA approved Genvoya, the TAF-based analogue to Gilead's TDF-based FDC Stribild, on November 5, 2015. Gilead then immediately began marketing Genvoya and cannibalizing the

sales of Stribild (as well as Viread, Truvada, and Atripla) to Genvoya.

243. The FDA approved Odefsey, the TAF-based analogue to Gilead's TDF-based FDC Complera, on March 1, 2016. Gilead then immediately began marketing Odefsey and cannibalizing the sales of Complera (as well as Viread, Truvada, and Atripla) to Odefsey.

244. The FDA approved Descovy, the TAF-based analogue to Gilead's TDF-based FDC Truvada, on April 4, 2016. Gilead then immediately began marketing Descovy and cannibalizing the sales of Truvada and Viread to Descovy.

245. As Gilead knew and intended, the FDA did not approve Vemlidy, Gilead's TAF standalone pill, until November 10, 2016, just over a year after approving Genvoya. By then Gilead had succeeded in converting more than half of all Stribild prescriptions to Genvoya, and of Complera prescriptions to Odefsey. That pattern of rapid cannibalization continued through 2018.

246. Gilead intentionally withheld standalone TAF from the market in the critical timeframe of November 2015 to November 2016. Had Gilead not done so, doctors and patients could have begun using standalone TAF in combination with other HIV drugs marketed by Gilead's competitors, rather than getting switched from their existing regimens to a Gilead TAF-based FDC. For example, widely used prescribing guidelines suggest that doctors and patients use Tenofovir in combination with (1) Gilead's FTC *or* generic 3TC; and (2) Japan Tobacco's EVG *or* ViiV's dolutegravir or Merck's raltegravir.

247. By withholding Vemlidy from the market while moving the TDF-based prescription bases to the TAF-based FDCs, Gilead used its control over Tenofovir to impair competition and maintain a dominant position in the cART Market. Without a standalone TAF on the market, Gilead forced anyone who wanted to buy TAF to also buy a Gilead TAF-based FDC. Those FDCs were unlawfully protected from competition by the amended—broader and lengthier—No-Generics Restraints.

2. Gilead anticompetitively withheld standalone TAF 10mg.

248. As part of the same anticompetitive scheme, Gilead also refused to make TAF available in 10mg strength—continuing to the present day—as either a standalone product or an FDC coformulated with FTC. In the United States, Gilead makes both standalone TAF and Descovy (TAF/FTC) only

formulated with 25mg of TAF rather than 10mg.

249. As noted in detail above, Genvoya and Stribild contain three of the same active ingredients (FTC, COBI, and EVG), while Stribild contains TDF and Genvoya contains TAF. COBI, a pharmacokinetic "booster" drug, increases the time that a component, EVG, stays in a patient's system (i.e., the drug's pharmacokinetic "half-life"). This allows patients to take Stribild or Genvoya once a day, rather than twice a day.

250. COBI, however, also increases the concentration of Tenofovir in the patient's blood. Thus, a patient taking Tenofovir with COBI will have a higher plasma concentration of Tenofovir than a patient who takes an equal dose of Tenofovir without COBI. This is true regardless of whether the Tenofovir is TDF or TAF.

251. Gilead knew from its long experience with Stribild that the presence of a booster drug such as COBI significantly increases the probability that Tenofovir will be more toxic to the patient's kidneys and bones. Gilead knew when formulating its TAF-based products that: (1) TAF, like TDF, has higher levels of toxicity when used together with a booster; and (2) when used together with a booster TAF would be effective at a dosage of just 10mg. Thus, when formulating its new line of TAF-based products, Gilead included only 10mg of TAF in its FDC, Genvoya, that contains COBI. Similarly, when coformulating TAF, FTC, and COBI together with Janssen's DRV (marketed as Symtuza beginning in July 2018), Gilead also used 10mg rather than 25mg of TAF. Gilead formulated all of its other TAF-based products—those without a booster—with 25mg of TAF.

252. Despite this knowledge, Gilead chose to make both Vemlidy (standalone TAF) and Descovy (TAF plus FTC) available only with 25mg of TAF. Gilead knew that, if Vemlidy and Descovy were available with a dosage of 10mg of TAF, many doctors and patients would prefer to prescribe or take Vemlidy or Descovy together with a booster other than Gilead's COBI and a non-Gilead third agent, rather than Gilead's Genvoya (and, later, Symtuza).

253. The purpose and effect of Gilead's making 10mg TAF available only in its own boosted FDCs was to force patients who want to avoid the increased risk of TAF when used with a booster to purchase the Gilead FDCs. For example, such a patient must purchase Genvoya rather than Descovy plus generic ATV plus generic RTV. Gilead is unlawfully putting patients who need to use boosters to an

untenable choice: either purchase Gilead's boosted FDCs or be forced to use an unnecessarily high dose of TAF, with the accompanying risk of toxicity.

254. Notably, in other parts of the developed world—including Europe, Japan, and Canada—Gilead makes available two versions of Descovy, one with 25mg of TAF and another with 10mg. The official prescribing information for Descovy from the European Medicines Agency—the regulatory agency covering all European Union countries, where the 10mg dose is available—makes clear that the doctor should prescribe the 10mg version, rather than the 25mg version, when also prescribing a booster. Authorities in these nations recommend that patients take the TAF 10mg version of Descovy as part of a boosted regimen, and take the TAF 25mg version when not used as part of a boosted regimen.

255. As part of its scheme to impair competition in the cART Market in the United States, Gilead has deprived American patients of that choice. Gilead has required American patients who want to avoid the risk of kidney and bone toxicity from a boosted TAF-based regimen to purchase Gilead's boosted FDCs.

3. Gilead anticompetitively withheld an HIV indication for standalone TAF.

256. Gilead similarly used its control over Tenofovir to impair competition in the cART Market by refusing to seek from the FDA an indication for use of standalone TAF in the treatment of HIV. Instead, Gilead sought FDA approval only for use in treatment of chronic Hepatitis B.

257. Gilead obviously knew that standalone TAF was active against HIV, as demonstrated by, among many other facts, Gilead's having sought FDA approval of HIV indications for numerous TAF-containing FDCs. Obtaining FDA approval of an HIV indication for standalone TAF would have been a trivial undertaking for Gilead. In connection with its November 5, 2014 application for approval of Genvoya, Gilead performed and submitted to FDA studies demonstrating the efficacy of both standalone TAF and TAF/FTC in the treatment of HIV. FDA approval of standalone TAF for treatment of HIV would have required, at most, that Gilead submit some bioequivalence data that would have been trivial and inexpensive for Gilead to obtain.

258. Gilead nevertheless chose not to seek an HIV indication for standalone TAF. As in Gilead's intentional delay in marketing TAF as a standalone product at all, and in its intentional refusal

to make TAF available as a 10mg pill, the purpose and effect of Gilead's continuing refusal to seek and obtain FDA approval for use of standalone TAF in the treatment of HIV is to force patients to purchase Gilead's FDCs rather than standalone TAF plus a competing HIV drug.

259. Gilead knew that if standalone TAF (Vemlidy) were indicated for use in treatment of HIV, many doctors and patients would prefer Vemlidy together with other competing HIV drugs, rather than Gilead's TAF-based FDCs. Those TAF-based FDCs are indicated for use in the treatment of HIV. So, if doctors or patients want to use TAF that is indicated for use in the treatment of HIV, they must purchase one of Gilead's TAF-based FDCs. (In theory, doctors could prescribe Vemlidy "off-label" for use in the treatment of HIV, but in fact most doctors will not do so.)

260. Gilead's Descovy (TAF/FTC) has an HIV indication, so doctors can and do prescribe Descovy together with non-Gilead third agents. That circumstance does not negate the anticompetitive effect of Gilead's forcing patients who want TAF to take a Gilead TAF-based FDC (including Descovy). The patents protecting the TAF molecule are set to expire in 2022. But Gilead has applied for patents that claim the formulation of TAF with FTC. *See, e.g.*, United States Patent Application Publication 2018/0177734 A1. When granted, those patents will extend far beyond 2022.

261. Withholding an HIV indication made economic sense for Gilead only because it impaired competition. Gilead in fact had already conducted the clinical trials necessary to get FDA approval for use of standalone TAF in treating HIV.

4. Gilead degraded standalone TAF with anticompetitive purpose and effect.

262. Basic economic facts demonstrate that Gilead's conduct had anticompetitive purpose and effect. Absent the intended effect of impairing and delaying competition, degrading standalone TAF would have been economically irrational for Gilead. Notably, Gilead marketed other TAF-containing products in 2015-2016, made TAF 10mg strength available in its FDCs that were to be boosted, and obtained an HIV indication for *all* of its other five TAF-containing products.

263. If Gilead had not degraded standalone TAF, Gilead would have made more than an additional $200 million in standalone TAF sales annually. Gilead's forgoing more than $200 million in additional annual TAF sales makes economic sense for Gilead solely because that conduct impairs

competition. The $200 million in annual lost standalone TAF sales is Gilead's investment in impairing and delaying competition in the cART Market.

264. Competition in the cART Maket was insufficient to mute the anticompetitive effects of Gilead's degrading standalone TAF (i.e., Gilead's refusal to make available standalone TAF in 2015-2016, to make it available in 10mg strength, and to make it available with an HIV indication).

265. Gilead's degrading of the product was a significant departure from Gilead's longstanding practice. Gilead first acquired the rights to Tenofovir in the early 1990s. As explained above, however, Tenofovir alone cannot be taken orally. To allow oral administration, Gilead formulated prodrugs of Tenofovir, thus allowing it to be marketed in the form of a pill that patients can swallow. Immediately upon marketing that form of Tenofovir—TDF—in 2001, Gilead made it available as a standalone product and obtained FDA approval for its use in treatment of HIV.

266. Gilead continued this pattern when it began marketing Tenofovir-based FDCs, beginning with Truvada in August 2004. At that time, TDF was the form of Tenofovir that Gilead used in its own FDCs; it used the same milligram strength in Truvada that it made available in its standalone Tenofovir (Viread); and it continued to make available for use in the treatment of HIV the same form of Tenofovir that it used in its FDCs. Gilead continued this pattern without interruption throughout the introduction and marketing of all of its other FDCs from 2004 through 2014.

267. Gilead had consistently and insistently cannibalized the sales of Viread (TDF) to the unlawfully protected TDF-based FDCs, but at least Gilead had made available for purchase as a standalone drug the same TDF that it used in its FDCs. Shortly after Gilead began marketing Tenofovir as a standalone product (Viread), doctors began to co-prescribe and co-administer it as a "backbone" drug for use with third agents. When developing and designing their third agents, Gilead's competitors relied on reasonable access to the best available form of Tenofovir as a backbone drug—with the same form, strength, and indications as the Tenofovir that Gilead used in its own FDCs. Gilead thus profited from Tenofovir's use both by selling it as an ingredient in its FDCs and by permitting competitors to market their third agents to be co-administered with the same form, strength, and indications of Tenofovir that Gilead used in its FDCs.

268. In order to even further impair competition in the cART Market—beyond the impairment

wrought by the No-Generics Restraints—Gilead began degrading standalone TAF in 2015. This marked an important change in Gilead's prior, voluntary pattern of conduct that had persisted for more than a decade. Gilead made a conscious choice to change this established pattern in order to impair competition. Gilead has never offered a public justification for its conduct in degrading standalone TAF, and it has no legitimate justification.

269. Competition within the cART Market has not been able to counter Gilead's anticompetitive conduct. Competitors had sunk substantial resources into promoting their third agents to be co-administered with Tenofovir. It is not feasible for them to start over from scratch and develop their own substitutes for Tenofovir. The high barriers to entry in the prescription pharmaceutical marketplace mean that the market is locked into Tenofovir as a principal backbone drug in the cART regimen for the foreseeable future.

270. Through its long-standing, voluntary course of dealing with its competitors, Gilead permitted and facilitated the use of Tenofovir as a principal component of the cART regimen and caused its competitors to anticipate and rely upon access to the best available form of Tenofovir, and the form that Gilead uses in its own FDCs, just as those competitors made the best forms of their third agents available for co-administration with Tenofovir. As a result, Gilead has a duty not to degrade standalone TAF for the purpose of denying its rivals the ability to continue to "interoperate" practically with Tenofovir.

271. Gilead refused to sell standalone TAF in 2015-16 and continues to refuse to sell standalone TAF in 10mg strength and with an HIV indication not because of any lack of consumer demand for that product, but precisely because there is a consumer demand for it. Gilead degraded standalone TAF in order to shift the undeniable consumer demand for that product to Gilead's TAF-based FDCs.

272. In degrading standalone TAF while making non-degraded TAF available as a component of Gilead FDCs, Gilead granted to purchasers of those FDCs a bundled discount that its rivals cannot match. Gilead's conduct impaired competition from equally efficient rivals who make less than all of the components in Gilead's exclusionary bundles, i.e., its TAF-based FDCs.

273. Gilead's degrading TAF has also artificially reduced the prescription base of Vemlidy

(standalone TAF) and Descovy (TAF plus FTC) that will be available for generic substitution when the principal patents on TAF and FTC expire in May 2022 and September 2023, respectively. Those artificial reductions in the prescription bases will: (1) dramatically increase the prices that patients will pay for TAF; and (2) reduce the pricing pressure that Gilead's TAF-based FDCs would otherwise face in the cART Market. Gilead has harmed the competitive process without a legitimate business justification. Gilead's conduct harmed competition on the merits, increased prices, limited the quality and availability of products, and increased costs.

G. Gilead's Unlawful Regulatory Gaming

274. Gilead's intentionally withholding an HIV indication from standalone TAF has another anticompetitive purpose and effect. That withholding triggers regulatory barriers to the timely and effective entry into the market of generic standalone TAF with an HIV indication ("TAF-HIV") and generic-TAF-based FDCs.

275. With the fair and open competition that the antitrust laws provide, beginning (at the latest) with the availability of generic TAF in May 2023, doctors and patients would have important competitive alternatives to Gilead's TAF-based FDCs. For example, doctors could begin prescribing generic TAF-HIV together with another NRTI (e.g., 3TC), and a third agent. And competing manufacturers could coformulate generic TAF-HIV with a large variety of antiretroviral agents to make FDCs for use in the treatment of HIV.

276. Gilead has unlawfully manipulated the regulatory framework in order to impair and delay that generic-TAF-based competition. Gilead is unlawfully maintaining its monopoly by refusing to get an HIV indication for Vemlidy (standalone TAF). Gilead's purpose in withholding an HIV indication is to force competitors—those seeking to market generic TAF-HIV and those seeking to use it as a component of competing FDCs—to conduct time-consuming and expensive clinical trials.

277. But for Gilead's gaming of the regulatory system, it would be entirely unnecessary for competitors to conduct those expensive and delay-inducing trials. Gilead in fact already conducted the clinical trials that are necessary for FDA approval of use of Vemlidy in treating HIV. Gilead nevertheless refused to ask the FDA for that indication, with a purpose of invoking this regulatory barrier to

competitors' entry.

278. Forgoing the HIV indication causes Gilead to lose more than $200 million in Vemlidy sales every year. But impairing competitors' entry into the marketplace is even more valuable to Gilead. Withholding an HIV indication for Vemlidy makes economic sense for Gilead only because of its anticompetitive effects, including impairing and delaying competition from generic-TAF-based competitors.

279. This regulatory gaming will help Gilead to maintain its monopoly in the cART Market. Unless enjoined by this Court, Gilead will succeed in preventing until as late as 2032 the flourishing of price competition and FDC innovation that should begin no later than May 2023.

1. TAF is vulnerable to generic competition in May 2023.

280. Absent Gilead's unlawful manipulation of the regulatory framework, generic TAF-HIV could enter the market by May 2023 at the latest. Gilead has NCE exclusivity for standalone TAF, which expires on November 5, 2020. That exclusivity prevented any manufacturer from filing an application with the FDA to make generic TAF until November 5, 2019. When manufacturers filed such applications, Gilead sued them for patent infringement, eliciting the 30-month stay under the Hatch-Waxman Act. Those stays will not expire until in or about May 2023. Absent Gilead's unlawful manipulation described below, manufacturers could easily "design around" Gilead's patents, get FDA approval, and begin marketing generic TAF-HIV, and use generic TAF as a component of a competing FDC, no later than May 2023.

281. Gilead's patents protecting TAF can be divided into two groups:

Group	**Patent No.**	**Patent Name**	**Patent Expiry**	**Description**
Group One	7,390,791	"Prodrugs of phosphonate nucleotide analogues"	7 May 2022	Tenofovir Alafenamide Molecule
	7,803,789	"Prodrugs of phosphonate nucleotide analogues"	2 Feb 2022	Tenofovir Alafenamide Molecule
Group Two	8,754,065	"Tenofovir alafenamide hemifumarate"	15 Aug 2032	Hemifumarate Salt
	9,296,769	"Tenofovir alafenamide hemifumarate"	15 Aug 2031	Hemifumarate Salt

282. The first group consists of United States Patents Nos. 7,390,791 and 7,803,788. Those two patents protect the basic prodrug molecule design—the drug composition and drug product—and expire in 2022 (subject to a patent extension that Gilead got on the '791 Patent, as described below in Section VII(I)).

283. The second group consists of United States Patents Nos. 8,754,065 and 9,296,769. Those two patents claim the hemifumarate salt of tenofovir alafenamide, i.e. the salt in which the ratio of fumaric acid to tenofovir alafenamide is approximately 0.5, and protect its use in pharmaceutical compositions. The hemifumarate salt is variously referred to as "GS-7340-03" or "TAF fumarate." These patents expire in 2032.

284. Manufacturers commonly use salts of pharmaceutical compositions to increase oral solubility, thereby improving manufacturability and stability. When a soluble salt dissolves in water, the positively charged component (e.g., tenofovir alafenamide) and the negatively charged component (the fumarate) separate.

285. As long as the pharmacokinetics and safety profile of two different salts of the same therapeutic moiety (e.g., tenofovir alafenamide) are bioequivalent, the different salts' clinical efficacy is identical. The FDA therefore permits manufacturers to use a streamlined process, under Section 505(b)(2) of the FD&C Act (21 U.S.C. § 355(b)(2)), to get approval for a drug that uses a salt different than that used by the reference drug. (See Section VI(D) above.) The manufacturer usually need not conduct any clinical trials, but must merely show that the salt that it proposes to use results in the same safety profile as, and is bioequivalent to, the reference drug. The FDA may also assign an AB-rating to the product, making it automatically substitutable for the reference drug at the pharmacy counter.

286. Thus, by making the drug with a different salt than the one used by the brand manufacturer, other manufacturers can get FDA approval while avoiding infringing the brand manufacturer's patents. This is known as "designing around" the patents. Designing around a brand manufacturer's patents on particular salts prevents those manufacturers from using secondary patents to extend their monopolies beyond the expiration of the basic patents that claim the therapeutic moiety itself.

287. Manufacturers could easily design around Gilead's later-expiring Group Two patents (i.e., the patents on the hemifumarate salt). That would allow generic entry in 2023 (when the NCE exclusivity, plus the 30-month stay expire), not 2032.

288. All of Gilead's current TAF-containing products use the hemifumarate salt of tenofovir alafenamide. But Gilead originally started clinical development of its TAF product line with the *mono*fumarate salt where the ratio of fumaric acid to tenofovir alafenamide is approximately 1. The monofumarate salt is variously referred to as "GS-7340-02" or "TAF monofumarate." Gilead transitioned to using the hemifumarate salt only during phase II and phase III development of many of its products and for final development.

289. Gilead used the monofumarate salt in some of its own phase II clinical trials, and used those studies to get FDA approval of the hemifumarate-containing final products. Based on Gilead's own data, the FDA concluded that "[the hemifumarate salt] is considered comparable to [the monofumarate salt] based on physical/chemical properties and pharmacokinetic data." FDA, "Pharmacology Review for NDA 207-561," https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207561Orig1s000PharmR

.pdf, at 12.

290. In fact, at least three of the initial clinical trials performed by Gilead to evaluate TAF, the GS-120-1101, GS-US-120-0104, and GS-US-292-0101 trials, used the monofumarate rather than hemifumarte salt. Gilead Sciences, Inc., "Protocol GS-US-320-0108, Amendment 2.1," https://clinicaltrials.gov/ProvidedDocs/36/NCT02836236/Prot_000.pdf, at 31.

2. Gilead withheld an HIV indication in order to impair competition.

291. Gilead's intentional withholding of the HIV indication impaired the sale of generic TAF-HIV for use in combination with other standalone NRTIs and third agents, in competition with Gilead's TAF-based FDCs. In order to obtain from the FDA an AB-rating to the reference drug, and thus to be automatically substitutable at the pharmacy counter, the applicant must show that the proposed generic drug is bioequivalent to the reference drug and has, among other requirements, the same *labeling* as the reference drug.

292. Accordingly, a proposed generic TAF-HIV must have the same label as Vemlidy. Gilead intentionally withheld an HIV indication from Vemlidy, so a manufacturer seeking an AB-rating for its standalone TAF product must also omit an HIV indication from its label. The only generic standalone TAF ANDA product—the only AB-rated ANDA product that will be automatically substitutable for brand Vemlidy at the pharmacy—is one that is *not* indicated for use in the treatment of HIV.

293. When a generic Vemlidy—*without* an HIV indication—becomes available, doctors could in theory prescribe it for "off-label" use. But, in fact, substantial numbers of doctors will not do so. And federal law (21 C.F.R. § 202.1) makes it unlawful for a pharmaceutical manufacturer to actively encourage doctors to prescribe the product for off-label use. The effect—intended by Gilead—will be to shield Gilead's TAF-based FDCs from competition from combinations of standalone products that include generic standalone TAF.

294. Gilead's conduct will also impair the sale of competing FDCs made with generic TAF. When generic TAF becomes available, competing manufacturers would be able to formulate FDCs with generic TAF and other antiretrovirals. But Gilead's withholding of the HIV indication for standalone TAF will substantially complicate, delay, and increase the expense of the regulatory pathway for

competing manufacturers.

295. When all of the components of a proposed FDC have previously received FDA approval for treatment of HIV, an applicant seeking FDA approval need provide only a study showing that the drugs are safe and effective when used together, and some bioavailability data showing that the FDC produces blood levels for each of the active ingredients adequate to achieve efficacy. Importantly, when all of the components of a proposed FDC have previously received FDA approval for treatment of HIV, the applicant need not provide to the FDA any new preclinical or safety and efficacy data.

296. In contrast, when all of the components of a proposed FDC have not previously received FDA approval for treatment of HIV, the applicant *must* provide new preclinical and safety and efficacy data. The cost and delays attendant upon obtaining and presenting that data to the FDA are substantial. As intended by Gilead, those costs and delays will impair competition to Gilead's TAF-based FDCs.

297. Moreover, Gilead is currently taking steps to ensure that competitors cannot avoid these costs and delays by formulating their FDCs with generic TAF/FTC once the FTC patents expire. As noted above, Gilead is already in the process of patenting the formulation of any salt of tenofovir alafenamide with FTC.

298. Absent the intended effect of impairing and delaying competition, Gilead's withholding of an HIV indication for TAF made no economic sense for Gilead. Gilead's motive in withholding an HIV indication from TAF was to impair and delay competition. Gilead's forgoing more than $200 million in annual standalone TAF sales is an investment in impairing and delaying competition.

H. Gilead's Anticompetitive Conduct to Delay Entry of Generic Viread, Truvada, and Atripla

299. Beginning in 2008, generic-drug manufacturer Teva Pharmaceuticals challenged the patents on Gilead's Viread, Truvada, and Atripla. Other generics manufacturers, including Mylan Pharmaceuticals, Lupin Pharmaceuticals, Cipla Ltd., Hetero Drugs Ltd., Amneal Pharmaceuticals, and Aurobindo Pharma, ultimately also challenged the patents on one or more of those products.

300. Viread, Truvada, and Atripla are formulated with TDF and/or FTC. Gilead had been sitting on TAF, the successor product to TDF, since at least 2004. These challenges to the TDF and FTC

patents prompted Gilead to finally dust TAF off and prepare to switch all of its TDF-based franchise to a TAF-based franchise.

301. Gilead's plan to transition the TDF franchise to a TAF franchise would be disrupted, however, if generic versions of Viread, Truvada, or Atripla entered the market before Gilead accomplished the switch to TAF-based products, which were protected by the broader and longer No-Generics Restraints. Gilead prevented the disruption of its anticompetitive schemes by enticing Teva and the other generic manufacturers to delay entry into the market with their generic TDF-based products.

1. Most-Favored-Entry and Most-Favored-Entry-Plus clauses delay generic entry.

302. Gilead compounded the anticompetitive effects of the No-Generics Restraints by including Most-Favored-Entry ("MFE") and Most-Favored-Entry-Plus ("MFEP") clauses in patent-settlement agreements with Teva and the other generics manufacturers. Gilead used these clauses to entice Teva to delay entry into the market in return for assurance that no other generic manufacturer would enter the market before Teva.

303. An agreement with an MFE clause arises when the brand manufacturer and the "first-filer"—the generic manufacturer that filed the first ANDA with a Paragraph IV certification—settle the patent litigation, with the generic manufacturer agreeing to delay entering the market until a specified date. The MFE clause provides that if any other generic manufacturer (a "second-filer") succeeds in entering the market before that date, the first-filer may enter at the same time. An MFE can delay generic entry by reducing a second-filer's incentive to try to enter the market before the first-filer.

304. A first-filer that is otherwise entitled to a 180-day period of ANDA Exclusivity can forfeit it. When a second-filer gets a final court decision that the brand manufacturer's patents are invalid or not infringed, the first-filer forfeits its ANDA Exclusivity if it does not enter the market within 75 days of the court decision. 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). The first-filer would forfeit the statutory exclusivity, for example, if it agreed to delay entry until Year 7 and a second-filer got a final court decision of patent invalidity in Year 5. Having agreed not to begin marketing until Year 7, the first-filer could not enter the market within 75 days of the second-filer's favorable court decision in Year 5. So the first-filer would

forfeit its ANDA Exclusivity. The MFE allows the first-filer to circumvent this statutory provision.

305. Absent an MFE clause, a second-filer could enter in Year 5 and get a substantial period of de facto (non-statutory) exclusivity in the generics sector of the market. The first-filer would be stuck on the sidelines while the second-filer enjoyed de facto exclusivity. Because it is the prospect of obtaining that period of de facto exclusivity that motivates a second-filer to incur the substantial costs and burdens of trying to enter the market before the entry date to which the first-filer agreed, and because an MFE would eliminate that possibility, an MFE would reduce the incentive for second-filers to try to enter the market before the first-filer.

306. Like an MFE, an MFE-*Plus* (MFEP) dramatically reduces a second-filer's incentive to try to enter the market before the first-filer. An MFEP provides that the brand manufacturer will not grant a license to any second-filer to enter the market until a defined period of time after the first-filer enters. The clause might provide, for example, that the brand manufacturer will not grant a license to any second-filer to enter the market until 180 days after the first-filer enters.

307. Absent the MFEP, a second-filer could use its challenge to the patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first-filer. And the first-filer's statutory ANDA Exclusivity would not prohibit that earlier entry if, for example, the first-filer forfeited the ANDA Exclusivity by having failed to get tentative FDA approval within 30 months. 21 U.S.C. 355 § (j)(5)(D)(i)(IV). The second-filer could thereby enjoy a substantial period of de facto exclusivity in the generic sector of the market. An MFEP would eliminate that possibility by ensuring that the second-filer could not successfully negotiate for an earlier licensed entry date.

308. In short, the Hatch-Waxman Amendments leave open at least two pathways for second-filers to enter the market before a first-filer that has agreed to delay entry into the market. The second-filer could win the patent litigation and trigger forfeiture of the first-filer's ANDA Exclusivity when it fails to enter the market within 75 days of the court decision; and the second-filer could negotiate an earlier entry date from the brand manufacturer and enter the market if the first-filer has forfeited statutory exclusivity by having failed to get FDA approval within 30 months. A brand manufacturer could use MFEs and MFEPs to close the two pathways to earlier generic entry that Congress left open.

309. The anticompetitive effects of MFEs and MFEPs may be compounded by increasing the

number of generic manufacturers to which the clauses apply. When one second-filer is deciding whether to initiate or continue a patent challenge, four other generic manufacturers might also have already started a patent challenge or be poised to do so. Knowing that the brand manufacturer has already granted an MFE to the first-filer and has offered to grant one to the second-filer himself, the second-filer knows that the brand manufacturer will also likely grant one to the third, fourth, fifth, and sixth filers.

310. In these circumstances, the second-filer faces the prospect that, even if it expends substantial resources to win the patent case, its "victory" would trigger simultaneous entry into the market by the first-filer, possibly an "authorized generic" marketed by the brand manufacturer, and four other generics. As shown in detail below, entry by that number of manufacturers would quickly compete prices down to near marginal cost.

311. The use of MFEs and MFEPs may therefore mean that no other generic manufacturer can profitably invest in using its patent challenge to try to get earlier entry than the first-filer.

2. Gilead used MFEs and MFEPs to delay generic entry.

312. Gilead used MFEPs and MFEs to delay the onset of generic competition to Viread, Truvada, and Atripla. The MFE agreements set a date for initial generic entry and provided that the first-filer, Teva, could enter sooner should a second-filer gain entry into the market by, for example, proving the Gilead patents invalid. The MFEP clauses compounded the anticompetitive effects of these provisions by promising that Gilead would not authorize further generic entry for a defined period after the initial entry. These anticompetitive clauses, together with the unlawful No-Generics Restraints that Gilead had already used, worked. All generic manufacturers agreed to stay out of the market for the period of time that Gilead granted to Teva in the MFEP, and Teva agreed to delay entry into the market.

a. Teva filed the first ANDAs with Paragraph IV certifications.

313. On September 26, 2008, Teva filed the first ANDA seeking FDA approval to sell generic Truvada before patent expiration. Teva's ANDA, which was assigned ANDA No. 90894, contained a Paragraph IV certification as to Gilead's patents 6,642,245 and 6,703,396 that claim the FTC enantiomer and methods of using it (the "FTC Enantiomer Patents"), which were set to expire on May 4, 2021 and

September 9, 2021, respectively. Teva asserted that the patents were invalid, unenforceable, or not infringed by its proposed generic version of Truvada.

314. Teva also filed the first ANDA seeking FDA approval to sell generic Atripla before patent expiration. Teva's ANDA, which was assigned ANDA No. 91215, contained a Paragraph IV certification as to the FTC Enantiomer Patents and to BMS's patents covering EFV.

315. Teva's Truvada and Atripla ANDAs eventually provided a Paragraph IV certification as to Gilead's patents claiming TDF and certain methods of using it—patents 5,922,695; 5,935,946; 5,977,089; and 6,043,230 (the "TDF Patents"). Teva asserted that the TDF patents were invalid, unenforceable, or not infringed.

316. On or about November 3, 2008 and March 30, 2009, Teva notified Gilead of its Paragraph IV certifications for Truvada and Atripla, respectively, explaining in detail why the patents were invalid and not infringed by Teva's ANDA products.

317. On December 12, 2008, Gilead filed suit in the United States District Court for the Southern District of New York (No. 08-cv-10838), alleging that Teva's generic Truvada would infringe the FTC Enantiomer Patents. On September 25, 2009, Gilead filed an amended complaint, adding allegations that Teva's generic Atripla would infringe the FTC Enantiomer Patents. Gilead filed the patent infringement lawsuit without regard to its merits. In fact, Gilead knew that there was a substantial risk that it would lose the patent litigation.

318. On July 1, 2009, Teva filed the first ANDA seeking FDA approval to sell generic Viread before patent expiration. Teva's ANDA, which was assigned ANDA No. 91692, contained a Paragraph IV certification as to the TDF Patents, claiming that they were invalid, unenforceable, or not infringed. On or about January 25, 2010, Teva notified Gilead that Teva had filed ANDA No. 91692, detailing why the TDF Patents were invalid and not infringed by Teva's ANDA product.

319. On March 5, 2010, Gilead filed suit in the United States District Court for the Southern District of New York (No. 10-cv-01796) alleging that Teva's generic Viread would infringe the TDF Patents. Gilead filed the patent infringement lawsuit against Teva without regard to the lawsuit's merits. In fact, Gilead knew that there was a substantial risk that it would lose the patent litigation.

320. Thereafter, the litigation of the TDF patents, which affected Teva's applications for

Viread, Truvada, and Atripla (all of which contain TDF) was conducted in Southern District of New York (No. 10-cv-01796). The litigation of the FTC Enantiomer Patents, which affected Teva's applications for Truvada and Atripla (both of which contain FTC), was conducted in Southern District of New York (No. 08-cv-10838).

321. Subsequent events set the stage for Gilead to use MFEPs and MFEs to elicit delayed entry from Teva and all other generic manufacturers that sought to market generic Viread, Truvada, and Atripla.

b. Second-filers posed a threat to Teva.

322. From March 2010 to February 2013 (when Gilead enticed Teva into a settlement on Viread), six more generic-drug manufacturers—Lupin, Cipla, Hetero, Aurobindo, Strides Pharma, and Macleods Pharmaceuticals—filed ANDAs seeking FDA approval to sell generic Viread. The first two of those six manufacturers included Paragraph IV certifications with respect to the TDF Patents. Gilead and Teva knew and understood that the other four of those six intended to enter the market as soon as possible and would amend their ANDAs to include Paragraph IV certifications (as is common in the industry) if it appeared that they had an opportunity for a period of de facto exclusivity.

323. These competitors posed a significant threat to Teva. The FD&C Act's forfeiture provisions (see Section VI(C) above) created the prospect that, if Teva agreed to a long delay in entry, without the protection of an MFEP and MFE, a second-filer would: (a) obtain a judgment of invalidity or noninfringement and enter the market years before Teva; or (b) would use the leverage of its patent challenge to negotiate a better licensed-entry date from Gilead. Without those clauses, Teva faced a substantial risk that it would be stuck on the sidelines while second-filers entered the market years in advance and reaped the corresponding gains of being the first ANDA entrants.

324. Gilead enticed Teva to enter into the settlement for Viread in part by using MFE and MFEP clauses to forestall generic competition to Teva after it entered the market. This reduction in generic competition was enormously valuable to Teva. For every week that Teva was on the market as the only generic manufacturer of a standalone product such as Viread, it could expect to sell all of the generic units at about 90% of the price of branded Viread. Entry of other generics, however, would

significantly cut Teva's unit sales and the profits per sale. A third generic version would cut Teva's unit share to a third and permit a price of only 44% of the branded price; entry of a seventh version would cut Teva's unit share to one-seventh and permit a price of only 23% of the brand price.

325. In 2017 (the year that Teva eventually entered the market) Viread had United States sales of $591 million, or about $11 million per week. Generics collectively (however many there were) could expect to take 80% of Viread's unit sales. Thus, as the sole generic on the market Teva could expect to make $7.9 million for every week of sales; with seven generics on the market, Teva could expect to make only $289,000 for every week of sales.

326. Gilead's efforts to forestall generic competition increased Teva's sales by $7.6 million for every week in which it was the only generic Viread seller. Moreover, Teva's competitive advantage would not be limited to just the period when no other manufacturer was selling the product. With a date-certain, single-entrant launch date, Teva could ramp up its production and negotiate contracts with its customers to effectively stuff the distribution channel with many more weeks of product before the second-filers entered the market, and to lock in high prices with long-term sales contracts. The difference between the single-generic price and the price with multiple generic competitors would translate into a significant cost to consumers.

c. Gilead gave Teva an MFEP and put MFEs in all Viread agreements.

327. In order to delay entry of generic Viread, Gilead in fact gave Teva an MFEP and put MFE clauses in all of its settlement agreements with the generic manufacturers. Those clauses caused Teva to agree to delay entry, and they prompted all of the second-filers to agree to delay entry until at least six weeks after Teva entered.

328. The first MFE appeared on November 27, 2012 in an interim agreement between Gilead and Teva, in which Teva agreed that it would not enter the market with Viread or Truvada while the TDF patent litigation was pending, until the earlier of (i) various events in the patent litigation (e.g., a finding of invalidity), or (ii) a second-filer entered the market. Gilead and Teva put this MFE in the public record, so all of the second-filers knew that any final agreement between Gilead and Teva was also very likely to include an MFE.

329. In February 2013, Gilead and Teva agreed in principle to settle their litigation over the TDF Patents, and they finalized the agreement in April 2013. Under the agreement, Teva agreed to delay marketing its generic Viread until December 15, 2017.

330. The MFE and MFEP allowed Gilead to extract an exceedingly late entry date—just six weeks before the end of the patent term. The MFE provided that, if any second-filer entered the market before December 15, 2017, Teva's entry date would be moved up accordingly. The MFEP provided that Gilead would not grant any other manufacturer a license to enter the market with generic Viread until at least six weeks after Teva's agreed entry date.

331. The MFE and MFEP caused allowed Gilead to obtain a later entry date than Teva otherwise would have agreed to. Without the clauses, Teva faced the prospect of simultaneous entry by as many as six other generic manufacturers. With the clauses, Teva was nearly guaranteed a period of time as the only generic on the market, and was absolutely guaranteed that no other generic manufacturer would enter before it.

332. When agreeing to the delayed December 15, 2017 entry date, Teva knew that: (1) Gilead was willing to include the anticompetitive MFEs in settlement agreements with second-filers; (2) it was in Gilead's financial interest to include such clauses in agreements with all second-filers; (3) the second-filers knew that the Gilead/Teva agreement included an MFE; (4) given the MFE and MFEP, it was not in any second-filer's interest to incur the costs of patent litigation to try to enter the market before Teva; and (5) the MFEs' deterrent effect would grow with every additional one that Gilead included in another settlement.

333. Upon information and belief, Gilead advised the second-filers of the existence of the MFE and MFEP in the Gilead/Teva agreement.

334. Teva concluded, correctly, that the MFE and MFEP would protect it from competition from any other generic manufacturer until the end of the TDF Patent terms on January 26, 2018—six weeks after Teva entered.

335. By the time that Gilead and Teva finalized their agreement in April 2013, Gilead had filed patent infringement lawsuits against Lupin and Cipla, both of which had provided Paragraph IV certifications with respect to the TDF Patents. On May 28, 2014 and July 29, 2014, Gilead settled those

patent litigations with Lupin and Cipla, respectively. Both generic manufacturers agreed under their respective settlements not to launch generic Viread until six weeks after Teva. And Gilead included an MFE clause in both of those settlement agreements.

336. Just as Gilead intended, the MFE and MFEP in the Teva agreement, and the MFEs in the Lupin and Cipla agreements, caused the other ANDA filers—Hetero, Aurobindo, Strides, and Macleods—to not amend their ANDAs to include Paragraph IV certifications. Absent Gilead's anticompetitive conduct they all would have done so; those manufacturers made Paragraph IV certifications with respect to Truvada.

337. On January 26, 2018, six weeks to the day after Teva entered the market, five additional generic manufacturers (Cipla, Hetero, Aurobindo, Strides, and Macleods) received final FDA approval, and four of them immediately began marketing their generic Viread.

338. During the six weeks it had the only generic Viread on the market, Teva stuffed the supply chain with product, selling at least 14 weeks' supply of product and locking in high prices through long-term sales contracts. Thus, Teva made at least $106 million more than it would have absent the MFEP and MFEs. Absent the MFEP and MFEs, Teva and the second-filers would have entered the market much sooner than they did, on dates to be determined by the jury. The delay in generic entry protected more than $2 billion in Gilead's Viread branded sales, all at the expense of Plaintiffs and other class members.

339. Gilead's delaying the entry of generic Viread also had the effect of delaying the entry of Gilead's TAF-based line of products. Gilead withheld those products from the market until the entry of generic TDF was imminent. The delay in that generic entry caused Gilead to delay the introduction of its TAF-based products.

d. Gilead put MFEPs and MFEs in the Truvada and Atripla agreements.

340. Having successfully delayed generic entry for Viread, Gilead then also used MFE/MFEP clauses to delay generic entry for Truvada and Atripla.

341. Following various amendments and pretrial proceedings in Gilead's patent litigation against Teva, only the FTC Enantiomer Patents, as they related to both Truvada and Atripla, were left for

trial. The trial, which began on October 8, 2013 and concluded on October 28, 2013, focused on Teva's contention that the patents were invalid for obviousness-type double patenting because the (-)-enantiomer "species" patents were anticipated by earlier expiring "genus" patents, which claimed all enantiomeric forms of the FTC compound, and that the claimed (-)-enantiomer was disclosed as part of the genus patents' claims. The parties settled the case in February 2014 while they were awaiting the trial court's decision.

342. The '396 patent (the later of the two FTC Enantiomer Patents) does not expire (with pediatric exclusivity) until September 9, 2021. As with Viread, Teva faced a threat from a number of second-filers, which had ample time and incentive to challenge the relevant patents and enter earlier than Teva. By February 2014 Gilead had pending a patent lawsuit against Lupin, which had provided Paragraph IV certifications with respect to Truvada. Teva also knew that several generics had already filed ANDAs for Truvada and Atripla and that many Paragraph IV challenges would come in the near future. Indeed, at least nine second filers ultimately filed Paragraph IV certifications, starting almost immediately following Teva's settlement. At least Mylan, Aurobindo, Hetero, Macleods, Amneal, Strides, Laurus, and Zydus filed ANDAs with Paragraph IV certifications with respect to Truvada. And at least Lupin, Aurobindo, Hetero, and Macleods filed Paragraph IV certifications with respect to Atripla. Following their respective Paragraph IV certifications, Gilead pursued patent litigation against each of these second-filers. (BMS's EFV patents expired before Gilead's FTC Enantiomer Patents, so BMS sued and settled with Teva knowing that the generic entry date would be determined by resolution of Gilead's lawsuit against Teva.)

343. Teva and these second-filers faced much the same economic dynamics that they did regarding Viread: Teva's getting an MFE and MFEP would dissuade the second-filers from continuing to litigate and would provide Teva a period of exclusivity. Moreover, *Teva had forfeited its 180-day ANDA Exclusivity with respect to Truvada and Atripla* by having failed to obtain tentative FDA approval within 30 months of submitting its application. 21 U.S.C. 355 § (j)(5)(D)(i)(IV). (*See* Section VI(C) above).

344. Under the February 2014 settlement agreement, Teva will not be able to launch generic Truvada and generic Atripla until September 30, 2020. Gilead was able to extract that late entry date—just one year before the last expiring FTC Enantiomer Patent—by giving Teva an MFE and MFEP. The

MFE provided that, if any second-filer entered the market before Teva's agreed entry date, Teva's permitted entry would be moved up accordingly. The MFEP provided that Gilead would not grant a license to any other manufacturer to enter the market with generic Truvada or generic Atripla until at least *six months* after Teva's agreed entry date.

345. Upon information and belief, Gilead advised the second-filers of the existence of the MFE and MFEP in the Gilead/Teva agreement.

346. Gilead succeeded in delaying entry of generic Truvada and Atripla just as it did with respect to Viread. Gilead settled with Lupin in September 2014; with Mylan in October 2015; with Aurobindo in September 2016; with Hetero in August 2016; with Amneal in April 2017; with Macleods in December 2017; with Laurus in November 2018; with Strides in January 2019; and with Zydus in August 2019. Gilead included an MFE in each of those settlement agreements, and all of the manufacturers agreed to delay entering the market until six months after Teva's entry.

347. The MFE and MFEP had very substantial value to Teva. In 2014, combined United States sales for Atripla and Truvada were approximately $4 billion. Using the methodology described in detail above, six months of exclusive sales of those generic products was worth more than $1.5 billion to Teva. Absent the MFEP and MFEs, Teva and the second-filers would have entered the market much sooner than they did, on dates to be determined by the jury. The delay in generic entry protected more than $25 billion in Gilead's Truvada and Gilead/BMS's Atripla branded sales, all at the expense of Plaintiffs and other class members.

I. Gilead's Unlawful Delay-and-Extend

348. Gilead has obtained from the PTO an extension of approximately three years on the term of its principal patent covering TAF. Gilead's conduct in obtaining that extension is a perversion of the Hatch-Waxman Act's patent-term-extension ("PTE") provisions. Congress designed PTE to benefit pharmaceutical manufacturers who encounter delays in getting their products to market as a result of government-imposed regulatory hurdles. Gilead lost time on the market with TAF by intentionally delaying its clinical development and approval as part of an anticompetitive scheme.

349. Gilead's intentional delay was part of an anticompetitive delay-and-switch tactic. Gilead's

plan, which succeeded, was to delay development/approval of TAF in order to hold it in abeyance until generic competition to TDF was imminent far in the future. Then Gilead would switch its Tenofovir-based franchise from TDF-based to TAF-based drugs. Gilead's intentional delay of TAF made economic sense for Gilead only as part of the anticompetitive delay-and-switch tactic. And obtaining PTE on the TAF patents was essential to make that tactic work for Gilead. Gilead's delay-and-switch was profitable for Gilead because it was able to delay-yet-extend.

350. In the context of Gilead's monopolization scheme of which its application for PTE was a part, the combination of Gilead's intentional delay of TAF and extension of the TAF patent was a gross abuse of the Hatch-Waxman PTE provisions and unlawful exclusionary conduct under Section 2 of the Sherman Act.

1. In granting patent extensions, the PTO has no authority to consider anticompetitive delay tactics like Gilead's.

351. Gilead's principal patents on TAF are Patent No. 7,390,791 (the '791 Patent) and Patent No. 7,803,788 (the '788 Patent). Generally, the '791 Patent claims a genus of compounds which include TAF, and the '788 Patent claims methods of using TAF in antiviral therapy.

352. On December 14, 2015, Gilead filed an application with the PTO for a Patent Term Extension ("PTE") under 35 U.S.C. § 156 for the '791 Patent and the '788 Patent. The regulations permit the applicant to request PTE for multiple patents on the same drug, but the PTO will grant PTE for only one. 37 C.F.R. § 1.785.

353. Absent PTE, the '788 Patent and '791 Patent would expire on February 2, 2022 and May 7, 2022, respectively. On February 19, 2020, the PTO made a final determination that the '791 Patent was eligible for PTE of 1,076 days, extending that patent to April 17, 2025. On March 18, 2020, Gilead elected to accept the PTE on the '791 rather than the '788 Patent. The PTE thus extended the '791 Patent's term to April 17, 2025, giving Gilead approximately an extra three years of exclusivity on TAF.

354. Congress designed PTE to compensate the NDA applicant for the patent term that it loses due to the regulatory process, through no fault of its own. Congress granted PTE in order to "respond to … unintended distortions of the … [normal] patent term produced by the requirement that certain

products must receive premarket regulatory approval." *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 669 (1990).

355. Specifically, PTE extends the period of a pharmaceutical patent's term in order to compensate for a portion of the patent term that the patentee lost—the period in which it was not able to market the patent-protected product—while the product was in clinical development and/or awaiting FDA approval. Subject to certain limitations, the applicant is entitled to PTE equal to one-half of the time in the testing phase (from the effective date of the filing of the investigational new drug (IND) application to the filing date of the new drug application (NDA)), plus all of the time in the approval phase (from the filing of the NDA until the FDA approves the product). 35 U.S.C. §§ 156(c)(2), 156(g)(1)(B).

356. In granting PTE, the regulatory agencies (the FDA and PTO, working together) did not consider whether the PTE was part of an anticompetitive scheme or whether Gilead intentionally delayed clinical development or request for FDA approval as part of such a scheme. In calculating whether and to what extent the applicant is entitled to PTE, the agencies consider and adjust for any time in which the applicant failed to exercise due diligence only to the extent that the lack of diligence occurred *after the patent issued*. 35 U.S.C. § 156(c)(1). The agencies have no statutory or regulatory authority, and therefore cannot and do not exercise any discretion, to refuse or reduce PTE for the period of time that the applicant intentionally delayed development/approval before the patent issued.

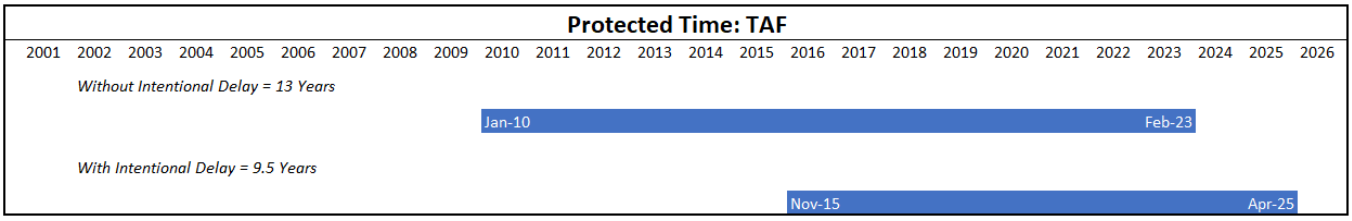
2. PTE on the TAF patents was a key part of a scheme that made sense for Gilead only because it impairs competition.

357. As alleged in detail above, Gilead intentionally delayed the clinical development and FDA approval of TAF, holding the product in abeyance to market it only later once entry of generic TDF was imminent. The unlawful No-Generics Restraints and Defendants' other anticompetitive conduct made it commercially feasible for Gilead to withhold TAF from the market.

358. Gilead's intentional delay in developing and gaining approval for TAF made economic sense for Gilead only as part of its scheme to use its dominance of Tenofovir to monopolize the markets for Tenofovir-based products and the overall cART market. Gilead's intentional delay of TAF, even with

the PTE, made economic sense for Gilead only as part of that scheme.

359. For example, if Gilead had not intentionally delayed its development/approval of TAF, Gilead would have obtained FDA approval of its first TAF-based product, Genvoya, in January 2010 (assuming the same development and approval time as actually occurred). In those circumstances, the latest of Gilead's principal TAF patents, with PTE, would have expired in February 2023.[1] The period of time in which Gilead's TAF-based products would be both on the market and protected by the TAF patents would have been about 13 years (January 2010 to February 2023). By intentionally delaying TAF approval until November 2015, the period of time in which Gilead's TAF-based products will be both on the market and protected by the TAF patents, even with PTE, is 9.5-years (November 2015 to April 2025).



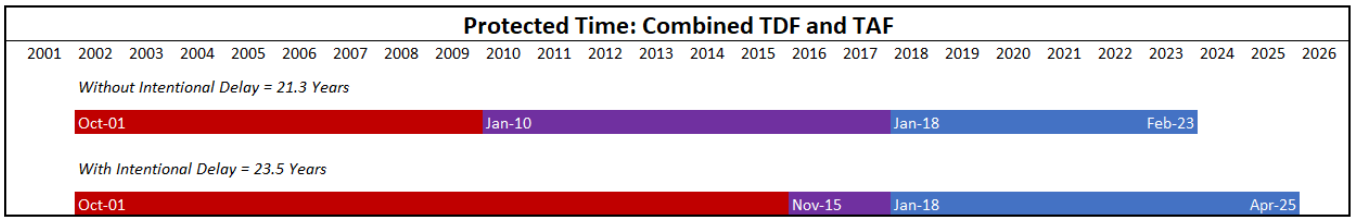
360. Viewed in isolation, and not as part of a broader anticompetitive scheme, Gilead's intentional delay in developing/approving TAF made no economic sense for Gilead. The delay delivered only 9.5 years of exclusivity rather than the 12 years that Gilead could have achieved absent the delay.

361. In fact, however, the intentional delay made perfect economic sense for Gilead, precisely because, and only because, it was part of Gilead's overall monopolization scheme. When deciding to pause the development of TAF in 2004, Gilead already knew that it would dominate Tenofovir sales, and consequently monopolize the relevant markets, by dominating TDF. Using the No-Generics Restraints and other anticompetitive tactics to unlawfully protect TDF and TDF-based products from competition, Gilead could safely put TAF on the shelf until generic competition to TDF occurred far in the future.

[1] The applicant is entitled to PTE for the time it loses in the development and the approval process only after the patent has issued. 35 U.S.C. § 156(c). The '791 Patent issued in June 2008 and the '788 Patent issued in September 2010. Assuming the same product-development and FDA review periods as actually occurred, Genvoya would have been approved in January 2010, so Gilead would have been eligible for only a year of PTE on the '791 patent and none on the '788 patent.

362. When entry of generic TDF finally became imminent, Gilead could implement the next phase of its monopolization scheme: transitioning its Tenofovir franchise from TDF-based to TAF-based products. In November 2010, just as Gilead was taking TAF out of mothballs, Gilead COO (and future CEO) confessed the scheme to investors: "I really think you could replace the whole Viread [TDF] franchise with 7340 [TAF] into the second half of this decade and that could provide a great deal of longevity for that." He emphasized to investors that "our ability to develop and get [TAF] onto the market prior to patent expiration [for TDF] will be key to us, to maintain the longevity."

363. Delaying the development/approval of TAF made economic sense for Gilead because it was part of a monopoly-extension scheme. The TAF delay increased the *combined* period of time in which Gilead *Tenofovir*-based (TDF *or* TAF) products would be both on the market and protected by *either* the TDF or the TAF patents. With the intentional delay in developing/approving TAF, that combined period of time, with PTE, will be 23.5 years (October 2001 to April 2025). Without the intentional delay (the first marketing of a TAF-based product occurring in January 2010), the combined period of time, with PTE, would have been 21.3 years (October 2001 to February 2023).



364. These facts lead to two unmistakable conclusions. First, as shown in the top figure above, Gilead's intentionally delaying TAF avoided the overlapping TDF/TAF period shown in purple. The delay enabled Gilead to withhold TAF from the market until the very last moment, ensuring that it maximized the *combined* period of market exclusivity for TDF/TAF, even though it considerably shortened the period for TAF considered alone.

365. Second, the difference in combined periods of exclusivity—with the delay versus without—is 2.2 years. Thus, the three years of additional exclusivity that Gilead will obtain is *essential* to making Gilead's anticompetitive delay-and-switch tactics work.

366. Other facts reinforce that conclusion. The patentee is entitled to PTE only for the time it

loses in the development and the approval process *after the patent has issued*. 35 U.S.C. § 156(c). In filings made with the PTO in order to get PTE, Gilead acknowledged that it began preparing to reactivate its TAF IND on September 28, 2010. That is exactly the day that the PTO issued the second of the TAF patents, the '788 Patent. That timing confirms that Gilead intentionally delayed TAF development and approval, and that obtaining PTE on one of the TAF patents was essential to making that delay-and-switch tactic work.

367. Gilead's conduct is both a perversion of the Hatch-Waxman Act PTE provisions and exclusionary conduct under Section 2 of the Sherman Act. Gilead obtained the three-year PTE despite having intentionally delayed the development and approval of TAF. But PTE is specifically intended to compensate patentees who lose patent-protected time on the market due to regulatory delays, through no fault of their own. And the delay-and-switch tactic, of which getting the PTE is an inextricable part, made economic sense for Gilead solely because it was part of an anticompetitive monopolization scheme.

368. The combination of Gilead's intentional delay and obtaining PTE on the '791 Patent is unlawfully exclusionary conduct in the context of some or all of the following circumstances:

a. Gilead intentionally delayed the clinical development and request for FDA approval of TAF;

b. Gilead intentionally delayed the clinical development and request for FDA approval of TAF for the purpose of extending a monopoly that Gilead obtained and maintained, in substantial part, by means of the intentional delay;

c. Gilead intentionally delayed the clinical development and request for FDA approval of TAF until after the '791 Patent and the '788 Patent had issued;

d. Gilead intentionally delayed the clinical development and request for FDA approval of TAF where the delay made economic sense for Gilead only as part of a scheme to impair competition; and

e. Gilead obtained the PTE as part of an overall scheme to monopolize one or more relevant antitrust markets.

369. Gilead's PTE-related conduct caused and, unless remedied by this Court will continue to cause, massive harm to Plaintiffs and the Class. As noted in detail above, TAF has a substantially lower

incidence than TDF of significant adverse side effects. Gilead itself sponsored research that concluded that requiring patients to take TDF-based rather than TAF-based products likely resulted in more than 16,000 excess deaths and 150,000 excess kidney, bone, and renal injuries over a nine-year period. *See Am J Manag Care.* 2018;24 (Spec. Issue No. 8): SP322-SP328. In treatment for pre-exposure prophylaxis, Gilead told the FDA that TAF-based Descovy has an "[i]mproved renal and bone safety profile compared with [TDF-based] Truvada." *See Descovy for PrEP*, Antimicrobial Drugs Advisory Committee Meeting, NDA 208215/S-012 (Aug. 7, 2019) at CC-19, CC-59.

370. By delaying TAF and obtaining PTE on the '791 Patent, Gilead prevented, and unless enjoined by this Court will continue to prevent, Plaintiffs and members of the Class from obtaining superior products at prices similar to or lower than those of the inferior products they in fact purchased.

VIII. MARKET POWER

371. At all relevant times, Gilead had market power over each of Viread, Emtriva, Truvada, Vemlidy, Descovy, Tybost, Stribild, Genvoya, and their generic equivalents; Gilead and BMS had market power over each of Atripla and Evotaz and their generic equivalents; Gilead and Janssen had market power over each of Complera, Odefsey, Prezcobix, and Symtuza and their generic equivalents; BMS had market power over Reyataz and its generic equivalents; and Janssen had market power over each of Edurant and Prezitsa and their generic equivalents. The Defendants had the power to maintain the price of those brand drugs at supracompetitive levels without losing sufficient sales to other products, except for AB-rated generic versions of those brand drugs, to make the supracompetitive prices unprofitable.

372. A small but significant, non-transitory increase in the brand drugs' price above the competitive level did not cause a loss of sales sufficient to make the price increase unprofitable. At competitive prices, none of the brand drugs exhibits significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of the brand drugs.

373. Each of the brand drugs is differentiated from all drug products other than AB-rated generic versions. Due to, among other reasons, its use and varying ability to treat the conditions for which it is prescribed, and its side-effects profile, each of the brand drugs is differentiated from all drug

products other than AB-rated generic versions.

374. Additionally, once the physician and patient find that one of these drugs is well tolerated, at competitive prices the doctor and patient are very unlikely to switch to a different HIV drug based on variations of price of 10% or less.

375. The Defendants' power to profitably raise these prices to the competitive level results in substantial part from a significant imperfection in the United States marketplace for prescription pharmaceuticals. Branded drug manufacturers can exploit this imperfection in order to obtain or maintain market power.

376. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and payment obligation, the product's price plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to reduce their prices to the competitive level.

377. The pharmaceutical marketplace, however, is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including all of those at issue in this complaint, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while the patient (and in most cases his or her insurer) has the obligation to pay for it.

378. Brand manufacturers, including Gilead, BMS, and Janssen, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of costs, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

379. The relative unimportance of price in the pharmaceutical marketplace reduces the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price-elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost

without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is market power. The result of these pharmaceutical marketplace imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including all of those at issue in this complaint.

380. The existence of other branded HIV drugs has not constrained the price of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, or Symtuza to the competitive level.

381. Each Defendant needed to control only each of its brand drugs and its AB-rated generic equivalents, and no other products, in order to maintain the price of the brand drug profitably at supracompetitive prices. Only the market entry of a competing, AB-rated version of the brand drug would render the brand manufacturer unable to profitably maintain its brand-drug prices at supracompetitive levels.

382. Defendants sold these brand drugs at prices well in excess of marginal costs, substantially in excess of the competitive price, and enjoyed unusually high profit margins.

383. Defendants had the ability to control the prices of these drugs and exclude relevant competitors. Among other things: (a) generic versions of each drug would have entered the market at substantial discounts to the brands but for the Defendants' anticompetitive conduct; (b) the gross margin on each drug was at all times at least 70%; and (c) Defendants never lowered the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs.

384. At all relevant times, Gilead's gross profit margin on its cART drugs, collectively, has exceeded 75% and has reached as high as 91%. These margins are approximately 15 times those that indicate substantial market power.

385. To the extent that Plaintiffs are required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant product market depends on the practice that the court is examining.

386. At least two types of markets are relevant here: (a) the market for each of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz,

Prezista, Prezcobix, Edurant, and Symtuza and its AB-rated generic equivalent; and (b) the cART Market.

387. As noted in detail above, the purpose and effect of Defendants' No-Generics Restraints was to impair competition in multiple ways. To the extent that Plaintiffs are required to define a relevant market in which that conduct is evaluated, it is properly evaluated in multiple markets.

A. The Market for Specific cART Drugs

388. One purpose and effect of Defendants' No-Generics Restraints was to impair competition from generic versions of each of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, and Symtuza. Similarly, a purpose and effect of Gilead's degrading of Stribild and standalone TAF and regulatory gaming with respect to standalone TAF was to impair competition from generic versions of Stribild and standalone TAF and generic versions of TAF-containing FDCs, and a purpose of Gilead's delaying the entry of generic versions of Viread, Truvada, and Atripla was to impair competition from generic versions of those products.

389. A relevant market for evaluating that conduct is the market for each of those products and its AB-rated generic equivalent. As demonstrated by the indicia noted above:

- from October 2001 to December 17, 2017, Gilead had market power in the market for Viread and its AB-rated generic equivalents, and during that time had 100% of the shares of that market:
- from November 10, 2016 to the present Gilead has had market power in the market for Vemlidy and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;
- from April 4, 2016 to the present Gilead has had market power in the market for Descovy and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;
- from July 7, 2003 to the present Gilead has had market power in the market for Emtriva and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;
- from September 2014 to the present Gilead has had market power in the market for Tybost and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;
- from August 2, 2004 to the present Gilead has had market power in the market for

Truvada and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

- from July 12, 2006 to the present Gilead and BMS have had market power in the market for Atripla and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from August 10, 2011 to the present Gilead and Janssen have had market power in the market for Complera and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from March 1, 2016 to the present Gilead and Janssen have had market power in the market for Odefsey and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from August 27, 2012 to the present Gilead has had market power in the market for Stribild and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from November 5, 2015 to the present Gilead has had market power in the market for Genvoya and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from June 20, 2003 to December 2017 BMS had market power in the market for Reyataz and its AB-rated generic equivalents, and during that time had 100% of the shares of that market;

- from April 4, 2014 to the present Gilead and BMS have had market power in the market for Evotaz and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from June 23, 2006 to the present Janssen has had market power in the market for Prezista and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

- from March 31, 2014 to the present Gilead and Janssen have had market power in the market for Prezcobix and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

- from May 20, 2011 to the present Janssen has had market power in the market for Edurant and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market; and

- from September 22, 2017 to the present Gilead and Janssen have had market power in the market for Symtuza and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market.

390. Defendants also had market power during relevant times in broader markets comprising the branded drug and comparable versions of it. For example, Gilead and Janssen have market power in the market for Complera and comparable versions made of genericTDF/3TC/RPV, and have market power in the market for Symtuza and comparable versions made of genericTAF/genericFTC (or 3TC)/RTV/DRV.

B. The Market for cART Drugs

391. Another purpose and effect of Defendants' No-Generics Restraints was to impair competition among drugs used in the cART regimen. That was also one of the purposes and effects of Gilead's degrading (and supra-profit-maximizing pricing) of Stribild, degrading of standalone TAF, regulatory gaming with respect to standalone TAF, delaying the entry of generic versions of Viread, Truvada, and Atripla, and unlawful TAF patent delay-and-extend. To the extent that Plaintiffs are required to define a relevant market in which that purpose and effect is evaluated, it is properly evaluated in the market for such drugs, i.e., the cART Market, and narrower markets therein.

392. As noted in detail above, a cART regimen is a course of treatment distinct from other drugs and regimens that might be used to treat HIV. The term "cART drugs" refers to all antiretroviral drugs used in the treatment of HIV as part of a combination therapy. Demand for cART drugs is a function of demand for combination therapies that can effectively treat HIV. Active pharmaceutical ingredients (APIs) used to treat HIV may be available in standalone form and/or as fixed-dose combinations – but they are inputs into combination treatment and not treatments by themselves. The cART drugs that comprise the cART Market include Agenerase, Aptivus, Atripla, Biktarvy, Cimduo, Combivir, Complera, Crixivan, Delstrigo, Descovy, Dovato, Edurant, Emtriva, Epivir, Epzicom, Evotaz, Fortovase, Fuzeon, Genvoya, Hivid, Intelence, Invirase, Isentress, Juluca, Kaletra, Lexiva, Norvir, Odefsey, Odefsey, Pifeltro, Prezcobix, Prezista, Rescriptor, Retrovir, Retrovir Iv Inf, Reyataz, Selzentry, Stribild, Sustiva, Symfi, Symtuza, Temixys, Tivicay, Triumeq, Trizivir, Trogarzo, Truvada, Tybost, Videx, Viracept, Viramune, Viread, Vitekta, Zerit, Ziagen, and their AB-rated generic substitutes.

393. Effective cART reduces the concentration of HIV virus in treated patients to undetectable levels. Patients on effective cART can live healthy lives and have a normal life expectancy. And a patient

living with HIV who maintains an undetectable viral load durably cannot transmit the virus to others. Under the guidelines of the HHS, WHO, and all major HIV-treatment organizations, every HIV treatment regimen, with inconsequential exceptions, is a cART regimen.

394. From a clinical perspective, the antiretroviral drugs used in a cART regimen are reasonably interchangeable with respect to their use. Although different types of antiretrovirals target different steps in the HIV life cycle, all of them are used to prevent successful reproduction of the HIV virus. In treating HIV, doctors and patients choose among the drugs that comprise the cART market.

395. In addition to interchangeability of use, price competition—though weak—exists among drugs within the cART market. For the reasons noted in detail above, price competition in many prescription drug therapeutic classes tends to be weak. That is true in the cART market, with doctors and patients selecting among brand-drug antiretrovirals based principally on clinical criteria rather than price. But price competition among brand cART drugs is not altogether absent.

396. Without that price competition, however weak, prices of brand cART drugs would be even higher than they are. The existence of this broader market imposes some price constraints on brand cART drugs but without approximating the more competitive prices that generic versions of each of the brand drugs would generate. This limited price competition imposes a limited constraint on brand cART drug prices. The fact that this price competition is *limited* means that each of the brand cART drugs has market power (is priced above the level that a generic version of the drug would generate); the fact that *some* price competition exists means that brand cART drug prices would be even higher without it.

397. Gilead's dominance of the cART market lessens the degree of price competition that might otherwise exist among branded cART drugs. It is well-recognized that a monopolist raises price until some economic substitution makes further price increases unprofitable. This substitution comes from products that may have been weak substitutes at competitive prices, but at the monopolist's supracompetitive prices may become viable alternatives for consumers. At a high enough price, even otherwise less-than-ideal substitutes look good to purchasers.

398. In this case, many of these "viable alternatives" are also controlled by Gilead. Gilead sells not one but a portfolio of cART products. When reacting to substitution to other products, the monopolist limits the price rise if the substitution goes to competitors. If consumers responsd to a price increase on a

particular drug by moving to another one of the monopolist's products, the monopolist is not hurt at all, and this form of substitution does not constrain its pricing power.

399. In economics, it is well established that a monopolist selling two substitute products will raise price higher than would two firms, each with a monopoly on the products individually. With a portfolio of cART drugs, Gilead has another layer of market power over and above the more usual brand manufacturer's ability to price its product above the generic-level price. With its portfolio backstopping substitution away from any individual drug, Gilead can—and did—elevate prices above the level at which a typical brand manufacturer would have been able to price its product above generic-level prices.

400. As alleged in detail above, the Defendants significantly impaired competition among the brand drugs used in the cART regimen. To the extent that Plaintiffs are required to define the market in which that conduct is evaluated, the relevant market is the cART market. Defining a broad relevant market for this purpose is consistent with decades of antitrust jurisprudence and analysis. For example, when antitrust authorities examine the likely effect of mergers between brand-drug manufacturers, they often define broad markets that include all or many of the drugs within a therapeutic class.

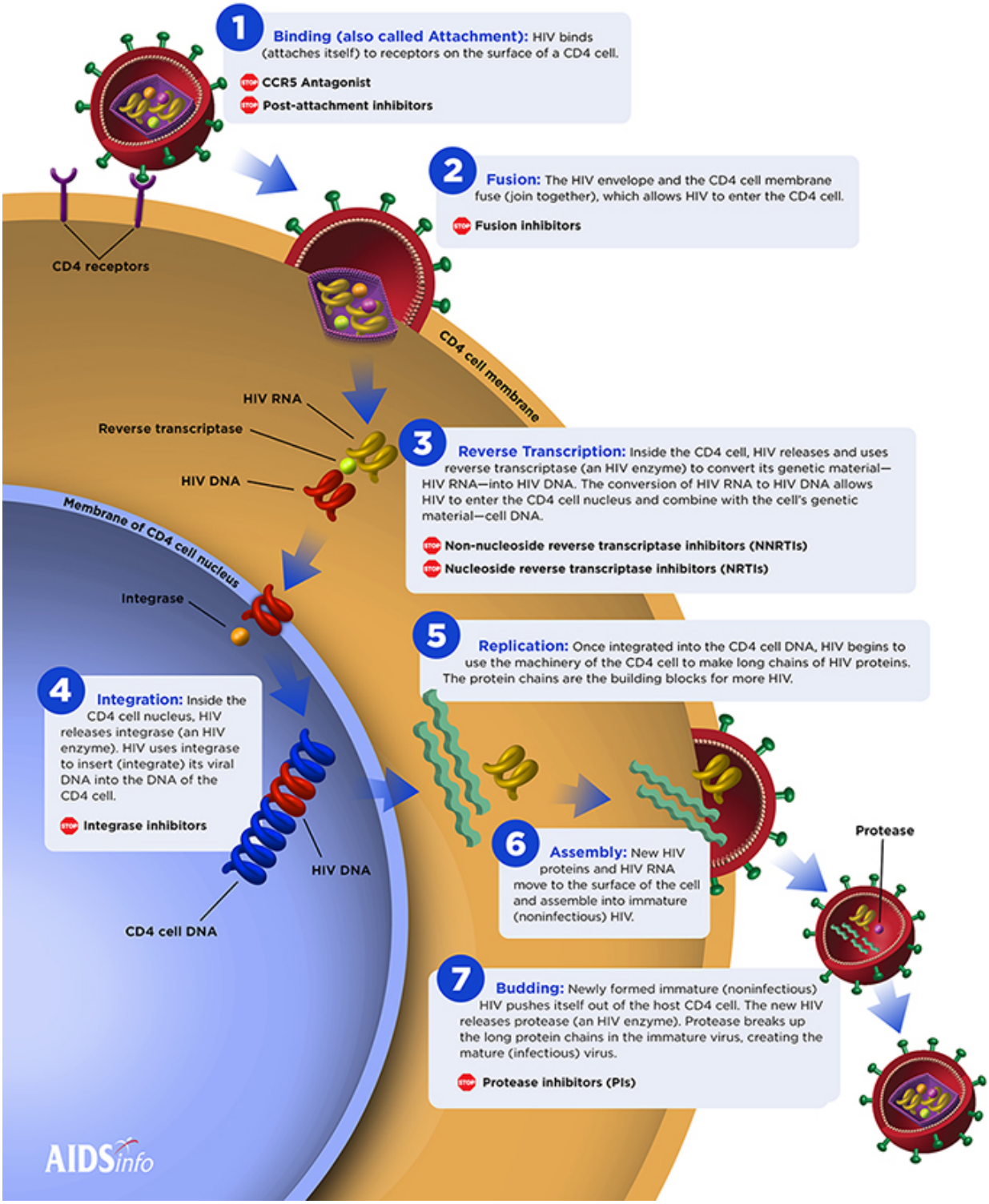
1. Gilead Dominates the Market for cART Drugs

401. Modern antiretroviral drug regimens comprise a combination or "cocktail" of drugs, most often consisting of two NRTIs taken with at least one third agent, such as an integrase inhibitor. These combinations of antiretrovirals create multiple obstacles to HIV replication, all but eliminating the probability that the virus will successfully produce a mutation that is resistant to all of the drugs in the cocktail. Thus, the standard of care is to use combinations of antiretroviral drugs, referred to as a "cART regimen."

402. The U.S. Department of Health and Human Services ("HHS") regularly publishes widely followed prescribing Guidelines for treatment of HIV. The Guidelines illustrate the interchangeability of use of different types of cART drugs. Various iterations of the Guidelines have recommended regimens that include as alternative third agents Non-Nucleoside Reverse Transcriptase Inhibitors, Integrase Strand Transfer Inhibitors, and Protease Inhibitors, with the doctor free to choose among them. The Guidelines have also recommended as alternative regimens those that include only APIs such as those instead of (rather than in addition to) NRTIs.

403. These various types of antiretroviral agents attack the HIV virus at different stages of its lifecycle. HIV is a retrovirus that infects the "host" cell in order to make copies of itself. CD4 cells are the prime targets, with the HIV virus binding to, and infecting, CD4+ cells. After the cell is infected, it produces secondary HIV virions, gradually depleting the host's population of CD4+ cells. This ultimately depletes the infected person's ability to trigger an immune defense, leaving the body vulnerable to opportunistic infections.

404. The principal steps in the HIV lifecycle, and the types of antiretroviral drugs that target the virus at each of those steps, is depicted here:


The HIV Life Cycle
HIV medicines in seven drug classes stop (STOP) HIV at different stages in the HIV life cycle.
1 Binding (also called Attachment): HIV binds (attaches itself) to receptors on the surface of a CD4 cell.
CCR5 Antagonist
Post-attachment inhibitors
CD4 receptors
2 Fusion: The HIV envelope and the CD4 cell membrane fuse (join together), which allows HIV to enter the CD4 cell.
Fusion inhibitors
CD4 cell membrane
HIV RNA
Reverse transcriptase
HIV DNA
3 Reverse Transcription: Inside the CD4 cell, HIV releases and uses reverse transcriptase (an HIV enzyme) to convert its genetic material—HIV RNA—into HIV DNA. The conversion of HIV RNA to HIV DNA allows HIV to enter the CD4 cell nucleus and combine with the cell's genetic material—cell DNA.
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
Nucleoside reverse transcriptase inhibitors (NRTIs)
Membrane of CD4 cell nucleus
Integrase
5 Replication: Once integrated into the CD4 cell DNA, HIV begins to use the machinery of the CD4 cell to make long chains of HIV proteins. The protein chains are the building blocks for more HIV.
4 Integration: Inside the CD4 cell nucleus, HIV releases integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of the CD4 cell.
Integrase inhibitors
HIV DNA
CD4 cell DNA
6 Assembly: New HIV proteins and HIV RNA move to the surface of the cell and assemble into immature (noninfectious) HIV.
Protease
7 Budding: Newly formed immature (noninfectious) HIV pushes itself out of the host CD4 cell. The new HIV releases protease (an HIV enzyme). Protease breaks up the long protein chains in the immature virus, creating the mature (infectious) virus.
Protease inhibitors (PIs)
AIDSinfo

405. The initial step of HIV viral entry is the attachment of the virus to the CD4 molecule located on the host cell. Once bound, the virus fuses with the cell membrane and transfers the nucleocapsid containing viral RNA into the host cell cytoplasm.

406. *Entry Inhibitors* interfere with the receptor-mediated entry of the virus into a cell. Two subclasses of drugs known as “fusion inhibitors” and “CCR5 antagonists” interfere with the binding, fusion, and entry process of HIV into a human cell by blocking one of several targets. The principal fusion inhibitor is enfuvirtide (Fuzeon), and the principal CCR5 antagonist is maraviroc (Selzentry). Compared to other leading antiretrovirals, these types have significant drawbacks, including the need for twice-daily injections (enfuvirtide) or an expensive patient-specific test to determine efficacy (maraviroc). They are not recommended as part of any of the HHS-recommended first-line cART regimens.

407. As noted above, HIV is an RNA virus and therefore unable to become directly integrated into the DNA in the nucleus of the human cell. The HIV virion must be "reverse" transcribed into DNA via the viral protein “reverse transcriptase.” That enzyme allows the virion to convert its single-stranded RNA into double-stranded DNA.

408. *NRTIs* (Nucleoside/Nucleotide Reverse Transcriptase Inhibitors) work by preventing other nucleosides from being incorporated into the HIV DNA that the virion is trying to build up. Essentially, they terminate the DNA chain. Modern cART regimens usually include two NRTIs: (1) one of TDF, TAF, or 3TC, and (2) one of FTC or abacavir. HIV virions that are resistant to an NRTI of the first group are typically susceptible to an NRTI of the second group, and vice-versa. Compared to other leading antiretrovirals, NRTIs have significant advantages, including a long history of success when co-administered with a third agent. During the relevant period, they have been recommended as part of nearly all of the HHS-recommended first-line cART regimens. The principal NRTIs are Gilead’s TDF, TAF, and FTC, which were APIs in more than 79% of prescriptions containing one or more NRTIs in 2014-19.

409. Doctors and patients using a cART regimen almost always choose two NRTIs. For very substantial medical reasons, doctors and patients overwhelmingly choose Tenofovir as one of those two

NRTIs. Among other reasons, all other NRTIs are triple phosphorylated by host kinases to be activated. Tenofovir, by contrast, needs to be phosphorylated only twice by host kinases, into its active form, tenofovir diphosphate (TFV-DP). (See Section V above.) The following chart identifies all NRTIs that have been available in the United States since 1987.

Drug Name	Symbol	Date of Approval	Manufacturer	Notes
Zidovudine (Retrovir)	AZT	Mar, 19 1987	ViiV (Burroughs Wellcome)	Used less commonly due to side effects.
Didanosine (Videx)	ddI	Oct, 9 1991	Bristol-Myers Squibb	Not used commonly due to side effects\inferiority
Zalcitabine (Hivid)	ddC	June 22, 1992	Roche	DISCONTINUED in 2001 due to toxicity
Stavudine (Zerit)	d4T	June 24, 1994	Bristol-Myers Squibb	Usage strongly discouraged by WHO
Lamuvidine (Epivir)	3TC	November 17, 1995	ViiV (Glaxo)	Interchangeable with FTC if used as HIV treatment
Abacavir (Ziagen)	ABC	December 18, 1998,	ViiV (Glaxo)	Cannot be used in patients in HLA-B*5701 + pts.
Tenofovir Disoproxil Fumarate	TDF	October 26, 2001	Gilead	
Emtricitabine	FTC	July 02, 2003	Gilead	Interchangeable with FTC if used as HIV treatment
Tenofovir Alafenamide Fumarate	TAF	November 5, 2015	Gilead	**First approved as a single table regimen (Genvoya)**

410. Zidovudine is not a significant competitor to Tenofovir because of Zidovudine's impact on the bone marrow, gastrointestinal side effects, mitochondrial toxicity, and inferior antiviral potency when used with some third agents. In 2018, Zidovudine's United States sales, including when coformulated with 3TC, were less than $60 million.

411. Didanosine is not a significant competitor to Tenofovir because of Didanosine's tendency to cause peripheral neuropathy and pancreatitis, the requirement that it be taken on an empty stomach, and its inferior antiviral potency when used with some third agents. In 2018, Didanosine's sales in the United States were less than $2 million.

412. In 2001, all United States sales of Zalcitabine were halted due to toxicity side effects.

413. The WHO strongly discourages doctors from prescribing Stavudine (d4T) due to

lipodystrophy, peripheral neuropathy, and other severe side effects. Stavudine's United States sales were less than $3 million in 2018.

414. For many doctors and patients, abacavir is not a realistic substitute for Tenofovir in a cART regimen. Gilead noted at a 2016 investors conference, for example, that "[a]bacavir is a molecule that is the most difficult of the … [NRTIs] to administer and has both short-term and long-term problems associated with it."

415. Specifically, a substantial number of patients are HLA-B*5701 positive, meaning that they are at an increased risk of a hypersensitivity reaction to abacavir, resulting in a severe systemic illness that can result in death. Consequently, doctors will not prescribe abacavir to patients without first requiring that they get either a blood test or cheek-swab test to screen them for HLA-B*5701. This dissuades many doctors from prescribing abacavir and prevents them altogether from starting patients on abacavir without the required screening. This is a significant barrier to treatment. Most modern treatments programs are based on the "test and treat" paradigm in which doctors encourage patients to begin HIV treatment on the day they are diagnosed, so they will not subsequently be lost to follow up.

416. At all relevant times, Gilead's dominance with respect to Tenofovir allowed it to exercise market power in the cART Market. From October 26, 2001 through December 15, 2017, Gilead had 100% of the unit shares of all sales in the United States of Tenofovir. Even after the entry of generic TDF in December 2017, Defendants' unlawful conduct has allowed Gilead to maintain at least 93% of all prescriptions containing Tenofovir in the United States. And Defendants' unlawful conduct has allowed Gilead to maintain its share of prescriptions containing NRTIs in the United States at an average of more than 79%, and never less than 76%, in the period from 2014 to 2019.

417. *Non-Nucleoside Reverse Transcriptase Inhibitors* (NNRTIs) also attack the HIV virus at the third step depicted above. Unlike NRTIs, NNRTIs interfere with reverse transcription by directly binding to the reverse transcriptase enzyme and retarding its function. Compared to other leading antiretrovirals, NNRTIs have significant disadvantages, including significant side effects and a relatively low genetic barrier for the development of resistance. The principal NNRTIs include efavirenz, which is the sole API in BMS's Sustiva and is also an API in Gilead/BMS's Atripla, and rilpivirine, which is the sole API in Janssen's Edurant and is also an API in Gilead/Janssen's Complera and Odefsey.

Defendants' unlawful conduct allowed Gilead to maintain its share of prescriptions containing NNRTIs in the United States at an average of more than 80%, and never less than 77%, in the period from 2014 to 2019.

418. Converting its RNA to DNA allows the HIV virion to enter the nucleus of the CD4 cell. There, the HIV virion uses its enzyme "integrase" to inserts its DNA into that of the CD4 cell. This is a key part of the HIV-replication process.

419. *Integrase Strand Transfer Inhibitors* ("INSTIs") prevent HIV integrase from incorporating viral DNA into the human host cell, thereby halting the HIV strand transfer. Compared to other leading antiretrovirals, INSTIs have significant advantages because they have no human homolog, allowing the drug to precisely target the HIV virion, leading to superior efficacy and minimal toxicity. Today they are recommended as part of all five of the HHS-recommended first-line cART regimens. The principal INSTIs are elvitegravir, which is the sole API in Gilead's Vitekta and is an API in Gilead's Stribild and Genvoya; bictegravir, which is an API in Gilead's Biktarvy; dolutegravir, which is the sole API in Viiv's Tivicay and is an API in ViiV's Triumeq and Dovato; and raltegravir, which is the sole API in Merck's Isentress. Defendants' unlawful conduct allowed Gilead to grow its share of prescriptions containing INSTIs in the United States from 30% in 2014 to 55% in 2019.

420. After HIV has integrated itself into the infected cell's DNA, the infected cell transcribes the proviral HIV genome into messenger RNA ("mRNA") which codes for specific viral proteins. This mRNA is converted or "translated" by the infected cell's ribosomes into viral proteins. These viral proteins are not initially functional and are known as "polyproteins." They must be processed by another viral enzyme, HIV protease, which breaks the initially translated polyproteins into their constituent parts.

421. *Protease Inhibitors* ("PI"s) act as competitive inhibitors that directly bind to HIV protease and prevent it from subsequently breaking up the initially translated polyproteins, thus preventing the secondary virions from being infectious. Compared to other leading antiretrovirals, PIs have significant disadvantages, including that in long-term treatment they tend to be have side effects such as inducing metabolic syndromes (e.g., dyslipidemia, insulin-resistance, and lipodystrophy/lipoatrophy) and cardiovascular and cerebrovascular diseases. There are currently 8 PIs, including atazanavir, which is the sole API in BMS's Reyataz and is an API in Gilead/BMS's Evotaz; and darunavir, which is the sole API

in Janssen's Prezista and is an API in Gilead/Janssen's Prezcobix and Symtuza. Defendants' unlawful conduct allowed Gilead to grow its share of prescriptions containing PIs in the United States from 45% in 2014 to 65% in 2019.

422. When a doctor is trying to decide how to treat an HIV patient, these five types of antiretroviral drugs are the tools that she has in her toolbox (with one of the types—Entry Inhibitors—playing a substantially less important role than the others). From a clinical perspective, doctors and patients decide which of the antiretrovirals to use based on, among other considerations, their efficacy, complexity of use, and side-effect profile. Different types of antiretrovirals may be called for based on the patient's pregnancy, coinfection with hepatitis B virus or hepatitis C virus, or history of drug-resistance or adverse effects. A host of considerations can tip the decision one direction or another.

423. As noted above, HHS prescribing Guidelines often play a role in the doctor's drug-product selection. Confirming the interchangeability of use of the principal cART drugs, throughout the relevant period the HHS Guidelines included among their preferred or alternative regimens NRTIs, NNRTIs, PIs, and INSTIs. Throughout the relevant period, almost all of the preferred regimens included two NRTIs, and Gilead's products dominated the NRTIs in the preferred regimens. Moreover, Gilead always controlled at last one of the preferred third agents. The following chart summarizes much of the relevant information in the HHS Guidelines:

HHS GUIDELINES: 2012 – 2019

Month/Year	**Number of Preferred Regimens**	**Number of Preferred Regimens Requiring Two NRTIs**	**Gilead Control of Recommended NRTIs in Preferred Regimens**	**Preferred or Alternative Regimen Includes All Four ARV Types***	**Gilead Controls at Least One Preferred Third Agent**
March 2012	4	4	100%	Yes	Yes
Feb. 2013	4	4	100%	Yes	Yes
May 2014	7	7	86%	Yes	Yes

Nov. 2014	7	7	86%	Yes	Yes
July 2016	5	5	80%	Yes	Yes
Oct. 2017	4	4	75%	Yes	Yes
Oct. 2018	4	4	75%	Yes	Yes
July 2019	4	4	75%	Yes	Yes
Dec. 2019	5	4	62%	Yes	Yes

- The four relevant ARV types are NRTIs, NNRTIs, PIs, and INSTIs.

424. With respect to price competition among branded products in the cART market, formularies and other cost-containment measures have achieved only modest success in constraining the prices of brand cART drugs. Rebates and other price discounts granted by brand cART manufacturers to commercial insurers for favorable formulary placement average less than 10% off of the list price.

425. The net prices of all branded cART drugs are far more than 10% higher than they would have been absent Defendants' unlawful conduct. Defendants' cART drugs have extraordinarily high prices, and have had extraordinary price increases. These prices and price increases are reflected in these per-tablet prices for all of Defendants' cART drugs that were on the market for the full period from 2014 through 2019:

DEFENDANT PER-PILL PRICES
2014:Q1 – 2019:Q4

DRUG	PRICE 2014	PRICE 2019	PERCENT INCREASE
Atripla	$57.04	$81.18	42.3%
Complera	$58.40	$81.73	39.9%
Edurant	$23.75	$31.49	32.6%
Emtriva	$15.15	$15.80	4.3%

Prezista	$17.42	$23.70	36.1%
Reyataz	$34.08	$40.57	19.0%
Stribild	$72.77	$96.66	32.8%
Sustiva	$21.51	$27.59	28.3%
Truvada	$36.00	$48.53	34.8%
Viread	$26.48	$35.50	34.1%

Source: IQVIA NSP data, price per pill for the most commonly prescribed dose

426. During the same timeframe—2014 to 2019—the total increase in the Consumer Price Index was only 9%. That is, starting at already astronomical prices per pill in 2014, Defendants' cART drugs increased on average at a rate about 4 times the CPI. And they increased at a rate about double that of the all-prescription-pharmaceutical average. Defendants' unlawful conduct also allowed them to introduce their more recent products at even more outrageous prices. For example, the 2019 per-pill prices were $92.61 for Gilead's Biktarvy and $92.01 for its Genvoya, and $111.66 for Gilead/Janssen's Symtuza.

427. Other branded cART drugs, not sold by these Defendants, have followed the Defendants' cART drugs up in price. Given Gilead's dominance of the cART market, the monopoly prices on its products had the predictable effect of causing its competitors to raise prices on their cART drugs. For example, from July 2011 to October 2017, Gilead raised its price on Complera by 45%. During that same period, ViiV Healthcare raised the price of Selzentry (a CCR5 coreceptor antagonist) by 47%. Likewise, until it encountered generic competition Boehringer Ingelheim's NNRTI, Viramune XR, similarly followed Gilead's price increases up in lockstep. In fact, Defendants' unlawful monopolization of the cART market caused the price of every drug in the market to be substantially higher than it would have been absent that conduct.

428. The result of Defendant's unlawful conduct has been extraordinary price inflation in the cART market as a whole. In 2012, the annual price of a cART regimen recommended for treatment-naïve patients ranged from $24,970 to $35,160 and increased to $36,080 to $48,000 in 2018. In that time, the average annual price of cART recommended for most patients increased 34%.

429. In absolute dollars cART is the nation's fifth costliest therapeutic class. Moreover, cART drugs cost more per prescription than those in three of the four therapeutic classes that rank above it in absolute dollar spend (that is, three of the four have a greater dollar spend because there are far more prescriptions written for those drugs). Throughout the cART market, prices are far higher than they would have been absent the Defendants' anticompetitive conduct.

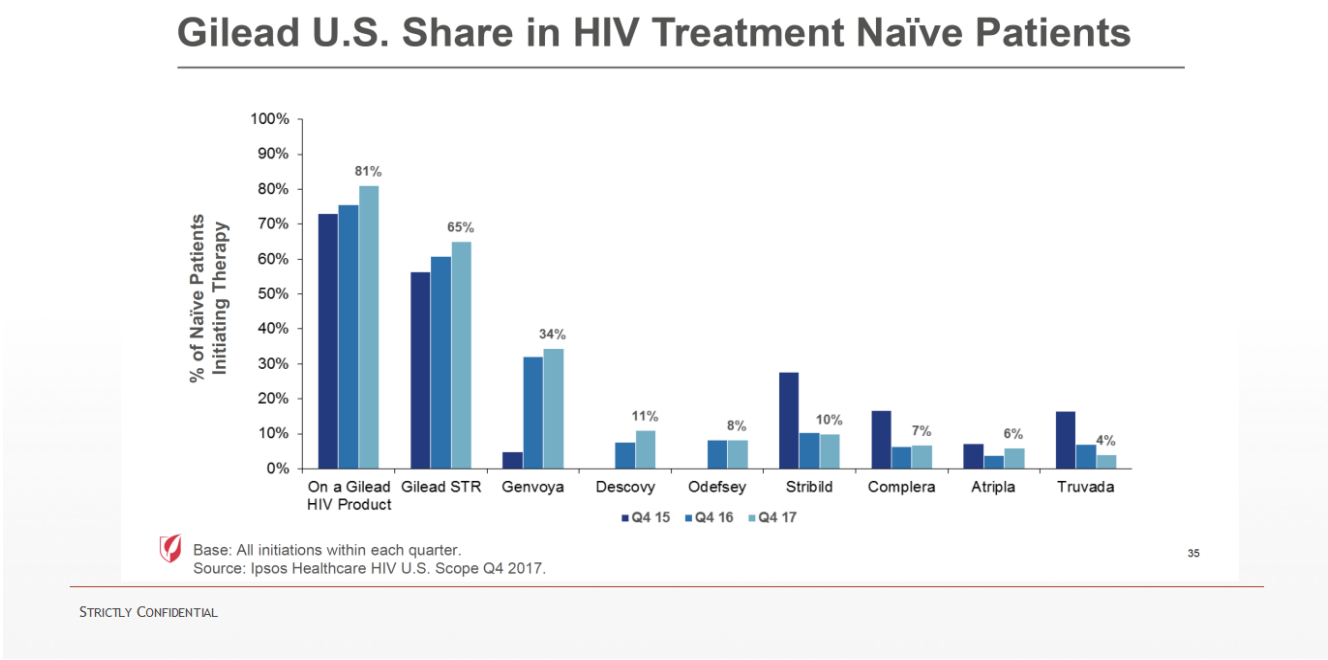
430. The very significant increases in the prices of cART drugs did not cause a loss of sales to non-cART drugs or other HIV treatments sufficient to make the price increase unprofitable. Indeed, the average annual price of the drugs used in cART therapy for most people with HIV increased by 34% from 2012 to 2018.

431. As noted above, certain cART drugs are also used to *prevent* HIV infection and for other treatment, such as for hepatitis B. Such drugs are part of the cART market regardless of other uses because the other uses did not (and do not) prevent Gilead and the other defendants from increasing their prices above the competitive level. For example, Gilead has charged the same supracompetitive price for Viread regardless of whether the patient bought the product for use in a cART regimen or for treatment of hepatitis B, and has charged the same supracompetitive prices for Truvada and Descovy regardless of whether the patient bought them for use in a cART regimen or for PReP.

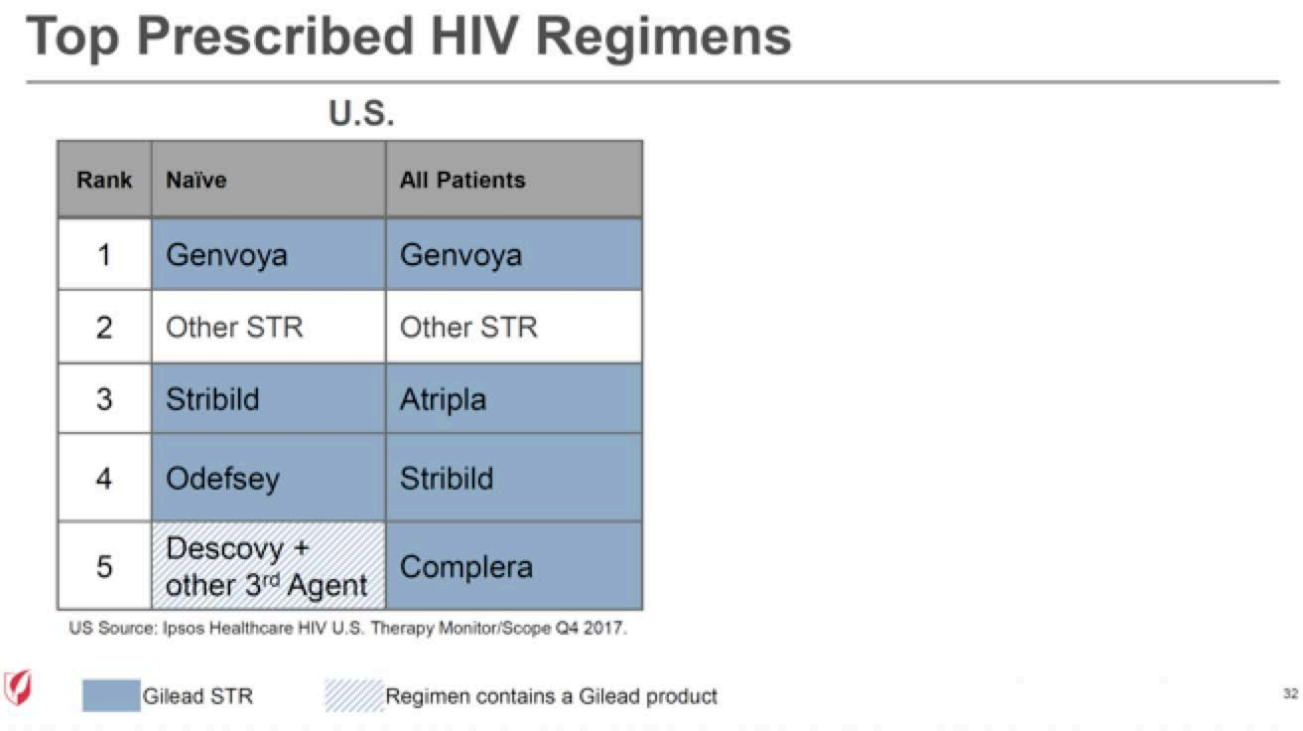
2. Gilead's Dominant Share

432. At all relevant times, Gilead's share of the cART market has exceeded 70% and was 75% in 2019. Gilead has repeatedly acknowledged, indeed touted, its monopoly share in the cART Market.

433. As early as 2007 Truvada and Atripla alone accounted for 82% of new starts in treatment-naïve (those new to therapy) HIV patients. And as recently as 2018 a Gilead presentation to investors highlighted the fact that 81% of treatment-naïve HIV patients regularly took at least one Gilead product. Gilead provided this chart:



434. In the same presentation, Gilead touted the fact that it produced and marketed four of the top five cART drugs for treatment-naïve patients and all patients in the United States:



435. Gilead's reference in the chart above to "STR" is to a Single-Tablet Regimen. An STR is a single tablet that contains all of the agents needed for a full cART regimen. For example, Odefsey is an STR comprising the two NRTI backbone components, TAF and FTC, plus the third agent RPV. Doctors and patients often prefer an STR to combinations of other pills because an STR reduces the patient's pill burden and can thereby increase compliance with the drug regimen.

436. Defendants' unlawful conduct allowed Gilead to maintain its share of prescriptions of STRs in the United States at an average of more than 81% in the period from 2014 to 2019. Gilead's share of STR prescriptions was never less than 75% during that period, and was more than 78% in 2019.

437. As noted above, Defendants' unlawful conduct has similarly allowed Gilead to dominate all other important subcategories of cART drugs. In 2019, Gilead had the following percentages of prescriptions in the United States:

GILEAD U.S. SHARES: 2019

DRUG TYPE	**% SHARE***
All cART Drugs	73%
NRTI	80%
NNRTI	71%
INSTI	55%
PI	65%
STR	78%

*Shares for "all cART drugs" based on dollar sales; all other shares based on prescriptions

438. At all relevant times, the Defendants were protected by high barriers to entry with respect to the above-defined relevant markets due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The

products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or may be covered by patents or other forms of intellectual property. Defendants' unlawful No-Generics Restraints and other unlawful conduct further restricted entry. Thus, existing and potential market entrants lack the ability to enter the market and/or expand output quickly in the short run in response to Defendants' higher prices or reductions in output.

439. The relevant geographic market for each of the drugs and each of the product markets is the United States and its territories.

IX. MARKET EFFECTS

440. Defendants willfully and unlawfully engaged in schemes for the anticompetitive purpose of delaying and impairing competition and thereby maintaining supracompetitive prices for their products.

441. Each scheme had the purpose and effect of restraining competition unreasonably and injuring competition by protecting the relevant products from competition. This exclusionary conduct in fact enabled Defendants to sell their products free from vigorous price competition. But for Defendants' unlawful conduct, each of the relevant drugs would already be facing competition from AB-rated drugs, would be facing competition from comparable FDCs, or would face such competition sooner than it will; competition in the cART Market would be substantially more vigorous than it is; Vemlidy and Stribild would be better products; and Defendants would have marketed better products sooner.

442. Defendants' unlawful conduct caused Plaintiffs and the Class to pay more than they would have paid for Defendants' drugs and other cART drugs absent that conduct.

443. Typically, AB-rated versions of branded drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon entry of the AB-rated drug it rapidly takes sales away from the originator drug. As more AB-rated versions of the branded drug enter the market, prices predictably plunge even further. Competition from an FDC that is comparable to, rather than AB-rated to, an FDC—e.g., one made with generic TDF and 3TC rather than TDF and FTC—also would have substantially reduced the relevant prices.

444. Absent Defendants' unlawful conduct, Plaintiffs and members of the Class would have paid less for the products by: (a) substituting purchases of less-expensive AB-rated versions of the products for purchases of more-expensive branded versions; (b) receiving discounts on their remaining branded purchases; (c) purchasing the AB-rated versions at lower prices sooner; (d) paying lower prices for FDCs comparable to those marketed by Defendants; and (e) obtaining superior products at prices similar to or lower than those of the inferior products they in fact purchased.

445. Given Gilead's dominance of the cART Market (see Section VIII above), the monopoly prices on its products had the predictable effect of causing its competitors to raise prices on their cART drugs. For example, from July 2011 to October 2017, Gilead raised its price on Complera by 45%. During that same period, ViiV Healthcare raised the price of Selzentry (a CCR5 coreceptor antagonist) by 47%. Likewise, until it encountered generic competition Boehringer Ingelheim's NNRTI, Viramune XR, similarly followed Gilead's price increases up in lockstep. In fact, Defendants' unlawful monopolization of the cART Market caused the price of every drug in the market to be higher than it would have been absent that conduct.

446. Defendants' unlawful conduct has harmed Plaintiffs and the Class and deprived them of the benefits of competition, and unless enjoined will further harm them by, among other things:

- Delaying and preventing competition from AB-rated competition to Defendants' products, thereby causing Plaintiffs and the Class to pay overcharges on those products;
- Delaying and preventing competition from FDCs comparable to Defendants' FDCs, thereby causing Plaintiffs and the Class to pay overcharges on Defendants' FDCs;
- Impairing generic competition to Viread, Emtriva, Truvada, Vemlidy, Descovy, Reyataz, Prezista, Edurant, and the TDF-based FDCs, thereby causing Plaintiffs and the Class to pay overcharges on those products and on Defendants' FDCs;
- Degrading and artificially raising the price of Stribild, thereby causing Plaintiffs and the Class to pay inflated prices for that product;
- Causing Defendants to refrain from marketing superior FDCs, thereby denying to Plaintiffs and the Class the benefits of those products and causing them to pay overcharges on Defendants' FDCs;
- Causing Defendants to delay the introduction of TAF and TAF-based FDCs, thereby denying to Plaintiffs and the Class the benefits of those products and

causing them to pay overcharges on Viread and Defendants' TDF-based FDCs;

- Intentionally degrading standalone TAF, thereby causing Plaintiffs and the Class to pay overcharges on Viread, Vemlidy, and Defendants' FDCs;
- Delaying and impairing competition from standalone generic TAF and from generic-TAF-based FDCs, thereby causing Plaintiffs and the Class to pay overcharges on those products;
- Delaying and preventing competition from AB-rated competition to Viread, Truvada, and Atripla, thereby causing Plaintiffs and the Class to pay overcharges on those products and on Defendants' FDCs.
- Delaying and extending the patent on TAF, thereby causing Plaintiffs and the Class to pay overchanges on TAF-containing products.

447. Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT AND EFFECT ON INTERSTATE AND INTRASTATE COMMERCE

448. During the relevant period, Plaintiffs and members of the Class purchased, or reimbursed for purchases of, substantial amounts of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Sumtuza, and/or other cART drugs other than for resale. As a result of Defendants' unlawful conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, artificially inflated prices for these purchases. Those prices were substantially greater than the prices that Plaintiffs and members of the Class would have paid absent the unlawful conduct alleged herein, because: (1) the prices of the branded products were artificially inflated by Defendants' unlawful conduct; (2) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic or comparable versions of the branded products sooner; and/or (3) the quality of the products was artificially reduced.

449. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

450. Defendants' unlawful restraints on competition and exclusionary conduct have substantially affected interstate and intrastate commerce.

451. At all material times, each Defendant manufactured, promoted, distributed, and sold substantial amounts of the relevant products in a continuous and uninterrupted flow of commerce across state lines and throughout the United States.

452. At all material times, each Defendant transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of the relevant products.

453. In furtherance of their efforts to restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate and intrastate commerce.

454. Defendants' anticompetitive conduct has substantial intrastate effects in that, among other things, retailers within each state were impaired in offering less expensive generic drugs and generic-based FDCs to end-payors inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

XI. CLASS ACTION ALLEGATIONS

455. Plaintiffs, on behalf of themselves and all Class members, seek damages, measured as overcharges, multiplied as provided by law, against Defendants, as well as injunctive and other equitable relief, based on the anticompetitive conduct alleged above.

456. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a) and (b)(2) and (b)(3), as representative of a class of end-payor purchasers defined as follows:

> All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for any cART drug, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 14, 2015 through and until the anticompetitive effects of Defendants' unlawful conduct cease.

457. Excluded from the Class are:

a) Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b) All federal governmental entities;

c) All states (and sub-units of government and their entities) that, by law, preclude their participation as plaintiffs in private class action litigation;

d) Persons who are asserting claims for personal injuries against Gilead Sciences, Inc. or its affiliates alleged to be caused by the consumption of a TDF-containing product; and

e) The judges in this case and any members of their immediate families.

458. Members of the Class are so numerous that joinder is impracticable. The Class numbers in the many hundreds of thousands. Further, the Class is readily identifiable from information and records in the possession of Defendants and of entities in the pharmacy chain of distribution.

459. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants, i.e., they paid artificially inflated prices for the products and were deprived of earlier and more robust competition as a result of Defendants' wrongful conduct.

460. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

461. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

462. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

463. Questions of law and fact common to the Class include:

- Whether the No-Generics Restraints entered into between Gilead and each of BMS and Janssen were in unlawful restraint of trade;

- Whether Gilead unlawfully degraded Stribild;
- Whether Gilead unlawfully degraded standalone TAF;
- Whether Gilead unlawfully created artificial price differences between Stribild and Genvoya;
- Whether Gilead unlawfully impaired competition through its regulatory gaming with respect to standalone TAF;
- Whether Gilead anticompetitively delayed the entry of generic versions of Viread, Truvada, and Atripla;
- Whether Gilead anticompetitively delayed and extended the patent on TAF;
- Whether Gilead and its coconspirators unlawfully obtained or maintained a monopoly in the cART Market;
- Whether the law requires definition of a relevant market when direct proof of market power is available, and if so the definition of the relevant market;
- Whether Defendants' conduct as alleged herein substantially affected interstate and intrastate commerce;
- Whether, and if so to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiffs and the members of the Class; and
- The quantum of aggregate overcharge damages to the Class.

464. Defendants' anticompetitive conduct has imposed, and unless enjoined will continue to impose, a common antitrust injury on Plaintiffs and all members of the Class. Defendants' anticompetitive conduct and their relationships with the class members have been substantially uniform. Defendants have acted and refused to act on grounds that apply generally to the class, and injunctive and other equitable relief is appropriate respecting the class as a whole.

465. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweigh

potential difficulties in management of this class action.

466. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude litigating it as a class action.

XII. ONGOING AND FUTURE HARM

467. As noted in detail above, Defendants' unlawful No-Generics Restraints have already caused massive anticompetitive effects by depriving drug purchasers of comparable FDCs once generic TDF became available and, in the case of Evotaz, once generic ATV became available. Generic compositions are already available in the marketplace that, absent the No-Generics Restraints, would have prompted competitors untainted by the Defendants' unlawful conduct to make substitutable or comparable versions of Complera, Symtuza, and Evotaz. And such competitors would have challenged the applicable patents and would already have entered the market with substitutable or comparable versions of Atripla, Prezcobix, and Odefsey.

468. Unless enjoined by this Court, Defendants' unlawful conduct will have additional and intensified anticompetitive effects once generic versions of any of FTC, TAF, COBI, or DRV become available. Absent the No-Generics Restraints, an untainted competitor in Janssen's position would make a substitutable version of Complera when generic FTC becomes available.

469. Absent the No-Generics Restraints, when generic TAF becomes available, an untainted competitor in Janssen's position would produce and market a comparable version of Odefsey, comprising generic TAF, generic 3TC, and RPV. Such a competitor would also make a substitutable version of Odefsey once generic versions of TAF and FTC become available. Moreover, that competitor would have accelerated the availability of generic versions of those compositions by challenging Gilead's patents on them. Assuming that Janssen were subject to NCE exclusivity that protected Odefsey and did not obtain a waiver of it (see Section VII(C) above), an untainted competitor in Janssen's position would have sought FDA approval for a substitutable version of Odefsey as early as November 5, 2019, and, after waiting out the 30-month stay, begun marketing the substitutable FDC on May 5, 2023. Unless enjoined by this Court, however, the unlawful No-Generics Restraint will prevent that competition until March 2026.

470. Absent the No-Generics Restraints, when generic TAF becomes available, an untainted competitor in Janssen's position would also produce and market a comparable version of Symtuza, comprising generic TAF, generic FTC (or generic 3TC), generic RTV, and DRV. Such a competitor would also make a substitutable version of Symtuza once generic versions of TAF, FTC, and COBI become available. Moreover, that competitor would have accelerated the availability of generic versions of those compositions by challenging Gilead's patents on them. Assuming that Janssen were subject to NCE exclusivity that protected Symtuza and did not obtain a waiver of it (see Section VII(C) above), an untainted competitor in Janssen's position would have sought FDA approval for a substitutable version of Symtuza as early as November 5, 2019, and, after waiting out the 30-month stay, begun marketing the substitutable FDC in May 2023. Unless enjoined by this Court, however, the unlawful No-Generics Restraint will prevent that competition until 2026.

471. Absent the No-Generics Restraint, an untainted competitor in Gilead's position would have produced and marketed a substitutable version of Symtuza as soon as possible. Such a competitor would have submitted an application for a product containing TAF, FTC, COBI, and generic DRV as early as FDA approval of Symtuza's NDA (Gilead controlled the NCE exclusivity for Symtuza). After waiting out the 30-month stay, that competitor would have begun marketing the substitutable FDC on January 17, 2021. By that date, the only non-expired Orange Book patents owned by Janssen will be those covering certain pseudopolymorphic forms of DRV, which expire on February 16, 2024 and December 26, 2026 (assuming no pediatric exclusivity is later awarded). Those patents are invalid and can easily be designed around. But the unlawful No-Generics Restraint resulted in Gilead's agreeing not to compete until at least July 17, 2028. Unless enjoined by this Court, the unlawful pact will continue to deprive drug purchasers of such a competing FDC.

472. Gilead's unlawful degrading of Stribild and standalone TAF, and its regulatory gaming with respect to TAF, also significantly distorted the market, are causing ongoing harm, and threaten future harm. That unlawful conduct requires this Court's intervention. Without affirmative relief from the Court to help restore competitive conditions, that unlawful conduct will continue to deprive drug purchasers of the benefits of competition to which they are entitled. For example, Gilead's regulatory gaming with respect to TAF, unless enjoined by this Court, will significantly delay and impair the

competition from generic standalone TAF and from generic-TAF-based FDCs that should flourish in or about May 2023.

473. Gilead's anticompetitively delaying generic versions of Viread, Truvada, and Atripla is similarly causing ongoing harm that requires this Court's intervention. Unless enjoined by this Court, Gilead's anticompetitive conduct with respect to Truvada will cause Teva to delay entry until September 30, 2020, and cause all other generic manufacturers that are stacked up behind Teva to delay entry until March 30, 2021. That delay will cost purchasers of Truvada more than $1 billion in addition to the billions that Defendants' other unlawful conduct has already caused on purchases of Truvada.

474. Those delays are particularly destructive because Truvada is the only FDA-approved drug indicated for pre-exposure prophylaxis (PrEP), i.e., for *preventing* HIV in HIV-negative people. Gilead currently sells a year supply of Truvada for about $24,000. Generic Truvada will sell for a fraction of that—less than $7,000 after multiple generics enter the market. Gilead's anticompetitively delaying generic Truvada will result in hundreds of thousands of people being unable to access PrEP and cause tens of thousands of them to needlessly become infected with HIV.

475. Unless enjoined by this Court, Gilead's anticompetitive conduct will also cause Teva to delay entry with generic Atripla until September 30, 2020, and cause all other generic manufacturers that are stacked up behind Teva to delay entry until March 30, 2021. That delay will cost purchasers of Atripla more than $1 billion in addition to the billions that Defendants' other unlawful conduct has already caused on purchases of Atripla.

476. Defendants' conduct is also continuing to unlawfully delay the entry of generic TAF. As noted in detail above (see Section VII(D)(2)(b)), Defendants' conduct resulted in Gilead's delaying the introduction of TAF and TAF-based FDCs from 2006 to 2015. Absent that delay, the NCE exclusivity for TAF would have expired by 2011, and 30-month stays on generic entry would have expired by 2013. But with Gilead's delaying the introduction of TAF to 2015, no generic has yet been able to enter the market, because the NCE exclusivity does not expire until November 5, 2020. Moreover, Gilead anticompetitively obtained a patent-term extension on the '791 Patent that protects TAF, from May 2022 to April 2025.

477. In order to help restore competitive conditions, this Court should enjoin Gilead from

enforcing any of its TAF-related NCE exclusivities and 30-month stays. Other affirmative relief, including compulsory licenses to the affected products, will also be required.

XIII. CLAIMS FOR RELIEF

COUNT ONE

CONSPIRACY TO MONOPOLIZE IN VIOLATION OF SECTIONS 1 AND 2 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. §§ 1, 2) (Against All Defendants)

478. Plaintiffs repeat and incorporate by reference all preceding allegations.

479. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

480. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

481. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS and Janssen in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and

- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

482. Each of BMS and Janssen consciously committed to the monopolization when each provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the No-Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those restraints.

483. Each of BMS and Janssen knew that Gilead was seeking to obtain and maintain monopoly power in the cART market and the markets for specific cART drugs. Each knew that: (1) Tenofovir was a critical backbone of cART therapies and TDF would dominate the cART market; (2) TDF had a limited patent life, and (3) Gilead was pursuing a strategy of creating FDCs with other manufacturers and developers of cART components with longer or stronger patent life so as to extend the "product life cycle" of TDF and TDF-based cART regimens.

484. Each of BMS and Janssen carefully monitors sales in the cART market and the contractual arrangements between and among participants in that market.

485. By the time it received the Evotaz No-Generics Restraint from Gilead in October 2011, BMS knew that Gilead had a market share of greater than 70% of the cART market. As of that date, BMS also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with Janssen in 2009 protecting Gilead's cART monopoly from competition, and that the Gilead-Janssen No-Generics Restraint was substantially identical to BMS's No-Generics Restraint. And BMS knew that its No-Generics Restraints and Janssen's enabled Gilead, BMS and Janssen to tie up more than 75% of sales of of NRTIs, more than 50% of sales of third agents, and more than 70% of sales of all cART drugs. BMS therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART Market.

486. BMS participated in the conspiracy to monpolize because BMS benefitted directly from it, including from: (a) the Atripla No-Generics Restraint, which incentivized Gilead to switch patients to Atripla thereby increasing BMS's sales of its third agent EFV as a component of Atripla; (b) Gilead's unlawful deals with Teva to delay entry of generic versions of Atripla, which increased BMS's profits on

the sales of Atripla; and (c) the No-Generics Restraint protecting BMS's third agent ATV and its FDC Evotaz from competition. BMS also benefitted from the other elements of Gilead's scheme which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed BMS to charge higher prices on its other cART drugs.

487. When it provided its first No-Generics Restraint to Gilead in July 2009 on Complera, Janssen knew that Gilead had a market share of more than 70% of the cART market. As of that date, Janssen also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with BMS protecting Gilead's drugs from competition.

488. By December 2014 when it entered into No-Generics Restraints on Odefsy and Symtuza, Janssen knew that Gilead's scheme included switching its Tenofovir-based cART monopoly to TAF-based FDCs. It also knew that Gilead's cART market share was more than 70%; nine out of ten patients new to treatment were prescribed a Gilead medicine and approximately 85% of all patients receiving cART therapy were on a Gilead drug. And Janssen knew that its No-Generics Restraints and BMS's enabled Gilead, BMS and Janssen to tie up more than 80% sales of of NRTIs, more than 50% of sales of third agents, and more than 75% of sales of booster drugs. Janssen therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART Market.

489. Janssen participated in the conspiracy to monopolize because Janssen benefitted directly from it, including from: (a) the Complera and Odefsy No-Generics Restraints, which incentivized Gilead to switch patients to those drugs and thereby increased Janssens's sales of its third agent RPV as a component of Complera and Odefsy; (b) the lump-sum payments and above-market royalty payments that Janssen received from Gilead; (c) the degrading of standalone TAF, which increased sales of Odefsy; and (d) the No-Generics Restraints protecting Janssen's Prezcobix and Symtuza from competition. Janssen also benefitted from the other elements of Gilead's scheme which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed Janssen to charge higher prices on its cART drugs.

490. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive

scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

491. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Defendants' continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT TWO

CONSPIRACY TO MONOPOLIZE IN VIOLATION OF SECTIONS 1 AND 2 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. §§ 1, 2) (Against Gilead and BMS)

492. Plaintiffs repeat and incorporate by reference all preceding allegations.

493. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

494. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

495. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from

standalone TAF, in order to raise rivals' costs and delay their entry into the market;

- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

496. BMS consciously committed to the monopolization when it provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the No-Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those restraints.

497. BMS knew that Gilead was seeking to obtain and maintain monopoly power in the cART market and the markets for specific cART drugs. It knew that: (1) Tenofovir was a critical backbone of cART therapies and TDF would dominate the cART market; (2) TDF had a limited patent life, and (3) Gilead was pursuing a strategy of creating FDCs with other manufacturers and developers of cART components with longer or stronger patent life so as to extend the "product life cycle" of TDF and TDF-based cART regimens.

498. BMS carefully monitors sales in the cART market and the contractual arrangements between and among participants in that market.

499. By the time it received the Evotaz No-Generics Restraint from Gilead in October 2011, BMS knew that Gilead had a market share greater than 70% of the cART market. As of that date, BMS also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with Janssen in 2009 protecting Gilead's cART monopoly from competition, and that the Gilead-Janssen No-Generics Restraint was substantially identical to BMS's No-Generics Restraint. And BMS knew that its No-Generics Restraints and Janssen's enabled Gilead, BMS and Janssen to tie up more than 75% of sales of NRTIs, more than 50% of sales of third agents, and more than 70% of sales of all cART drugs. BMS therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART Market.

500. BMS participated in the conspiracy to monopolize because BMS benefitted directly from it, including from: (a) the Atripla No-Generics Restraint, which incentivized Gilead to switch patients to Atripla thereby increasing BMS's sales of its third agent EFV as a component of Atripla; (b) Gilead's

unlawful deals with Teva to delay entry of generic versions of Atripla, which increased BMS's profits on the sales of Atripla; and (c) the No-Generics Restraint protecting BMS's third agent ATV and its FDC Evotaz from competition. BMS also benefitted from the other elements of Gilead's scheme which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed BMS to charge higher prices on its other cART drugs.

501. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

502. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Defendants' continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT THREE

CONSPIRACY TO MONOPOLIZE IN VIOLATION OF SECTIONS 1 AND 2 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. §§ 1, 2) (Against Gilead and Janssen)

503. Plaintiffs repeat and incorporate by reference all preceding allegations.

504. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

505. That market power is coupled with strong regulatory and contractual barriers to entry into the cART Market.

506. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting Janssen in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shieleded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

507. Janssen consciously committed to the monopolization when it provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the No-Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those restraints.

508. Janssen knew that Gilead was seeking to obtain and maintain monopoly power in the cART market and the markets for specific cART drugs. It knew that: (1) Tenofovir was a critical backbone of cART therapies and TDF would dominate the cART market; (2) TDF had a limited patent life, and (3) Gilead was pursuing a strategy of creating FDCs with other manufacturers and developers of cART components with longer or stronger patent life so as to extend the "product life cycle" of TDF and TDF-based cART regimens.

509. Janssen carefully monitors sales in the cART market and the contractual arrangements between and among participants in that market.

510. When it provided its first No-Generics Restraint to Gilead in July 2009 on Complera, Janssen knew that Gilead had a market share of more than 70% of the cART market. As of that date, Janssen also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with BMS protecting Gilead's drugs from competition.

511. By December 2014 when it entered into No-Generics Restraints on Odefsy and Symtuza,

Janssen knew that Gilead's scheme included switching its Tenofovir-based cART monopoly to TAF-based FDCs. It also knew that Gilead's cART market share was more than 70%; nine out of ten patients new to treatment were prescribed a Gilead medicine and approximately 85% of all patients receiving cART therapy were on a Gilead drug. And Janssen knew that its No-Generics Restraints and BMS's enabled Gilead, BMS, and Janssen to tie up more than 80% of sales of NRTIs, more than 50% of sales of third agents, and more than 75% of sales of booster drugs. Janssen therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART Market.

512. Janssen participated in the conspiracy to monopolize because Janssen benefitted directly from it, including from: (a) the Complera and Odefsy No-Generics Restraints, which incentivized Gilead to switch patients to those drugs and thereby increased Janssens's sales of its third agent RPV as a component of Complera and Odefsy; (b) the lump-sum payments Janssen received from Gilead; (c) the degrading of standalone TAF, which increased sales of Odefsy; and (d) the No-Generics Restraints protecting Janssen's Prezcobix and Symtuza from competition. Janssen also benefitted from the other elements of Gilead's scheme which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed Janssen to charge higher prices on its other cART drugs.

513. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

514. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Defendants' continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT FOUR

CONSPIRACY TO MONOPOLIZE IN VIOLATION OF STATE ANTITRUST LAWS
(Against All Defendants)

515. Plaintiffs repeat and incorporate by reference all preceding allegations.

516. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

517. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

518. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS and Janssen in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that were shieleded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the xx'791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

519. Each of BMS and Janssen consciously committed to the monopolization when each provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the

No-Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those restraints.

520. Each of BMS and Janssen had the knowledge and motivation alleged in detail above in Counts One through Three.

521. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

522. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the following state laws:

(a) Ala. Code §8-10-3 with respect to purchases in Alabama by members of the Class.

(b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in the United States by members of the Class.

(d) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(e) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(f) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(g) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(h) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the Class.

(i) Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for the product in actions and transactions occurring substantially within Massachusetts.

(l) Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

(m) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(n) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class.

(o) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(p) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(q) Nev. Rev. Stat. Ann. § 598A, et seq., with respect to purchases in Nevada by members of the Class.

(r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.

(s) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.

(u) N.D. Cent. Code § 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(w) R.I. Gen. Laws §§ 6-36-4, et seq. with respect to purchases in Rhode Island by members of the Class.

(x) S.D. Codified Laws Ann. § 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the Class.

(y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by residents of Utah who are members of the Class.

(z) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(aa) Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

(bb) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(cc) Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

523. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully obtained and maintained monopoly power in the relevant market in violation of the following state laws:

(a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(b) Cal. Bus. & Prof Code §§ 16720, et seq., and California common law with respect to purchases in the United States by members of the Class.

(c) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(f) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(g) Iowa Code §§ 553.5, et seq., with respect to purchases in Iowa by members of the Class.

(h) Kansas Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(i) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases in Minnesota by members of the Class.

(n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(o) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(p) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class.

(q) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

(r) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(s) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

(t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(v) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island by members of the Class.

(w) S.D. Codified Laws §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class.

(x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(y) Utah Code Ann. §§ 76-10- 3101, et seq., with respect to purchases in Utah by members of the Class.

(z) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the Class.

(aa) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(bb) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

524. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Defendants' continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT FIVE

CONSPIRACY TO MONOPOLIZE IN VIOLATION OF STATE ANTITRUST LAWS (Against Gilead and BMS)

525. Plaintiffs repeat and incorporate by reference all preceding allegations.

526. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's

products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

527. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

528. That market power is coupled with strong regulatory and contractual barriers to entry into the cART Market.

529. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that were shieleded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

530. BMS consciously committed to the monopolization when it provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the No-Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those restraints.

531. BMS knew that Gilead was seeking to obtain and maintain monopoly power in the cART market and the markets for specific cART drugs. It knew that: (1) Tenofovir was a critical backbone of cART therapies and TDF would dominate the cART market; (2) TDF had a limited patent life, and (3) Gilead was pursuing a strategy of creating FDCs with other manufacturers and developers of cART

components with longer or stronger patent life so as to extend the "product life cycle" of TDF and TDF-based cART regimens.

532. BMS carefully monitors sales in the cART market and the contractual arrangements between and among participants in that market.

533. BMS had the knowledge and motivation alleged in detail above in Counts One and Two.

534. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

535. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the following state laws:

(a) Ala. Code §8-10-3 with respect to purchases in Alabama by members of the Class.

(b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in the United States by members of the Class.

(d) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(e) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(f) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(g) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(h) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the Class.

(i) Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for the product in actions and transactions occurring substantially within Massachusetts.

(l) Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

(m) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(n) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class.

(o) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(p) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(q) Nev. Rev. Stat. Ann. § 598A, et seq., with respect to purchases in Nevada by members of the Class.

(r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.

(s) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.

(u) N.D. Cent. Code § 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(w) R.I. Gen. Laws §§ 6-36-4, et seq. with respect to purchases in Rhode Island by members of the Class.

(x) S.D. Codified Laws Ann. § 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the Class.

(y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by residents of Utah who are members of the Class.

(z) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(aa) Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

(bb) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(cc) Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

536. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully obtained and maintained monopoly power in the relevant market in violation of the following state laws:

(a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(b) Cal. Bus. & Prof Code §§ 16720, et seq., and California common law with respect to purchases in the United States by members of the Class.

(c) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(f) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(g) Iowa Code §§ 553.5, et seq., with respect to purchases in Iowa by members of the Class.

(h) Kansas Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(i) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases in Minnesota by members of the Class.

(n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(o) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(p) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class.

(q) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

(r) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(s) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

(t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(v) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island by members of the Class.

(w) S.D. Codified Laws §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class.

(x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(y) Utah Code Ann. §§ 76-10- 3101, et seq., with respect to purchases in Utah by members of the Class.

(z) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the Class.

(aa) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(bb) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

COUNT SIX

CONSPIRACY TO MONOPOLIZE IN VIOLATION OF STATE ANTITRUST LAWS (Against Gilead and Janssen)

537. Plaintiffs repeat and incorporate by reference all preceding allegations.

538. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

539. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

540. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting Janssen in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that were shieleded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

541. Janssen consciously committed to this overarching scheme when it provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the No-Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those restraints.

542. Janssen knew that Gilead was seeking to obtain and maintain monopoly power in the cART market and Specific cART Drug Markets. Each knew that: (1) Tenofovir was a critical backbone of cART therapies and TDF would dominate the cART market; (2) TDF had a limited patent life, and (3) Gilead was pursing a strategy of creating FDCs with other manufacturers and developers of cART components with longer patent life so as to extend the "product life cycle" of TDF and TDF-based cART regimes.

543. Janssen carefully monitors sales in the cART Market and the contractual arrangements between and among participants in that market.

544. Janssen had the knowledge and motivation alleged in detail above in Counts One and

Three.

545. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

546. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the following state laws:

(a) Ala. Code §8-10-3 with respect to purchases in Alabama by members of the Class.

(b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in the United States by members of the Class.

(d) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(e) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(f) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(g) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(h) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the Class.

(i) Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for the product in actions and transactions occurring substantially within Massachusetts.

(l) Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

(m) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(n) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class.

(o) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(p) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(q) Nev. Rev. Stat. Ann. § 598A, et seq., with respect to purchases in Nevada by members of the Class.

(r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.

(s) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.

(u) N.D. Cent. Code § 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(w) R.I. Gen. Laws §§ 6-36-4, et seq. with respect to purchases in Rhode Island by members of the Class.

(x) S.D. Codified Laws Ann. § 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the Class.

(y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by residents of Utah who are members of the Class.

(z) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(aa) Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

(bb) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(cc) Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

547. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully obtained and maintained monopoly power in the relevant market in violation of the following state laws:

(a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(b) Cal. Bus. & Prof Code §§ 16720, et seq., and California common law with respect to purchases in the United States by members of the Class.

(c) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(d) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(f) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(g) Iowa Code §§ 553.5, et seq., with respect to purchases in Iowa by members of the Class.

(h) Kansas Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(i) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(l) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(m) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases in Minnesota by members of the Class.

(n) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(o) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(p) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class.

(q) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

(r) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(s) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

(t) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(u) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(v) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island by members of the Class.

(w) S.D. Codified Laws §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class.

(x) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(y) Utah Code Ann. §§ 76-10- 3101, et seq., with respect to purchases in Utah by members of the Class.

(z) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the Class.

(aa) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(bb) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

COUNT SEVEN

MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 2) (Against Gilead)

548. Plaintiffs repeat and incorporate by reference all preceding allegations.

549. At all relevant times, Gilead has possessed substantial market power (i.e. monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

550. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

551. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market and narrower markets therein using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

552. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

553. As stated more fully above, Gilead knowingly, willfully, and wrongfully obtained and maintained its monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

554. Gilead's anticompetitive conduct identified above is exclusionary conduct the purpose and effect of which is to willfully maintain Gilead's monopoly power, which harms the competitive process and consumers, in violation of Section 2 of the Sherman Act.

555. To the extent that Gilead is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable such justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

556. Plaintiffs and the Class have been injured, and unless Gilead's unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead's continuing

monopolization in violation of Section 2 of the Sherman Act.

COUNT EIGHT

MONOPOLIZATION IN VIOLATION OF STATE ANTITRUST LAWS
(Against Gilead)

557. Plaintiffs repeat and incorporate by reference all preceding allegations.

558. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

559. That market power is coupled with strong regulatory and contractual barriers to entry into the cART market.

560. As alleged extensively above, Gilead willfully obtained and maintained its monopoly power in the cART market and narrower markets therein using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

561. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

562. As stated more fully above, Gilead knowingly, willfully, and wrongfully obtained and maintained its monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from

standalone TAF, in order to raise rivals' costs and delay their entry into the market;

- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

563. Gilead's anticompetitive conduct identified above is exclusionary conduct the purpose and effect of which is to willfully maintain Gilead's monopoly power, which harms the competitive process and consumers.

564. Plaintiffs and the Class have been injured, and unless Gilead's unlawful conduct is enjoined will continue to be injured, in their business and property, as a result of Gilead's continuing monopolization.

565. By engaging in the foregoing conduct, Gilead has intentionally and wrongfully obtained and maintained monopoly power in the relevant market in violation of the following state laws:

(a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(b) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(c) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(d) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(e) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(f) Iowa Code §§ 553.5, et seq., with respect to purchases in Iowa by members of the Class.

(g) Kansas Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(h) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the Class.

(i) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(j) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases in Minnesota by members of the Class.

(m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(n) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(o) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class.

(p) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

(q) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(r) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

(s) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(t) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(u) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island by members of the Class.

(v) S.D. Codified Laws §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class.

(w) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(x) Utah Code Ann. §§ 76-10- 3101, et seq., with respect to purchases in Utah by members of the Class.

(y) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by members of the Class.

(z) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

COUNT NINE

ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 2)
(Against Gilead)

566. Plaintiffs repeat and incorporate by reference all preceding allegations.

567. At all relevant times, Gilead possessed substantial market power (i.e., monopoly power), or possessed a dangerous probability of achieving monopoly power, in the cART market and narrower markets therein.

568. With the specific intent to achieve a monopoly, Gilead attempted to acquire and/or willfully maintain monopoly power in the cART market and narrower markets therein by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

569. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

570. As stated more fully above, Gilead knowingly, willfully, and wrongfully attempted to

acquire and/or maintain monopoly power by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

571. Gilead's anticompetitive conduct identified above is exclusionary conduct the purpose and effect of which is to willfully attempt to acquire and/or maintain monopoly power through exclusionary means, in violation of Section 2 of the Sherman Act.

572. To the extent that Gilead is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable such justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

573. Plaintiffs and the Class have been injured, and unless Gilead's unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead's continuing attempt to monopolize in violation of Section 2 of the Sherman Act.

COUNT TEN

ATTEMPTED MONOPOLIZATION IN VIOLATION OF STATE ANTITRUST LAWS (Against Gilead)

574. Plaintiffs repeat and incorporate by reference all preceding allegations.

575. At all relevant times, Gilead possessed substantial market power (i.e., monopoly power), or possessed a dangerous probability of achieving monopoly power, in the cART market and narrower markets therein.

576. With the specific intent to achieve a monopoly, Gilead attempted to acquire and/or willfully maintain monopoly power in the cART market and narrower markets therein by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby.

577. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

578. As stated more fully above, Gilead knowingly, willfully, and wrongfully attempted to acquire and/or maintain monopoly power by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market;
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla; and
- Obtaining a patent-term extension on the '791 Patent, despite having intentionally delayed the development and approval of TAF as part of the anticompetitive scheme.

579. Gilead's anticompetitive conduct identified above is exclusionary conduct the purpose and effect of which is to willfully attempt to acquire and/or maintain monopoly power through exclusionary means.

580. To the extent that Gilead is permitted to assert one, there is and was no cognizable, non-

pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable such justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

581. Plaintiffs and the Class have been injured, and unless Gilead's unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead's continuing attempt to monopolize the cART market.

582. By engaging in the foregoing misconduct, Gilead has violated the following state laws:

(a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(b) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(c) D.C. Code §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(d) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(e) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(f) Iowa Code §§ 553.5, et seq., with respect to purchases in Iowa by members of the Class.

(g) Kansas Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(h) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to purchases in Maine by members of the Class.

(i) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(j) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in

Michigan by members of the Class.

(l) Minn. Stat. §§ 325D.49, et seq., and Minn. Stat. § 8.31, et seq., with respect to purchases in Minnesota by members of the Class.

(m) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(n) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(o) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class.

(p) N.M. Stat. Ann. §§ 57-1-2, et seq., with respect to purchases in New Mexico by members of the Class.

(q) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(r) N.C. Gen. Stat. §§ 75-2.1, et seq., with respect to purchases in North Carolina by members of the Class.

(s) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(t) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(u) R.I. Gen. Laws §§ 6-36-5 et seq., with respect to purchases in Rhode Island by members of the Class.

(v) S.D. Codified Laws §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class.

(w) Tenn. Code Ann §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(x) Utah Code Ann. §§ 76-10- 3101, et seq., with respect to purchases in Utah by members of the Class.

(y) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by

members of the Class.

(z) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(aa) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

COUNT ELEVEN

VIOLATION OF STATE CONSUMER PROTECTION LAWS
(Against All Defendants)

583. Plaintiffs repeat and incorporate by reference all preceding allegations.

584. Defendants willfully, knowingly, and intentionally engaged in unfair competition or unconscionable acts or practices that were not reasonably avoidable by consumers were not outweighed by any countervailing benefits to consumers or competition in violation of the state consumer protection statutes listed below.

585. Defendants willfully, knowingly, and intentionally engaged in deceptive or fraudulent conduct directed at consumers that has a tendency to mislead by deliberately omitting or concealing from Plaintiffs and members of the Class the existence and nature of the conspiracy between Gilead and the other Defendants to monopolize the cART market and maintain artificially high prices for their brand and generic products that Plaintiffs purchased for their own use, in violation of the state consumer protection statutes listed below.

586. Defendants deliberately omitted or concealed the existence and nature of the foregoing conspiracy from Plaintiffs and members of the Class with the intent or knowledge that Plaintiffs and the Class would rely on the integrity of cART drug pricing and pay artificially high prices for Defendants' brand and generic drugs.

587. The hidden existence and nature of the conspiracy between Gilead and the other Defendants to monopolize the cART market and maintain artificially high prices for their brand and generic products constitute material facts of which Plaintiffs and members of the Class, acting as reasonable consumers, should have been in possession before deciding whether or not to purchase

Defendants' products.

588. Plaintiffs, consumers of these products Defendants made in the regular course of Defendants' business, relied on Defendants' material misrepresentations and concealment in purchasing branded and generic products as Plaintiffs had no other means of discovering the hidden conspiracy.

589. As a direct and proximate result of Defendants' unfair, unconscionable unscrupulous, deceptive, and fraudulent conduct in violation of the state consumer protection statutes listed below, Plaintiffs and members of the Class have paid more on their purchases of the brand and generic products than they would otherwise have paid, and/or were prevented from substituting a less expensive, generic or comparable alternative for their purchases of the more expensive brand and/or the more expensive generic products.

590. There was a gross disparity between the price that Plaintiffs and the Class members paid for the brand and generic products and the value received, given that a less expensive substitute generic or comparable product should have been available.

591. The Defendants concealed their conspiracy, allowing them to charge supracompetitive prices, intending or knowing that the plaintiffs would unknowingly rely on the integrity of the market for establishing cART drug pricing, with the end result being plaintiffs paying more than they should have.

592. By engaging in the foregoing conduct, Defendants have violated the following state unfair trade practices and consumer protection laws:

(a) Arizona Rev. Stat. §§ 44-1522, et seq., with respect to purchases in Arizona by members of the Class.

(b) Arkansas Code Annotated, § 4-88-101, et seq., with respect to purchases in Arkansas by members of the Class.

(c) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to purchases in the United States by members of the Class.

(d) D.C. Code §§ 28-3901, et seq., with respect to purchases in the District of Columbia by members of the Class.

(e) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(f) Iowa Code §§ 714.16, et seq., with respect to purchases in Iowa by members of the Class.

(g) Idaho Code Ann. §§ 48-601, et seq., with respect to purchases in Idaho by members of the Class.

(h) 815 Ill. Comp. Stat. Ann. §§ 505/1, et seq., with respect to purchases in Illinois by members of the Class.

(i) Me. Rev. Stat. tit. 5 §§ 207, et seq., with respect to purchases in Maine by members of the Class.

(j) Mass. Gen. Laws ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(k) Mich. Comp. Laws Ann. §§ 445.901, et seq., with respect to purchases in Michigan by members of the Class.

(l) Mo. Ann. Stat. §§ 407.010, et seq., with respect to purchases in Missouri by members of the Class.

(m) Mont. Code Ann. §§ 30-14-101, et seq., with respect to purchases in Montana by members of the Class.

(n) Neb. Rev. Stat. §§ 59-1601, et seq., with respect to purchases in Nebraska by members of the Class.

(o) Nev. Rev. Stat. §§ 598.0903, et seq., with respect to purchases in Nevada by members of the Class.

(p) N.H. Rev. Stat. Ann. §§ 358-A:1, et seq., with respect to purchases in New Hampshire by members of the Class.

(q) N.M. Stat. Ann. §§ 57-12-1, et seq., with respect to purchases in New Mexico by members of the Class.

(r) N.Y. Gen. Bus. Law §§ 349, et seq., with respect to purchases in New York by members of the Class.

(s) N.C. Gen. Stat. §§ 75-1.1, et seq., with respect to purchases in North Carolina by members of the Class.

(t) R.I. Gen. Laws §§ 6-13.1-1, et seq., with respect to purchases in Rhode Island by members of the Class.

(u) Tenn. Code Ann. §§ 47-18-101, et seq., with respect to purchases in Tennessee by members of the Class.

(v) Utah Code Ann. §§ 13-11-1, et seq., with respect to purchases in Utah by members of the Class.

(w) W. Va. Code §§ 46A-6-101, et seq. with respect to purchases in West Virginia by members of the Class.

593. Plaintiffs and the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair, or unconscionable acts alleged herein. Their injury consists of being compelled to pay artificially inflated prices for Defendants' brand and generic products. This injury is of the type the state consumer protection statutes were designed to prevent and is causally connected Defendants' unlawful conduct.

594. Additionally, Plaintiffs and the Class have been injured in their business and property by reason of Defendants' deceptive acts alleged herein. Their injury consists of being compelled to pay for Defendants' brand and generic products, without being in possession of the highly material facts of Defendants' conspiracy being the but-for cause for the artificially inflated prices they did pay for them, as alleged herein. This injury and corresponding calculation of damages and/or restitution, which includes the total amounts plaintiffs and members of the Class paid for Defendants' brand and generic products, are of the type the state consumer protection statutes were designed to prevent and directly resulted from Defendants' unlawful conduct. In addition, Defendants willful, flagrant conduct entitles Plaintiffs to punitive or treble damages, as well as an award of attorneys' fees.

COUNT TWELVE

CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 1) (Against Gilead and Janssen)

595. Plaintiffs repeat and incorporate by reference all preceding allegations.

596. Gilead and Janssen have engaged in a continuing illegal contract, combination, and

conspiracy in restraint of trade by: (a) agreeing to and abiding by the No-Generics Restraints with respect to Complera, Odefsey, Prezcobix, and Symtuza; (b) agreeing that, and abiding by the agreement that, in exchange for Janssen's providing a No-Generics Restraint with respect to Odefsey, Gilead would provide a No-Generics Restraint with respect to Prezcobix and Symtuza; (c) agreeing to and abiding by mutual No-Generics Restraints with respect to Symtuza; and (d) entering into and abiding by the illegal post-patent-expiration royalty provisions. By entering into these unlawful agreements, Gilead and Janssen unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Gilead and Janssen are horizontal market allocation agreements between actual or potential competitors and are illegal per se. Alternatively, and at a minimum, they are unreasonable restraints of trade in violation of Section 1.

597. Plaintiffs and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiffs and members of the Class have paid more on their purchases of the brand and generic products than they would otherwise had paid, and/or were prevented from substituting a less expensive, generic or comparable alternative for their purchases of the more expensive brand and/or the more expensive generic products.

598. As a result of Defendants' unlawful conduct, Plaintiffs and the Class paid more than they would have paid for Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Complera, Odefsey, Prezista, Prezcobix, Edurant, Symtuza, and competing cART drugs absent that unlawful conduct. But for Gilead and Janssen's unlawful conduct, competitors would have begun marketing generic or comparable versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

599. If Gilead and Janssen had competed in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic or comparable products for the higher-priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining purchases, and/or would have received a superior product for the purchases that they made.

600. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of the products. As a result of Gilead and Janssen's unlawful conduct, Plaintiffs and the other

Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiffs and the Class members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic and comparable products instead of expensive brand products; (2) Plaintiffs and Class members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and Janssen's conduct.

601. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead and Janssen's continuing conspiracy in violation of Section 1 of the Sherman Act.

COUNT THIRTEEN

CONSPIRACY IN VIOLATION OF STATE ANTITRUST LAWS
(Against Gilead and Janssen)

602. Plaintiffs repeat and incorporate by reference all preceding allegations.

603. Gilead and Janssen have engaged in continuing illegal contracts, combinations, and conspiracies in restraint of trade by agreeing to and abiding by the No-Generics Restraints and the post-patent-expiration royalty provisions with respect to Complera, Odefsey, Prezcobix, and Symtuza, the purpose and effect of which was to impair competition. The agreements between Gilead and Janssen are horizontal market allocation agreements between actual or potential competitors and are illegal per se. Alternatively, and at a minimum, they are unreasonable restraints of trade.

604. By entering into these unlawful agreements, Gilead and Janssen unlawfully conspired in restraint of trade and violated the following state laws:

(a) Ala. Code §8-10-3 with respect to purchases in Alabama by members of the Class.

(b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class.

(c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq.,

with respect to purchases in the United States by members of the Class.

(d) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(e) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(f) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(g) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(h) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the Class.

(i) Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(j) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(k) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(l) Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

(m) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(n) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class.

(o) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(p) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.

(q) Nev. Rev. Stat. Ann. § 598A, et seq., with respect to purchases in Nevada

by members of the Class.

(r) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.

(s) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(t) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.

(u) N.D. Cent. Code § 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(v) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(w) R.I. Gen. Laws §§ 6-36-4, et seq. with respect to purchases in Rhode Island by members of the Class.

(x) S.D. Codified Laws Ann. § 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the Class.

(y) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by residents of Utah who are members of the Class.

(z) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(aa) Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

(bb) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(cc) Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

605. Plaintiffs and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiffs and members of the Class have paid more on their purchases of the brand and generic products than they would otherwise had paid,

and/or were prevented from substituting a less expensive, generic or comparable alternative for their purchases of the more expensive brand and/or the more expensive generic products.

606. As a result of Defendants' unlawful conduct, Plaintiff and the Class paid more than they would have paid for Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Complera, Odefsey, Prezista, Prezcobix, Edurant, Symtuza, and competing cART drugs absent that unlawful conduct. But for Gilead and Janssen's unlawful conduct, competitors would have begun marketing generic or comparable versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

607. If Gilead and Janssen had competed in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic or comparable products for the higher-priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining purchases, and/or would have received a superior product for the purchases that they made.

608. During the relevant period, Plaintiffs and the other Class members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and Janssen's unlawful conduct, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiffs and the Class members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic or comparable products instead of expensive brand products; (2) Plaintiffs and Class members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and Janssen's conduct.

609. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead and Janssen's continuing conspiracy.

COUNT FOURTEEN

CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 1)
(Against Gilead and BMS)

610. Plaintiffs repeat and incorporate by reference all preceding allegations.

611. Gilead and BMS have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by agreeing to and abiding by the No-Generics Restraints and the post-patent-expiration royalty provisions with respect to Atripla and Evotaz the purpose and effect of which was to impair competition. By entering into these unlawful agreements, Gilead and BMS unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Gilead and BMS are horizontal market allocation agreements between actual or potential competitors and are illegal per se. Alternatively, and at a minimum, they are unreasonable restraints of trade in violation of Section 1.

612. Plaintiffs and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiffs and members of the Class have paid more on their purchases of the brand and generic products than they would otherwise have paid, and/or were prevented from substituting a less expensive, generic alternative for their purchases of the more expensive brand and/or the more expensive generic products.

613. As a result of Defendants' unlawful conduct, Plaintiffs and the Class paid more than they would have paid for Viread, Emtriva, Truvada, Atripla, Tybost, Reyataz, Evotaz, and competing cART drugs absent that unlawful conduct. But for Gilead and BMS's unlawful conduct, competitors would have begun marketing generic versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

614. If Gilead and BMS had competed in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic products for the higher-priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining brand and/or generic purchases, and/or would have received a superior product for the purchases that they made.

615. During the relevant period, Plaintiffs and the other Class members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and BMS's unlawful conduct, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiffs and the Class members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic products instead of expensive brand products; (2) Plaintiffs and Class members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and BMS's conduct.

616. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead and BMS's continuing conspiracy in violation of Section 1 of the Sherman Act.

COUNT FIFTEEN

CONSPIRACY IN VIOLATION OF STATE ANTITRUST LAWS
(Against Gilead and BMS)

617. Plaintiffs repeat and incorporate by reference all preceding allegations.

618. Gilead and BMS have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by agreeing to and abiding by the No-Generics Restraints and the post-patent-expiration royalty provisions with respect to Atripla and Evotaz, the purpose and effect of which was to impair competition. The agreements between Gilead and BMS are horizontal market allocation and price agreements between actual or potential competitors and are illegal per se. Alternatively, and at a minimum, they are unreasonable restraints of trade.

619. By entering into these unlawful agreements, Gilead and BMS unlawfully conspired in restraint of trade and violated the following state laws:

(d) Ala. Code §8-10-3 with respect to purchases in Alabama by members of the Class.

(e) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to purchases in

Arizona by members of the Class.

(f) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in the United States by members of the Class.

(g) Conn. Gen. Stat. § 35-24, et seq., with respect to purchases in Connecticut by members of the Class.

(h) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class.

(i) Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

(j) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to purchases in Hawaii by members of the Class.

(k) Iowa Code § 553.4, et seq., with respect to purchases in Iowa by members of the Class.

(l) Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.

(m) Md. Code, Com. Law § 11-201, et seq., with respect to purchases in Maryland by members of the Class.

(n) Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class.

(o) Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.

(p) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to purchases in Michigan by members of the Class.

(q) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class.

(r) Miss. Code Ann. §§ 75-21-1, et seq., with respect to purchases in Mississippi by members of the Class.

(s) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska

by members of the Class.

(t) Nev. Rev. Stat. Ann. § 598A, et seq., with respect to purchases in Nevada by members of the Class.

(u) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.

(v) N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class.

(w) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.

(x) N.D. Cent. Code § 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class.

(y) Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.

(z) R.I. Gen. Laws §§ 6-36-4, et seq. with respect to purchases in Rhode Island by members of the Class.

(aa) S.D. Codified Laws Ann. § 37-1-3.1, et seq., with respect to purchases in South Dakota by members of the Class.

(bb) Utah Code Ann. §§ 76-10-3101, et seq., with respect to purchases in Utah by residents of Utah who are members of the Class.

(cc) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class.

(dd) Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.

(ee) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.

(ff) Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class.

620. Plaintiffs and all members of the Class have been injured in their business and property by

reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiffs and members of the Class have paid more on their purchases of the brand and generic products than they would otherwise have paid, and/or were prevented from substituting a less expensive, generic alternative for their purchases of the more expensive brand and/or the more expensive generic products.

621. As a result of Defendants' unlawful conduct, Plaintiffs and the Class paid more than they would have paid for Viread, Emtriva, Truvada, Atripla, Tybost, Reyataz, Evotaz, and competing cART drugs absent that unlawful conduct. But for Gilead and BMS's unlawful conduct, competitors would have begun marketing generic versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

622. If Gilead and BMS had competed in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic products for the higher-priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining brand and/or generic purchases, and/or would have received a superior product for the purchases that they made.

623. During the relevant period, Plaintiffs and the other Class members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and BMS's unlawful conduct, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiffs and the Class members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiffs and Class members were deprived of the opportunity to purchase lower-priced generic products instead of expensive brand products; (2) Plaintiffs and Class members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and BMS's conduct.

624. Plaintiffs and the Class have been injured, and unless Defendants' unlawful conduct is enjoined will continue to be injured, in their business and property as a result of Gilead and BMS's continuing conspiracy.

XIV. DEMAND FOR JUDGMENT

625. WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and Fed. R. Civ. P. 23(a) and (b)(2), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiffs the representatives of the Class;

B. Enter judgment against each Defendant in favor of Plaintiffs and the Class;

C. Adjudge and decree the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a), to be unlawful restraints of trade and unlawful exclusionary conduct in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

D. Grant permanent injunctive relief pursuant to Section 16 of the Clayton Act and applicable state law to remedy the ongoing anticompetitive effects of Defendants' unlawful conduct, including but not limited to adjudging and decreeing that:

1) Defendants have forfeited any NCE exclusivity that they may otherwise have had related to Vemlidy, Descovy, Odefsey, Genvoya, Symtuza, and any and all other FDCs that contain TAF;

2) Defendants have forfeited any 30-month stay under the Hatch-Waxman Act that they may otherwise have had related to Vemlidy, Descovy, Odefsey, Genvoya, Symtuza, and any and all other FDCs that contain TAF;

3) Defendants shall not enforce the No-Generics Restraints that would otherwise prohibit Janssen or BMS from making or marketing competing FDCs after the expiration of Gilead's relevant patents;

4) Defendants shall not enforce the No-Generics Restraints that would otherwise prohibit Gilead from making or marketing competing FDCs to Evotaz after the expiration of BMS's patents on ATV;

5) Defendants shall not enforce the No-Generics Restraints that would otherwise prohibit Gilead from making or marketing competing FDCs to Prezcobix or Symtuza after the expiration of Janssen's patents on DRV;

6) Defendants shall not enforce the post-patent-expiration royalty provisions;

7) Gilead shall issue licenses to TAF, FTC, and COBI to any willing licensee, for purposes of making and marketing competing versions of Evotaz, Prezcobix, and Symtuza, on terms to be determined by the Court;

8) Each of Janssen and BMS shall issue licenses to their third agents to any willing licensee on terms to be determined by the Court;

9) Gilead shall issue licenses to TDF, TAF, and FTC to any willing licensee on terms to be determined by the Court;

10) Gilead shall not enforce the '791 Patent.

11) The entry date of Teva, Lupin, Mylan, Aurobindo, Hetero, and Amneal under their patent settlement agreements with Gilead concerning Truvada shall be a date to be determined by the Court;

12) The entry date of Teva, Lupin, and Cipla under their patent settlement agreements with Gilead concerning Atripla shall be a date to be determined by the Court; and

E. Award to Plaintiffs and the Class damages (and multiple damages as provided by law) in amounts to be determined at trial;

F. Award to Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law;

G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Defendants' conduct, as the Court deems just.

XV. JURY DEMAND

626. Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of themselves and the proposed Class demand a trial by jury on all issues so triable.

Dated: May 21, 2020

HILLIARD & SHADOWEN LLP

By: */s/ Steve D. Shadowen*

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Addendum A to First Amended Consolidated Class Action Complaint

A1. Plaintiff MSP Recovery Claims, Series LLC ("MSPRC") is a Delaware series limited liability company with its principal place of business in Coral Gables, Florida. MSPRC's limited liability company agreement provides for the establishment of one or more specific Series. All records of all Series are maintained together with all assets of MSPRC. Numerous Medicare Advantage Plans ("MA Plans"), which provide drug benefits to their beneficiaries under Medicare Parts C and D, 42 U.S.C. §§ 1395w-21, et seq., have assigned their recovery rights to assert the claims alleged in this Complaint to MSPRC or subseries of MSPRC. The Assignors purchased and/or provided reimbursement for some or all of the purchase price for one or more of brand Viread, Emtriva, Truvada, Atripla, Complera, Stribild, Odefsey, Genvoya, Descovy, Vemlidy, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, Symtuza, Tybost, and other cART drugs other than for re-sale, in one or more of the following states—Alabama, Arizona, California, Connecticut, Florida, Massachusetts, Michigan, New York, Puerto Rico, Rhode Island, Tennessee, and Wisconsin—at supracompetitive prices during the Class Period and has thereby been injured. In addition, there is a substantial probability that the Assignors will in the future purchase one or more of these products manufactured by the Defendants, and it has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

A2. MSPRC adopts and incorporates by reference all allegations in the First Amended Consolidated Class Action Complaint filed in Staley, et al. v. Gilead Sciences Inc., et al., No. 19-cv-02573-EMC , ECF No. 304 (N.D. Cal. Apr. 21, 2020).

Dated: May 21, 2020

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By: */s/ Andrés Rivero*

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Corrected Addendum B to First Amended Consolidated Class Action Complaint

B1. Plaintiff Blue Cross Blue Shield Association ("BCBSA") is a national association of 35 independent and locally operated Blue Cross Blue Shield ("BCBS") companies with its principal place of business in Chicago, Illinois.

B2. BCBSA brings this action in its capacity as the carrier of the Service Benefit Plan, one of the Federal Employee Health Benefits Plans ("FEHBP"). Beginning in 1960, the Office of Personnel Management ("OPM") contracted with BCBSA under the Federal Employees Health Benefits Act ("FEHBA") to establish the government-wide FEHBP known as the Service Benefit Plan, also commonly known as the Federal Employee Program ("FEP"). FEP has the largest enrollment of any FEHBP. Under the contract with OPM and under the plan participation agreements, BCBSA has the sole authority to make decisions to bring actions on behalf of the FEP.

B3. BCBSA purchased and/or provided reimbursement for some or all of the purchase price for one or more of the brands Atripla, Biktarvy, Complera, Descovy, Evotaz, Genvoya, Odefsey, Prezcobix, Stribild, Symtuza, Truvada, and Viread other than for re-sale, at supracompetitive prices during the Class Period, in the following states: Alabama, Arizona, Arkansas, California, Connecticut, Washington D.C., Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin. In addition, there is a substantial probability that BCBSA will in the future purchase one or more of these products manufactured by the Defendants, and it has purchased and/or intends to purchase generic versions of those drugs, other than for re-sale, once they become available.

B4. BCBSA adopts and incorporates by reference all allegations in the foregoing First Amended Consolidated Class Action Complaint filed in *Staley, et al. v. Gilead Sciences Inc., et al.*, No. 19-cv-02573-EMC, ECF No. 347 (N.D. Cal. May 28, 2020).

Dated: December 15, 2021

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FILER'S ATTESTATION

Pursuant to Local Rule 5-1(h)(3) of the Northern District of California, regarding signatures, I, AbbyeR. Klamann Ognibene, attest that concurrence in the filing of this document has been obtained.

Dated: December 15, 2021

/s/ Abbye R. Klamann Ognibene
ABBYE R. KLAMANN OGNIBENE

CERTIFICATE OF SERVICE

I hereby certify that on December 15, 2021 the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the attorneys of record in this case.

/s/ Thomas M. Sobol
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