

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA**

**Case No.:** \_\_\_\_\_

MSP RECOVERY CLAIMS, SERIES LLC, a  
Delaware series limited liability company,

Plaintiff,

vs.

**CLASS ACTION**

GILEAD SCIENCES, INC., a Delaware for-profit corporation; GILEAD HOLDINGS, LLC, a Delaware limited liability company; GILEAD SCIENCES, LLC, a Delaware limited liability company; GILEAD SCIENCES IRELAND UC, an unlimited liability company organized under the laws of Ireland; BRISTOL-MYERS SQUIBB COMPANY, a Delaware for-profit corporation; E. R. SQUIBB & SONS, LLC, a Delaware for-profit corporation; JAPAN TOBACCO, INC., a corporation organized under the laws of Japan; JAPAN TOBACCO INTERNATIONAL USA, INC., a California for-profit corporation; AKROS PHARMA, INC., a New York for-profit corporation; JANSSEN R&D IRELAND, a private unlimited company organized under the laws of Ireland; and JOHNSON & JOHNSON, INC., a New Jersey for-profit corporation,

Defendants.

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**PLAINTIFF’S CLASS ACTION  
COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES**

MSP Recovery Claims, Series LLC (“MSPRC”), on behalf of itself and similarly-situated healthcare insurers (the “Class”), brings this class action 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”), Japan Tobacco, Inc., Japan Tobacco International U.S.A., Inc., and Akros Pharma, Inc. (together, “Japan

Tobacco”), Janssen R&D Ireland, and Johnson & Johnson, Inc. (together, “Janssen”) (collectively, “Defendants”) for damages, injunctive relief, and other relief pursuant to federal antitrust laws, and state antitrust and consumer protection laws.

### **NATURE OF THE ACTION**

1. Gilead and its co-conspirators have engaged in a long-running scheme to suppress competition with respect to 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 acquired and maintained a monopoly for drugs that comprise the modern HIV treatment regimen known as “combination antiretroviral therapy” (“cART”). The scheme enabled Gilead and its co-conspirators to unlawfully extend patent protection for their drugs, impair entry by generic competitors, and charge exorbitant, supra-competitive 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 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 remains the dominant maker, of Tenofovir— one of the principal NRTIs used in cART regimens. By controlling the market for Tenofovir, and through its collusive agreements with its co-conspirators, Gilead now dominates the cART market. Today, more than 80% of U.S. patients on

an HIV treatment regimen take one or more of Gilead's products daily. Gilead's sales of these products in the United States alone are more than \$11 billion annually.

3. Gilead maintains a stranglehold on the cART market even though Tenofovir was discovered more than 30 years ago. In 2001, Gilead began marketing its patented formulation of the compound known as tenofovir disoproxil ("TDF"), quickly achieving hundreds of millions of dollars in sales. Gilead expected generic manufacturers to challenge the validity of its Tenofovir patents and enter the market as early as 2009. To suppress generic competition, Gilead, and each of its co-conspirators, BMS, Janssen, and Japan Tobacco, entered into a series of collusive and illegal horizontal agreements providing that each co-conspirator would not compete against Gilead's Tenofovir, effectively blocking competition against Tenofovir, even after patent expiration.

4. Gilead and its co-conspirators co-formulated TDF with the co-conspirators' third agents into single pills known as fixed-dose-combination drugs ("FDCs"). Each of the joint development agreements prevented the co-conspirators 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. Gilead's most likely competitors—the companies that could formulate FDCs with generic alternatives to TDF—promised not to compete with Gilead. In exchange, the No-Generics Restraints and joint development agreements enabled Gilead and the co-conspirator to share the artificially inflated profits from each other's sales.

5. As part of its unlawful scheme, Gilead also agreed to shield BMS and Janssen's HIV drugs from imminent generic competition by allowing them to co-formulate 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 agreed not to market a competing FDC after the BMS and Janssen patents expired.

6. Collectively, the unlawful agreements between Gilead and each of its co-conspirators effectively foreclosed competition for drugs essential to cART regimens. In 2018, the agreements covered more than 75% of all sales of NRTIs, more than 50% of all sales of third agents, and more than 75% of all sales of booster drugs for use in cART regimens in the United States.

7. In a relentless effort to reap monopolistic profits, Gilead engaged in further anticompetitive conduct to reinforce the exclusionary effects of these illegal agreements. When generic competition to TDF became imminent, Gilead amended the No-Generics pacts to preclude its co-conspirators from competing, not only against Gilead's then-marketed TDF, but also against a new formulation of the compound, tenofovir alafenamide ("TAF"), further extending the term of the No-Generics Restraints. Gilead held 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, that hold exclusivity until at least 2032.

8. Gilead forced patients into treatment with TAF-based FDCs by intentionally degrading some of its key products. Before it sought FDA approval of Stribild, its TDF-based FDC, Gilead knew that it contained a much higher dosage of TDF than necessary, subjecting patients to increased risk of significant adverse side effects. But Gilead already planned to 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 and its much longer No-Generics Restraint.

9. Gilead also drove patients to TAF-based FDCs by intentionally delaying and degrading the standalone version of TAF. TAF has a substantially lower incidence of significant adverse side effects than TDF. 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 for 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 potential competitors to re-perform time-consuming and expensive clinical trials that Gilead had already performed. Forgoing this HIV indication cost Gilead hundreds of millions of dollars in sales of standalone TAF every year; however, blocking its competitors' entry into the HIV treatment market proved far more valuable.

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

12. This delay bought Gilead the time needed to move its customers from TDF-based FDCs (facing imminent generic competition) to TAF-based FDCs. By 2017, when TDF finally faced generic competition, Gilead already switched more than 60% of its HIV product sales to the reformulated, TAF-based FDCs which were protected from competition by its unlawful agreements with BMS, Janssen, and Japan Tobacco.

13. The consequences of Gilead and its co-conspirators' unlawful conduct were, and continue to be, burdensome to the government and catastrophic for many patients. The federal government alone spends over \$20 billion annually on HIV treatment, most of it on Defendants' dramatically and artificially overpriced drugs. Even more of these costs are borne by third-party payors, like Plaintiffs' Assignors. Worse, the high cost of these life-saving medications prevents many patients from gaining access to the drugs at all. As a result of the artificially high cART regimens prices, half of the HIV patients in the U.S. are not accessing their required medications, and 400,000 more receive no treatment at all.

14. Defendants' anticompetitive conduct also stifled innovation, causing tens of thousands of people living with HIV to needlessly suffer debilitating side effects from inferior

products. Gilead delayed the FDA approval of TAF for more than a decade while using illegal No-Generics Restraints, rather than product innovations, only to protect its market share. This unlawful stifling of competition denying competitors access to 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 foreclosed altogether 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 prevent HIV infection.

15. To remedy these and the other devastating effects of Defendants’ anticompetitive conduct set forth in detail below, Plaintiff seeks nationwide injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, because, unless enjoined, the Defendants’ unlawful conduct will continue unchecked and will continue to put an unbearable strain on third-party payers, such as Plaintiff’s assignors and the Class Members.

### **JURISDICTION AND VENUE**

16. This Court has jurisdiction over this action under 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 any Defendant.

17. This Court also has jurisdiction over this action under 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings 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.

18. This Court has supplemental jurisdiction over the pendent state-law claims under 28 U.S.C. § 1367.

19. This Court has personal jurisdiction over each of the Defendants because Defendants conduct business in Florida, maintain and carry on continuous and systematic contacts with Florida and this judicial district, regularly transact business within Florida and this judicial district, and regularly avail themselves of the benefits of their presence in Florida and this judicial district.

20. 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).

21. All conditions precedent to this action have occurred, been performed, or been waived.

### **THE PARTIES**

22. 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 paid for Defendants’ overly-priced drugs.

23. 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.

24. 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.

25. 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.

26. 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, Carrigtwohill, Co. Cork, Ireland. Gilead Sciences Ireland UC is a wholly-owned subsidiary of Gilead Sciences, Inc.

27. Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC are collectively referred to herein as “Gilead.”

28. 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.

29. 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.

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

31. Defendant Japan Tobacco, Inc. is a corporation organized and existing under the laws of Japan, with a principal place of business at JT Building, 2-1 Toranomom, 2-chome, Minato-ku, Tokyo 105-8422, Japan.

32. Defendant Japan Tobacco International U.S.A., Inc. is corporation organized and existing under the laws of California, with a principal place of business at 500 Frank W. Burr Blvd., Suite 24, Teaneck, New Jersey 07666.

33. Defendant Akros Pharma, Inc. is a corporation organized and existing under the laws of New York, with a principal place of business at 302 Carnegie Ctr., Suite 300, Princeton, New Jersey 08540.

34. 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.

35. 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.

36. Janssen R&D Ireland and Johnson & Johnson are collectively referred to herein as “Janssen.”

37. 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.

### **SCIENTIFIC BACKGROUND**

38. HIV is one of the deadliest human pandemics in history. Since the first cases were reported in the summer of 1981, more than 700,000 people in the U.S. and 35 million worldwide, 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 U.S. were living with HIV, nearly 40,000 people were newly diagnosed with it, and more than 5,000 Americans perished from it.

39. Left untreated, HIV infections severely weaken 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.

40. In 1987, the Food and Drug Administration (“FDA”) approved azidothymidine (“AZT”), the first drug to treat HIV infection, but effective therapy to treat the disease was not available until 1996.

41. Two innovations led to the introduction of effective therapy for HIV. The first 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.”

42. 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.

43. 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.

44. 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 U.S. 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.

45. Tenofovir is the most common NRTI used in cART regimens in the U.S. 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, Tenofovir’s dominance among NRTIs, and the need to use NRTIs in almost all cART regimens, allowed Gilead and its co-conspirators to monopolize the market for cART regimens.

46. 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 phosphona 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-D in the cell)).

47. 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”).

48. 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.

49. 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 U.S. 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.

50. 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 U.S. 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 co-conspirators prevented those price drops from occurring.

51. 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 co-formulated 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.”

52. 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.

53. 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.

54. Eleven distinct active pharmaceutical ingredients (“APIs”) are most pertinent to this case.

API	Abbreviation	Class of Drug
<b>Lamivudine</b>	3TC	NRTI
<b>Tenofovir Disoproxil Fumarate</b>	TDF	NRTI
<b>Emtricitabine</b>	FTC	NRTI
<b>Tenofovir Alafenamide Fumarate</b>	TAF	NRTI
<b>Efavirenz</b>	EFV	Third Agent—Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)
<b>Rilpivirine</b>	RPV	Third Agent—NNRTI
<b>Elvitegravir</b>	EVG	Third Agent—INSTI
<b>Atazanavir Sulfate</b>	ATV	Third Agent—Protease Inhibitor
<b>Darunavir Ethanolate</b>	DRV	Third Agent—Protease Inhibitor
<b>Ritonavir</b>	RTV	Booster
<b>Cobicistat</b>	COBI	Booster

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

<b><u>Drug Name/ NDA Holder/ Approval Date</u></b>	<b>1<sup>st</sup> NRTI</b>	<b>2<sup>nd</sup> NRTI</b>	<b>Third Agent</b>	<b>Booster</b>	<b>Type</b>
<b><u>Viread</u></b> Gilead Oct 26, 2001	TDF	--	--	--	Standalone
<b><u>Emtriva</u></b> Gilead Jul 2, 2003	--	FTC	--	--	Standalone
<b><u>Truvada</u></b> Gilead Aug 2, 2004	TDF	FTC	--	--	FDC
<b><u>Atripla</u></b> Gilead Jul 12, 2006	TDF	FTC	EFV	--	STR
<b><u>Complera</u></b> Gilead Aug 10, 2011	TDF	FTC	RPV	--	STR
<b><u>Stribild</u></b> Gilead Aug 27, 2012	TDF	FTC	EVG	COBI	STR
<b><u>Genvoya</u></b> Gilead Nov 5, 2015	TAF	FTC	EVG	COBI	STR
<b><u>Odefsey</u></b> Gilead Mar 1, 2016	TAF	FTC	RPV	--	STR
<b><u>Descovy</u></b> Gilead Apr 4, 2016	TAF	FTC	--	--	FDC
<b><u>Vemlidy</u></b> Gilead Nov 10, 2016	TAF	--	--	--	Standalone
<b><u>Prezista</u></b> Janssen Jun 23, 2006	--	--	DRV	--	Standalone
<b><u>Reyataz</u></b> BMS Jun 20, 2003	--	--	ATV	--	Standalone
<b><u>Evotaz</u></b> BMS Jan 29, 2015	--	--	ATV	COBI	FDC
<b><u>Prezcobix</u></b> Janssen	--	--	DRV	COBI	FDC



Jan 29, 2015					
<b><u>Edurant</u></b> Janssen May 20, 2011	--	--	RPV	--	Standalone
<b><u>Symtuza</u></b> Janssen July 17, 2018	TAF	FTC	DRV	COBI	STR
<b><u>Tybost</u></b> Gilead Sep 24, 2014	--	--	--	COBI	Standalone

### **REGULATORY BACKGROUND**

#### **1. Approval of Generic Drugs and Substitution of Generics for Branded Drugs**

56. 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 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).

57. 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).

58. 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.

#### **2. The Hatch-Waxman Amendments**

59. 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.

60. 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).

61. 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.

62. 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.

### **3. Paragraph IV Certifications**

63. 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").

64. 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.

65. 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.

66. 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).

67. 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.

68. 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.

69. 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.

#### **4. Approvals Under 21 U.S.C. § 355(b)(2)**

70. 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.

71. 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.

72. 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.

73. 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.

## **5. New Chemical Entity Exclusivity**

74. The Hatch-Waxman Amendments provide periods of exclusivity that benefit branded pharmaceutical manufacturers, one of which is a five-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).

75. 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 five-year NCE exclusivity period has expired. 21 C.F.R. § 314.108(b)(2).

76. Pursuant to the FDA’s “umbrella policy,” after a drug substance becomes eligible for five-year NCE exclusivity, products subsequently developed that contain the same drug substance also benefit from the original five-year NCE exclusivity until the original exclusivity period has expired. For example, in year one the FDA might approve standalone drug X, which contains new drug substance A, and grant it NCE exclusivity that expires in year six. If the FDA

later, in year four, approves an FDC that contains composition A, then the existing NCE exclusivity also applies to the FDC and also runs until year six.

77. 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 five-year NCE exclusivity life span. As an exception, the applicant may file an ANDA after the first four years of the five-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 five-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.

## **6. Effects of AB-Rated Generic Competition**

78. 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.

79. 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> (last accessed Dec. 18, 2019).

80. 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.

### **DEFENDANTS' ANTICOMPETITIVE CONDUCT**

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

82. But Gilead and its co-conspirators entered into a series of agreements that preclude the use of generic components in favor of Gilead's products even after its patents and regulatory exclusivities have expired, effectively creating a private hiatus from competition, which is *per se* illegal.

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



84. 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.

85. Absent the unlawful No-Generics Restraints, untainted competitors in the position of BMS, Janssen, and Japan Tobacco 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, lamivudine (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> (last accessed Dec. 18, 2019); 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](https://apps.who.int/iris/bitstream/handle/10665/70936/9789241503815_eng.pdf?sequence=1) (last accessed Dec. 18, 2019).

86. 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, Japan Tobacco, and Janssen would have begun making competing versions of the FDCs in December 2017 at the latest.

87. Instead of competing, each of BMS, Japan Tobacco, and Janssen helped Gilead protect its drugs from generic competition. In exchange, they each shared in the supra-competitive profits that the impairment of competition made possible.

88. 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." <https://seekingalpha.com/article/277464-johnson-and-johnson-gilead-deal-could-yield-more-combinations-in-hiv> (last accessed Dec. 18, 2019).

89. Gilead and each of Janssen and Japan Tobacco 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.

# **1. Unlawful No-Generics Restraints: Gilead and Japan Tobacco**

90. On October 26, 2001, Gilead received FDA approval for Viread, which contains only one active pharmaceutical ingredient, TDF; on July 2, 2003 received approval for Emtriva, which contains only one active pharmaceutical ingredient, FTC; and on August 2, 2004 received

approval for Truvada, an FDC containing only two active pharmaceutical ingredients, TDF and FTC.

91. In March 2005, Gilead and Japan Tobacco entered into a No-Generics Restraint under which Japan Tobacco granted to Gilead exclusive rights to develop and commercialize elvitegravir (“EVG”) in all countries of the world, excluding Japan (where Japan Tobacco retained such rights). This included an exclusive right for Gilead to make and sell in the U.S. any product containing EVG in combination with any other HIV drug. The agreement prevents Japan Tobacco or its licensees (except Gilead) from making and selling an EVG-containing FDC with generic TDF or generic FTC (or comparable compositions such as generic 3TC) even after the patents on TDF and/or FTC expire.

92. Under the agreement, Gilead was responsible for seeking regulatory approval in the U.S. and was required to use diligent efforts to commercialize a product for the treatment of HIV. Gilead bore all costs and expenses associated with the commercialization efforts. In addition, Gilead paid to Japan Tobacco an up-front license fee of \$15 million and was obligated to make total potential milestone payments of up to \$90 million upon the achievement of certain clinical, regulatory, and commercial objectives. Gilead was also obligated to pay royalties based on net sales.

93. Under the agreement, Gilead sets the price in the U.S. for products that contain EVG.

94. The agreement, including the No-Generics Restraint and obligation to pay royalties, expires on a product-by-product basis, at the later of (1) the expiration of the last of Japan Tobacco’s patents providing exclusivity for the product or (2) the ten-year anniversary of marketing the product.

95. On August 27, 2012, Gilead received FDA approval for Stribild, an FDC containing TDF, FTC, cobicistat (“COBI”), and EVG. On September 24, 2014, Gilead received FDA approval for both Vitekta, a drug whose only active ingredient is EVG, and Tybost, a drug whose only active ingredient is COBI.

96. When Gilead and Japan Tobacco entered into their No-Generics Restraint in early 2005, Gilead expected to encounter competition from generic TDF as early as 2009. The principal patents that protected EVG, however, were not scheduled to expire until October 26, 2026. Japan Tobacco’s patent claiming an FDC comprising TDF, FTC, and EVG is not scheduled to expire until April 24, 2030.

97. As contemplated by the unlawful No-Generics pact, in or about August 2012 Gilead began to cannibalize TDF and/or FTC sales, encouraging doctors to switch their prescribing from those products to Stribild. Defendants had unlawfully used the No-Generics Restraint to protect Stribild from competition.

98. On November 5, 2015, Gilead received FDA approval for Genvoya, an FDC containing TAF (rather than TDF), FTC, COBI, and EVG. Gilead listed a number of patents in the Orange Book for Genvoya, including two that cover a hemifumarate form of TAF. These ostensibly expire on August 15, 2032, but they are invalid because they claim only the hemifumarate form of TAF, which is obvious in light of the prior art, and in any event generic manufacturers can easily design around them.

99. By the time the FDA approved Genvoya for sale, the scheduled expiration of Gilead’s patents on TDF was less than 25 months away. As alleged in detail below, Gilead used anticompetitive tactics, including making Stribild even less safe than its other TDF-containing

drugs, to cannibalize sales from Stribild to Genvoya. The unlawful No-Generics Restraint protecting Genvoya from competition will not expire until April 2030.

100. After generic TDF became available in December 2017, purchasers and patients should have benefitted because an untainted competitor in Japan Tobacco's position would have competed with Gilead by marketing an FDC comprising EVG, generic TDF, generic 3TC, and generic RTV. The combined price of those products would have plummeted due to competition that should have ensued with the availability of generic TDF. That FDC would not have been subject to any NCE exclusivity, and an untainted competitor in Japan Tobacco's position would have begun marketing it immediately upon the availability of generic RTV in March 2018.

101. An untainted competitor in Japan Tobacco's position also would have offered a competing FDC comprising EVG and generic RTV. Such an FDC is both technologically and commercially feasible. Other manufacturers have successfully made FDCs comprising RTV and other third agents such as lopinavir and atazanavir, and Gilead's own researchers concluded that using RTV to boost EVG results in pharmacokinetic parameters similar to those observed with COBI boosting. Such an RTV-containing FDC would not have been subject to any NCE exclusivity. This product would have competed against both Stribild and Genvoya, because patients could have taken it together with Truvada (TDF/FTC) or Descovy (TAF/FTC). An untainted competitor in Japan Tobacco's position would have begun marketing that product immediately upon the availability of generic RTV in March 2018.

102. Moreover, an untainted competitor in Japan Tobacco's position would have challenged Gilead's patents and entered the market with competing products even before March 2018. The NCE exclusivity on Stribild expired on August 27, 2017. Absent the No-Generics Restraint, an untainted competitor in Japan Tobacco's position would have challenged Gilead's

patents, and it would have avoided any exclusivity by obtaining from Gilead a waiver of any NCE exclusivity that Gilead might have. Japan Tobacco's leverage to obtain such a contractual avoidance of any exclusivity is illustrated by, among other indicia, its having obtained ownership of the patents on an FDC comprising TDF/FTC/EVG.

103. Thus, an untainted competitor in Japan Tobacco's position would have submitted an application for an FDC containing EVG and generic versions of TDF, FTC, and COBI as soon as the FDA approved the NDA for Stribild. After waiting out the 30-month stay, an untainted competitor in Japan Tobacco's position would have entered the market with an FDC comprising EVG and those generic compositions as early as February 2015, on a date to be determined by the jury.

104. As a result of the unlawful No-Generics Restraint, however, drug purchasers will continue to be deprived of competing versions of Stribild until at least April 24, 2030 when the parties' unlawful No-Generics Restraint expires.

105. Unless enjoined by this Court, Gilead and Japan Tobacco's unlawful No-Generics Restraint will have additional anticompetitive effects when generic versions of any of FTC, TAF, or COBI become available. An untainted competitor in Japan Tobacco's position would make additional FDCs that are substitutable for, or comparable to, Stribild and Genvoya. These additional anticompetitive effects, and the need for injunctive relief to avoid them, are discussed below.

## **2. Unlawful No-Generics Restraints: Gilead and BMS**

106. 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.

107. 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.

108. Gilead and BMS initially shared marketing and sales efforts, jointly marketing the product in the U.S. 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.

109. 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.

110. 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.

111. 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. 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.

112. 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, at declining percentages over the three years. 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.

113. The co-conspirators 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.

114. 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 co-conspirators 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.

115. 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.

116. As contemplated by the co-conspirators' 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, this cannibalizing had significant anticompetitive effects.

117. 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.

118. 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.

119. 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.

120. 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.

121. 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.

122. 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 is prohibited from marketing an FDC with ATV even after generic versions of it become available.

123. Under the agreement, BMS sets the price of the FDC for sales in the U.S. 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.

124. 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.

125. Generic ATV became available in the U.S. 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.

126. 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.

127. Gilead began in August 2011 to market an FDC, Complera, and began in August 2012 to market another FDC, Stribild, 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.

128. 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.

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

### **3. Unlawful No-Generics Restraints: Gilead and Janssen**

130. 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").

131. 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.

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

133. Under the parties' agreement, with amendments through 2013, Janssen granted to Gilead a No-Generics Restraint for use of RPV in an FDC comprising TDF/FTC/RPV. The agreement prevents Janssen from marketing 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.

134. The agreement provides that Gilead is responsible for manufacturing Complera and distributing and commercializing it in the U.S. 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.

135. 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 co-conspirators agreed that in the U.S. 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%.

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

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

138. 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.

139. 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.

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 U.S. 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.

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, 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. 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 agreed with respect to DRV, just as it had with respect to RPV, not to produce or market 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 U.S. 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. 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.

160. 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.

161. 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.

162. 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.

163. 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, Prezcoibix and Symtuza. These additional anticompetitive effects, and the need for injunctive relief to avoid them, are discussed below.

#### **4. Increased Prices and Reduced Innovation**

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

##### ***A. The No-Generics Restraints increased prices.***

165. For each of BMS, Janssen, and Japan Tobacco, 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 co-conspirators to share in the supra-competitive profits that the impairment produced. Unless the restraints generated supra-competitive profits that the co-conspirators got to share in, their economic interests would have been to market generic-drug-based FDCs as soon as possible.

166. The agreements provided several means for Gilead's co-conspirators to share in the supra-competitive 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 co-conspirators' 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 co-conspirators through the royalty and other provisions of the joint-development agreements. For example, Gilead paid Janssen a \$100 million fee under their original agreement.

167. 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.

168. Gilead and the co-conspirators 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.

169. 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.

170. 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.

171. Gilead’s No-Generics Restraint schemes exploited this market defect. Gilead and its co-conspirators 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 co-conspirators’ 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.

172. Moreover, the No-Generics Restraints—express non-competition pacts—prevent Gilead’s co-conspirators 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 co-conspirators would not compete their supra-competitive profits back to consumers through price competition on sales of the FDC.

173. 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.

174. Absent the No-Generics Restraints' anticompetitive effects, untainted competitors in the position of BMS, Janssen, and Japan Tobacco 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.

175. 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 co-conspirators have unlawfully monopolized. FDCs that are originally formulated with a generic composition and a brand composition sell for about 40% to 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.

176. 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% to 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.

177. 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.

178. 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 co-conspirator's compositions and obtaining a license from the other co-conspirator to use its product in the FDC; or (2) successfully challenging the patents on both of the co-conspirators' 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.



179. The No-Generics Restraints also incapacitated the manufacturers that were best situated to challenge Gilead's patents—its co-conspirators. Absent the No-Generics Restraints, untainted competitors in the position of Japan Tobacco, 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 co-conspirators' vulnerable drugs.

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

***B. The No-Generics Restraints reduced innovation.***

181. 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.

***1) Reduced innovation by Gilead's competitors***

182. 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.

183. Gilead and its co-conspirators' No-Generics Restraints, together with the additional unlawful conduct detailed further below, 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.

184. Defendants' conduct has prevented competitors from developing at least 28 specifically identifiable FDCs. Absent Defendants' unlawful conduct, the cART Market would have about twice as many FDCs as are now available.

185. Defendants' unlawful conduct has delayed or prevented the development and marketing of at least the following FDCs and other HIV drugs:

- a. generic TDF/generic FTC/RPV;
- b. Generic TAF/generic FTC/RPV;
- c. TAF/FTC/COBI/generic DRV;
- d. COBI/generic DRV;
- e. genericTDF/3TC/genericCOBI/DRV;
- f. generic TDF/generic FTC/generic COBI/DRV;
- g. generic TAF/3TC/RTV/DRV;
- h. generic TAF/generic FTC/generic COBI/RTV;
- i. generic TAF/generic FTC/generic COBI/generic RTV;
- j. DRV/generic RTV;
- k. TDF (reduced dosage)/FTC/COBI/EVG;
- l. Generic TDF (reduced dosage)
- m. generic FTC/generic COBI/EVG;
- n. generic TDF/generic FTC/generic COBI/EVG;
- o. generic TAF/generic FTC/generic COBI/EVG;
- p. generic TDF/generic FTC/EFV;
- q. COBI/generic ATV;
- r. generic TDF/3TC/RPV;
- s. generic TAF/3TC/RPV;
- t. generic RTV/EVG;
- u. generic TDF/3TC/EVG;
- v. generic TAF/3TC/EVG;

- w. TDF/FTC/Dolutegravir;
- x. TDF/3TC/Dolutegravir;
- y. TAF/FTC/Dolutegravir;
- z. TAF/3TC/Dolutegravir;
- aa. generic TDF/generic FTC;
- bb. generic TDF/generic FTC/generic ATV;
- cc. TAF/FTC; TAF 10mg;
- dd. generic TAF 10mg;
- ee. TAF indicated for HIV treatment;
- ff. generic TAF indicated for HIV treatment;
- gg. generic TDF; and
- hh. generic FTC.

186. 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.

## 2) *Reduced innovation by Gilead*

187. Gilead and its co-conspirators' 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.

188. 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 U.S.; (2) in that same timeframe, Gilead developed exactly one new pharmaceutical compound—COBI. And even COBI did not debut until 2014, which 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.

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

a) Delaying TAF in 2003-2004

190. 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.

191. 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.

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

193. 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.

194. 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.

195. 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....”

196. 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....”

197. 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.”

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

199. 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.

200. 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 co-conspirators announced favorable results from an ongoing clinical trial of Atripla.

201. Throughout 2004 Gilead had also been negotiating and finalizing a No-Generics Restraint with Japan Tobacco. Three months after signing the unlawful BMS pact, Gilead concluded the one with Japan Tobacco. The prospect of that anticompetitive deal also led Gilead to shelve the TAF project.

202. These No-Generics Restraints fundamentally altered the competitive landscape that Gilead faced. They 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 Restraints 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.

203. 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...."

204. 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.

205. 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.

206. 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.

207. 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.”

208. 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.”

209. 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.

210. 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.



211. 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.”

212. 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.”

213. 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.

214. 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.

215. 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 will timely sue 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.

216. 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.

217. 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.

b) Forgoing Dolutegravir

218. A second example confirms the No-Generics Restraints' innovation-killing effects. Dolutegravir is a third agent—an integrase inhibitor—originally owned by Shionogi Inc. and later by ViiV Healthcare. In 2012 an FDC comprising TDF (and, later, TAF), FTC, and Dolutegravir would have been state-of-the-art, far and away the best available single-tablet regimen for HIV patients in that timeframe.

219. Rather than create this much-needed FDC, however, Gilead was satisfied instead to obtain FDA approval to market an FDC using TDF, FTC, COBI, and Japan Tobacco's EVG—what became known as Stribild. An FDC comprising TDF/FTC/Dolutegravir would have been markedly superior to Stribild. Among other things, Stribild requires a booster, COBI, in order to make EVG effective in a single dose. Gilead knew at the time, however, that COBI also has the effect of boosting TDF and thereby intensifying its risk of negative side effects, including kidney toxicity and loss of bone density. Dolutegravir does not require a boosting agent, and an FDC made with it rather than EVG would not have had the magnitude of side effects caused by Stribild.

220. Even disregarding negative side effects, Dolutegravir has a significant advantage as a third agent as compared to EVG, because it has a higher genetic barrier to resistance. Thus, Dolutegravir's efficacy is preserved for some strains of HIV that are resistant to EVG, and HIV has more difficulty evolving resistance to Dolutegravir compared to EVG.

221. The anticompetitive incentives created by the No-Generics Restraints nevertheless prompted Gilead to create an FDC formulated with the inferior third agent, EVG. Absent the No-Generics Restraint, the only way for an FDC to make profits is by being substantially better than the alternative therapies. But with a No-Generics Restraint and consequent impairment of generic competition, an FDC can make profits by simply being employed to impair generic competition. With the No-Generics Restraint covering Stribild, Gilead would make a substantial portion of profits simply by impairing generic competition regardless of the relative efficacy of EVG as compared to Dolutegravir.

222. Moreover, unlike Japan Tobacco, ViiV would not have given Gilead a No-Generics Restraint. ViiV owned 3TC as well as Dolutegravir, so it would be able to make a competing version of the FDC as soon as generic TDF became available.

223. Creating a TDF/FTC/Dolutegravir in 2012 would have made good economic sense for Gilead if its goal was to do what manufacturers in competitive markets must do: make the best possible products as soon as possible. That FDC would have been state-of-the-art and would have been a boon to patients living with HIV. But the No-Generics Restraint with Japan Tobacco ensured that Gilead was not operating in a competitive market. Gilead's goal was not to make the best possible product, but only one protected by a No-Generics Restraint that would impair competition. So, Gilead chose to make the inferior Stribild.

224. ViiV ultimately created its own FDC using Dolutegravir as the third agent, without access to Gilead's TDF (and, later TAF) and FTC. ViiV now markets that product as Triumeq, comprising abacavir, 3TC, and Dolutegravir.

225. Recognizing the medical superiority of Dolutegravir, Gilead searched for a manufacturer of Dolutegravir who would not make a Tenofovir/3TC/Dolutegravir FDC with generic Tenofovir once it became available. Gilead eventually found such a manufacturer: itself. On February 7, 2018, the FDA approved a Gilead FDC comprising TAF, FTC, and Bictegravir, an integrase inhibitor that Gilead produces itself. In an ongoing patent-infringement lawsuit, ViiV alleges that Bictegravir is merely a copy of Dolutegravir—essentially, that Gilead simply stole Dolutegravir.

c) Degrading Products

226. 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.

227. As set forth in detail below, 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.

228. Similarly, as set forth in detail below, 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.

229. 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.

## **5. Gilead's Unlawful Degrading of Stribild**

230. 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.

231. 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.

232. 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.

233. 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.

234. 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.

235. 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. With the No-Generics Restraints with Japan Tobacco in place, 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.

236. 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 supra-competitive prices.

237. Gilead's intentional degradation of Stribild, and price increases 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.

## **6. Gilead's Unlawful Degrading of Standalone TAF**

238. 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.

239. 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.

240. 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.

***A. Gilead anticompetitively withheld standalone TAF in 2015-2016.***

241. Tenofovir is an essential input in a cART regimen, and Gilead has control over Tenofovir. And as described in detail above, 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.



242. 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).

243. 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.

244. 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.

245. 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.

246. 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.

247. 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.

248. 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.

249. 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.

***B. Gilead anticompetitively withheld standalone TAF 10mg.***

250. 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 U.S., Gilead makes both standalone TAF and Descovy (TAF/FTC) only formulated with 25mg of TAF rather than 10mg.

251. 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.

252. 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.

253. 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.

254. 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).

255. 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.

256. 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.

257. As part of its scheme to impair competition in the cART Market in the U.S., 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.

***C. Gilead anticompetitively withheld an HIV indication for standalone TAF.***

258. 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.

259. 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.

260. 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.

261. 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.)

262. 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.*, U.S. Patent Application Publication 2018/0177734 A1. When granted, those patents will extend far beyond 2022.

263. 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.

***D. Gilead degraded standalone TAF with anticompetitive purpose and effect.***

264. 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.

265. 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.

266. Competition in the cART Market 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).

267. 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.

268. 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.

269. Gilead had consistently and insistentlly 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.

270. 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.

271. 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.

272. 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.

273. 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.

274. 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.

275. 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.

## **7. Gilead's Unlawful Regulatory Gaming**

276. 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.

277. 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.

278. 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.

279. 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.

280. 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.

281. 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.

***A. TAF is vulnerable to generic competition in May 2023.***

282. 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 prevents any manufacturer from filing an application with the FDA to make generic TAF until November 5, 2019. When manufacturers file such an application, Gilead will sue them for patent infringement, eliciting the 30-month stay

under the Hatch-Waxman Act. That stay will not begin to run until November 5, 2020 and will expire 30 months later, 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.

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

<b><u>Group</u></b>	<b><u>Patent No.</u></b>	<b><u>Patent Name</u></b>	<b><u>Patent Expiry</u></b>	<b><u>Description</u></b>
<b>Group One</b>	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
<b>Group Two</b>	8,754,065	"Tenofovir alafenamide hemifumarate"	15 Aug 2032	Hemifumarate Salt
	9,296,769	"Tenofovir alafenamide hemifumarate"	15 Aug 2031	Hemifumarate Salt

284. The first group consists of U.S. 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.

285. The second group consists of U.S. 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.

286. 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.

287. 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. 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.

288. 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.

289. 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.

290. 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 monofumarate 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.

291. 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](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207561Orig1s000PharmR.pdf), at 12 (last accessed Dec. 18, 2019).

292. 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](https://clinicaltrials.gov/ProvidedDocs/36/NCT02836236/Prot_000.pdf), at 31 (last accessed Dec. 18, 2019).

***B. Gilead withheld an HIV indication in order to impair competition.***

293. 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.

294. 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.

295. 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.

296. 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.

297. 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.

298. 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.

299. 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.

300. 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.

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

301. 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.

302. 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.

303. 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.

***A. Most-Favored-Entry and Most-Favored-Entry-Plus clauses delay generic entry.***

304. 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.

305. 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.



306. 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.

307. 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.

308. 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.

309. 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)(I)(aa)(BB). 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.

310. 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.

311. 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.

312. 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.

313. 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.

***B. Gilead used MFEs and MFEPs to delay generic entry.***

314. 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.

*1) Teva filed the first ANDAs with Paragraph IV certifications.*

315. On September 26, 2008, Teva filed the first ANDA seeking FDA approval to sell generic Truvada. 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 composition (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.

316. On the same day, Teva also filed the first ANDA seeking FDA approval to sell generic Atripla. 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. Teva also provided a Paragraph IV certification as to Gilead's basic 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.

317. On or about November 3, 2008, Teva notified Gilead that Teva had filed the ANDAs and explained in detail why the patents were invalid and not infringed by Teva's ANDA products.

318. On December 12, 2008, Gilead filed suit in the U.S. 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.

319. On July 1, 2009, Teva filed the first ANDA seeking FDA approval to sell generic Viread. 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.

320. On March 5, 2010, Gilead filed suit in the U.S. 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.

321. 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 the 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 the Southern District of New York (No. 08-cv-10838).

322. 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.

2) *Second-filers posed a threat to Teva.*

323. 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.

324. These competitors posed a significant threat to Teva. The FD&C Act's forfeiture provisions 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.

325. 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.

326. In 2017 (the year that Teva eventually entered the market) Viread had U.S. 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.

327. 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.

3) *Gilead gave Teva an MFEP and put MFEs in all Viread agreements.*

328. 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.

329. 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.

330. 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 and any TDF-containing product until December 15, 2017.

331. 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.

332. The MFE and MFEP also 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.

333. 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.

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

335. 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.

336. 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.



337. 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, at least Hetero and Aurobindo would have done so; those manufacturers made Paragraph IV certifications with respect to Truvada.

338. 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.

339. 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 Plaintiff and other class members.

340. 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.

4) *Gilead put MFEPs and MFEs in the Truvada and Atripla agreements.*

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

342. 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.

343. The '396 patent (the later of the two FTC Enantiomer Patents) does not expire (with pediatric exclusivity) until September 9, 2021. As with Viread, a number of second-filers had lined up behind Teva; by February 2014 Gilead had filed patent lawsuits on the FTC Enantiomer Patents against Lupin, Mylan, Aurobindo, Hetero, and Amneal, all of which had provided Paragraph IV certifications with respect to Truvada. And Gilead had filed a patent infringement lawsuit against other generic manufacturers, including Lupin, that had provided Paragraph IV certifications with respect to Atripla. (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.)

344. 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 may have forfeited it with respect to 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)(I)(aa)(BB).

345. 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 end of the patent term—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.

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

347. Gilead succeeded in delaying entry of generic Truvada and Atripla just as it did with respect to Viread. Gilead settled the FTC Enantiomer litigations with Lupin in September 2014; with Mylan in October 2015; with Aurobindo in September 2016; with Hetero in August 2016; and with Amneal in April 2017. 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.

348. The MFE and MFEP had very substantial value to Teva. In 2014, combined U.S. 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 Plaintiff’s assignors and other class members.

### **MARKET POWER**

349. At all relevant times, Gilead had market power over each of Viread, Emtriva, Truvada, Vemlidy, Descovy, Tybost, and their generic equivalents; Gilead and BMS had market power over each of Atripla and Evotaz and their generic equivalents; Gilead and Japan Tobacco had market power over each of Stribild and Genvoya 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. Defendants had the power to maintain the price of those brand drugs at supra-competitive levels without losing sufficient sales to other products, except for AB-rated generic versions of those brand drugs, to make the supra-competitive prices unprofitable.

350. 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.

351. 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.

352. Additionally, because of the nature of HIV treatment, 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.

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

354. 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.

355. 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. In most instances, the patient's insurance company (like Plaintiff's assignors) pays for the drug.

356. 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.

357. 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.

358. 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.

359. 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 supra-competitive 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 supra-competitive levels.

360. 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.

361. 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.

362. 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.

363. To the extent that Plaintiff is 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.

364. 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.

365. 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 Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in multiple markets.

366. 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, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, and Symtuza. 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 and Japan Tobacco have 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 and Japan Tobacco have 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 Prezcoibix 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.

367. 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.

368. Another purpose and effect of Defendants' No-Generics Restraints was to impair competition among drugs used in the cART regimen. To the extent that Plaintiff is 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.

369. 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. 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.

370. 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).

371. The following chart identifies all NRTIs that have been available in the U.S. since 1987.

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

372. 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 U.S. sales, including when coformulated with 3TC, were less than \$60 million.

373. 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.

374. In 2001, all U.S. sales of Zalcitabine were halted due to toxicity side effects. The WHO strongly discourages doctors from prescribing Stavudine (d4T) due to lipodystrophy, peripheral neuropathy, and other severe side effects. Stavudine's U.S. sales were less than \$3 million in 2018. The principal NRTIs for use in a cART regimen are Tenofovir, abacavir, FTC, and 3TC. Tenofovir-containing cART regimens usually also contain either FTC or 3TC, because a common mutation associated with resistance to FTC and 3TC increases the susceptibility of the virus to Tenofovir. Taking Tenofovir together with either FTC or 3TC makes it more difficult for the virus to become resistant to the cART regimen. Consequently, 3TC is a competitor to FTC, but is a complement to, not a substitute for, the use of Tenofovir or abacavir in a cART regimen.

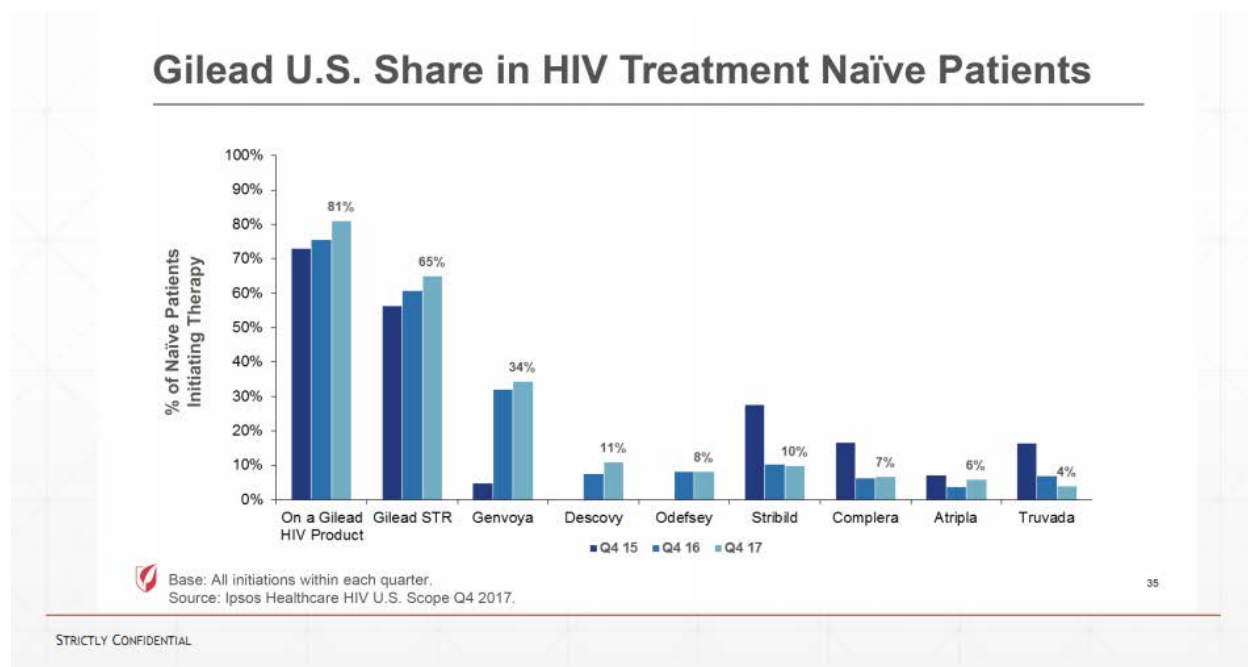
375. For many doctors and patients, abacavir is not a realistic substitute for Tenofovir in a cART regimen. Gilead noted at a 2016 investors conference, for example, that "[a]bacavir is a molecule that is the most difficult of the ... [NRTIs] to administer and has both short-term and long-term problems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

376. 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 treatment 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.

377. 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 U.S. of Tenofovir. Even after the entry of generic TDF in December 2017, Gilead has maintained at least 85% of all unit sales of Tenofovir in the U.S. At all relevant times, Gilead has maintained at least 70% of all unit sales of NRTIs in the U.S.

378. At all relevant times, Gilead's unit share of the cART Market has ranged from not less than 70% to as much as 93%. Gilead has repeatedly acknowledged, indeed touted, its monopoly share in the cART Market.

379. 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:



380. 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 U.S.:

## Top Prescribed HIV Regimens

U.S.

Rank	Naïve	All Patients
1	Genvoya	Genvoya
2	Other STR	Other STR
3	Stribild	Atripla
4	Odefsey	Stribild
5	Descovy + other 3 <sup>rd</sup> Agent	Complera

US Source: Ipsos Healthcare HIV U.S. Therapy Monitor/Scope Q4 2017.


 Gilead STR
  Regimen contains a Gilead product

32

381. As noted in detail above, a purpose and effect of Gilead's degrading (and supra-profit-maximizing pricing) of Stribild, degrading of standalone TAF, and regulatory gaming with respect to standalone TAF was to impair competition among drugs used in the cART regimen. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in the cART Market and narrower markets therein.

382. As noted in detail above, another purpose and effect of Gilead's degrading of standalone TAF and regulatory gaming with respect to standalone TAF was to impair competition from generic versions of standalone TAF and generic versions of TAF-containing FDCs. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in the markets for each of those products and their AB-rated equivalents.

383. As noted in detail above, the purpose and effect of Gilead's delaying the entry of generic versions of Viread, Truvada, and Atripla was to impair competition in multiple ways. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in: (1) the market for each of those products and its AB-rated generic equivalents; and (2) the cART Market and narrower markets therein.

384. At all relevant times, 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.

385. The relevant geographic market for each of the drugs and each of the product markets is the U.S. and its territories.

### **MARKET EFFECTS**

386. Defendants willfully and unlawfully engaged in schemes for the anticompetitive purpose of delaying and impairing competition and thereby maintaining supra-competitive prices for their products.

387. 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.

388. Defendants' unlawful conduct caused Plaintiff's assignors and the Class to pay more than they would have paid for Defendants' drugs and other cART drugs absent that conduct.

389. 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.

390. Absent Defendants' unlawful conduct, Plaintiff's assignors 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.

391. 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 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.

392. Defendants' unlawful conduct has harmed Plaintiff's assignors 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 Plaintiff's assignors and the Class to pay overcharges on those products;
- Delaying and preventing competition from FDCs comparable to Defendants' FDCs, thereby causing Plaintiff's assignors 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 Plaintiff's assignors and the Class to pay overcharges on those products and on Defendants' FDCs;
- Degrading and artificially raising the price of Stribild, thereby causing Plaintiff's assignors and the Class to pay inflated prices for that product;
- Causing Defendants to refrain from marketing superior FDCs, thereby denying to Plaintiff's assignors 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 Plaintiff's assignors 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 Plaintiff's assignors 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 Plaintiff's assignors and the Class to pay overcharges on those products;
- Delaying and preventing competition from AB-rated competition to Viread, Truvada, and Atripla, thereby causing Plaintiff's assignors and the Class to pay overcharges on those products and on Defendants' FDCs.

393. Defendants' unlawful conduct deprived Plaintiff's assignors and the Class of the benefits of competition that the antitrust laws were designed to ensure.

**ANTITRUST IMPACT AND EFFECT ON INTERSTATE AND INTRASTATE  
COMMERCE**

394. During the relevant period, Plaintiff's assignors and the Class Members 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, Plaintiff's assignors and the Class Members were compelled to pay, and did pay, artificially inflated prices for these purchases. Those prices were substantially greater than the prices that Plaintiff's assignors 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) Plaintiff 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.

395. As a consequence, Plaintiff's assignors 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.

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

397. 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 U.S.

398. 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.

399. In furtherance of their efforts to restrain competition, Defendants employed the U.S. 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.

400. 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 third-party payors inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

**PLAINTIFF'S ASSIGNORS WERE INJURED**

401. Certain series of Plaintiff have executed irrevocable assignments of any and all rights to recover payments made on behalf of their assignors' health plan members and enrollees. These assignments authorize the series and, in turn Plaintiff through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. Plaintiff's assignors paid for unlawfully inflated antiretroviral medication. For

several decades, Defendants have manufactured and distributed HIV-targeting antiretroviral medication throughout the U.S., for which Plaintiff's assignors paid on behalf of their enrollees. Plaintiff's assignors' payments include those payments for Defendants' unlawfully inflated antiretroviral medications, which were also manufactured, distributed, and sold during that same period.

402. In each instance, Plaintiff's assignors received a request to cover a prescription drug on behalf of an enrollee for a particular date of service. The assignors accepted coverage for these requests and paid the amounts indicated for unlawfully inflated HIV-targeting antiretroviral medication.

### **CLASS ACTION ALLEGATIONS**

403. Under Rule 23 of the Federal Rules of Civil Procedure, Plaintiff brings this class action on its own behalf and on behalf of all Class Members nationwide. Plaintiff, individually and on behalf of the Class, seeks class certification of the claims alleged in this action and judgment for damages against the Defendants.

404. The Class is defined as follows, and consists of:

All third-party payers who paid (directly or indirectly) for some or all of the purchase price for any drug for use in a cART regimen, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period of May 14, 2015 through and until the anticompetitive effects of Defendants' unlawful conduct cease.

Excluded from the Class are: the Defendants; any parent, subsidiary, or affiliate of any Defendants; any entity in which any of the Defendants have or had a controlling interest, or which any of the Defendants otherwise controls or controlled; and any officer, directors, employee, legal representative, predecessor, successor, or assign of any of the Defendants.

#### **1. Federal Rule of Civil Procedure 23(a)**

405. Federal Rule of Civil Procedure 23(a) provides for class certification where the representative plaintiff demonstrates that:

1. the class is so numerous that joinder of all members is impracticable;
2. there are questions of law or fact common to the class;
3. the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
4. the representative parties will fairly and adequately protect the interests of the class.

**A. Numerosity**

406. On information and belief, the Class includes hundreds of third-party payers throughout the U.S., such that individual joinder of each Class member is impracticable. Further, the Class is readily identifiable from information and records in the possession of Defendants and of entities in the pharmacy chain of distribution.

**B. Commonality**

407. Plaintiff and the Class Members assert claims that raise common questions of law and fact.

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

- Whether the No-Generics Restraints entered into between Gilead and each of BMS, Janssen, and Japan Tobacco 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 and its co-conspirators 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 Plaintiff and the members of the Class; and
- The quantum of aggregate overcharge damages to the Class.

409. The common questions identified above predominate over questions, if any, that may affect only individual Class Members.

410. Defendants subjected Plaintiff's assignors and the Class Members to the same harm and did so in the same manner.

### ***C. Typicality***

411. Plaintiff's claims are typical of the claims of Class Members because they are based on the same legal theory, arise from the similarity, uniformity, and common purpose of Defendants' unlawful conduct, and are not subject to any unique defenses. Members of the Class have sustained damages in the same manner as Plaintiff's assignors, as a result of Defendants' wrongful conduct; i.e., they paid artificially inflated prices for the products and were deprived of earlier and more robust competition a result of Defendants' wrongful conduct.

### ***D. Adequacy of Representation***

412. Plaintiff and its attorneys will fairly and adequately protect and represent the interests of the Class. Plaintiff is a member of the Class defined above, is committed to the active

and vigorous prosecution of this action, and has retained competent counsel experienced in litigation of this nature.

413. There is no hostility of interests between Plaintiff and the Class and there will be no difficulty in the management of this litigation as a class action.

**2. Federal Rule of Civil Procedure 23(b)**

414. Questions of fact or law common to Plaintiff's and the Class Members' claims predominate over any questions of law or fact affecting only individual Class Members. All claims by Plaintiff and Class Members arise from the Defendants' common course of unlawful conduct. The predominating questions of law and fact include those set forth above in Paragraph 408.

415. Common issues predominate where, as here, liability can be determined on a class-wide basis, even if there might be the need for some individualized damages determinations. As a result, in determining whether common questions predominate, courts focus on the liability issue, and if the liability issue is common to the class, as it is in this case, common questions will be held to predominate over individual questions.

416. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because a class action is the most manageable and efficient way to resolve the individual claims of each Class Member.

417. Specifically, a class action is the superior method of adjudicating Plaintiff's and the Class Members' claims because it will provide Class Members with what may be their only economically viable remedy. Moreover, there are no known Class Members who are interested in individually controlling the prosecution of separate actions. In addition, a class action will concentrate all litigation in one forum, which will conserve judicial and party resources with no unusual manageability problems, because issues regarding the Defendants' liability and the nature

of Class Members' damages will be determined by class-wide proof, while the amounts of Class Members' damages will be determined by class-wide methods of data processing and computation.

### **ONGOING AND FUTURE HARM**

418. 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 Stribild, Complera, Genvoya, 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.

419. 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 Japan Tobacco's position would produce and market a substitutable version of Stribild when generic FTC and generic COBI become available; and such a competitor in Janssen's position would make a substitutable version of Complera when generic FTC becomes available.

420. Absent the No-Generics Restraints, when generic TAF becomes available an untainted competitor in Japan Tobacco's position would produce and market a comparable version of Genvoya, comprising generic TAF, generic 3TC, generic RTV, and EVG. Such a competitor would also make a substitutable version of Genvoya 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. The competitor would have sought FDA approval for a substitutable version of Genvoya as early as November 5, 2019 (when the applicable NCE exclusivity expired), and if Gilead had timely sued, the 30-month stay would have expired on May 5, 2023, allowing the competitor to begin marketing the substitutable FDC. Unless enjoined by this Court, however, the unlawful No-Generics Restraint will prevent that competition until the pact expires on April 24, 2030.

421. 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, 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.

422. 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, 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.

423. 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.

424. 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.

425. 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.

426. 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.

427. 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.

428. Defendants' conduct is also continuing to unlawfully delay the entry of generic TAF. As noted in detail above, 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 challenge the relevant TAF patents, because the NCE exclusivity does not expire until November 5, 2020.

429. 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.

**CAUSES OF ACTION**

**COUNT I**

**Conspiracy to Monopolize in Violation of Sections  
1 and 2 of the Sherman Antitrust Act (15 U.S.C. §§ 1, 2)  
(Against All Defendants)**

430. Plaintiff incorporates by reference paragraphs 1 to 429 of this Complaint.

431. Plaintiff asserts a claim under 18 U.S.C. § 1964(c) on behalf of itself and the Class Members.

432. 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 U.S., and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART Market.

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

434. Through an overarching anticompetitive scheme, as alleged extensively above, Gilead willfully maintained its monopoly power in the cART Market using restrictive or

exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

435. Gilead's conscious objective was to further its dominance in the cART Market by and through the overarching anticompetitive scheme.

436. Janssen, Japan Tobacco, and BMS each consciously committed to the overarching anticompetitive scheme.

437. As stated more fully above, Gilead and its co-conspirator Defendants knowingly, willfully, and wrongfully maintained Gilead's monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that were illegally protected from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected FDCs;
- 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; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

438. 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 justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

439. Plaintiff's assignors 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 II**  
**Conspiracy to Monopolize in Violation of State Antitrust Laws**  
**(Against All Defendants)**

440. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

441. 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 U.S., and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

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

443. Through an overarching anticompetitive scheme, as alleged extensively above, Gilead willfully maintained its monopoly power in the cART Market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff's assignors and the Class thereby.

444. Gilead's conscious objective was to further its dominance in the cART Market by and through the overarching anticompetitive scheme.

445. Each of Janssen, Japan Tobacco, and BMS consciously committed to the overarching anticompetitive scheme.

446. As stated more fully above, Gilead and its co-conspirator Defendants knowingly, willfully, and wrongfully maintained Gilead's monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that were illegally protected from competition;

- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected FDCs;
- 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; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

447. 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 justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

448. 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 payments in Alabama by members of the Class.
- (b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to payments in Arizona by members of the Class.
- (c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to payments in the U.S. by members of the Class.
- (d) Conn. Gen. Stat. § 35-24, et seq., with respect to payments in Connecticut by members of the Class.
- (e) D.C. Code Ann. §§ 28-4501, et seq., with respect to payments in the District of Columbia by members of the Class.

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

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

(h) 740 Ill. Comp. Stat. 10/3, et seq., with respect to payments in Illinois by members of the Class.

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

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

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

(l) Mass. Gen. L. Ch. 93A, et seq., with respect to payments in Massachusetts by members of the Class, which paid substantially higher prices for the product in actions and transactions occurring substantially within Massachusetts.

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

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

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

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

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

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

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

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

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

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

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

(x) 10 L.P.R.A. § 251, et seq., with respect to payments in Puerto Rico by members of the Class.

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



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

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

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

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

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

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

449. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully 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 payments in Arizona by members of the Class.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(v) 10 L.P.R.A. §§ 260, et seq., with respect to payments in Puerto Rico by members of the Class.

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

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

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

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

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

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

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

**COUNT III**  
**Monopolization in Violation of Section 2**  
**of the Sherman Antitrust Act**  
**(Against Gilead)**

450. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

451. 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 U.S., and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the cART Market.

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

453. As alleged extensively above, Gilead willfully maintained its monopoly power in the cART Market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

454. Gilead's conscious objective was to further its dominance in the cART Market by and through its exclusionary conduct.

455. As stated more fully above, Gilead knowingly, willfully, and wrongfully maintained its monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that were illegally protected from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected FDCs;
- 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; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

456. 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.

457. 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 justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

458. Plaintiff 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 IV**  
**Monopolization in Violation of State Antitrust Laws**  
**(Against Gilead)**

459. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

460. 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 U.S., and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the cART Market.

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

462. As alleged extensively above, Gilead willfully maintained its monopoly power in the cART Market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

463. Gilead's conscious objective was to further its dominance in the cART Market by and through its exclusionary conduct.

464. As stated more fully above, Gilead knowingly, willfully, and wrongfully maintained its monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that were illegally protected from competition;

- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected FDCs;
- 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; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

465. 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.

466. Plaintiff 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.

467. By engaging in the foregoing conduct, Gilead has intentionally and wrongfully 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 payments in Arizona by members of the Class.
- (b) Conn. Gen. Stat. § 35-24, et seq., with respect to payments in Connecticut by members of the Class.
- (c) D.C. Code §§ 28-4501, et seq., with respect to payments in the District of Columbia by members of the Class.
- (d) Fla. Stat. §§ 501.201, et seq., with respect to payments in Florida by members of the Class.
- (e) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to payments in Hawaii by members of the Class.

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

(u) 10 L.P.R.A. §§ 260, et seq., with respect to payments in Puerto Rico by members of the Class.

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

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

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

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

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

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

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

**COUNT V**  
**Attempted Monopolization in Violation of Section 2**  
**of the Sherman Antitrust Act**  
**(Against Gilead)**

468. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

469. 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.

470. With the specific intent to achieve a monopoly, Gilead attempted to acquire and/or willfully maintain monopoly power in the cART Market by means of restrictive or exclusionary conduct rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

471. Gilead's conscious objective was to further its dominance in the cART Market by and through its exclusionary conduct.

472. 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;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that were illegally protected from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected FDCs;

- 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; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

473. 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.

474. 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 justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

475. Plaintiff 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 VI**  
**Attempted Monopolization in Violation of State Antitrust Laws**  
**(Against Gilead)**

476. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

477. 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.

478. With the specific intent to achieve a monopoly, Gilead attempted to acquire and/or willfully maintain monopoly power in the cART Market by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

479. Gilead's conscious objective was to further its dominance in the cART Market by and through its exclusionary conduct.

480. 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;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that were illegally protected from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected FDCs;
- 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; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

481. 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.

482. 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 justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

483. Plaintiff 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.

484. By engaging in the foregoing misconduct, Gilead has violated the following state laws:

- (a) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to payments in Arizona by members of the Class.
- (b) Conn. Gen. Stat. § 35-24, et seq., with respect to payments in Connecticut by members of the Class.
- (c) D.C. Code §§ 28-4501, et seq., with respect to payments in the District of Columbia by members of the Class.
- (d) Fla. Stat. §§ 501.201, et seq., with respect to payments in Florida by members of the Class.
- (e) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to payments in Hawaii by members of the Class.
- (f) Iowa Code §§ 553.5, et seq., with respect to payments in Iowa by members of the Class.
- (g) Kansas Stat. Ann. § 50-101, et seq., with respect to payments in Kansas by members of the Class.
- (h) Me. Rev. Stat. Ann. 10, §§ 1102, et seq., with respect to payments in Maine by members of the Class.
- (i) Md. Code, Com. Law § 11-201, et seq., with respect to payments in Maryland by members of the Class.
- (j) Mass. Gen. L. Ch. 93A, et seq., with respect to payments in Massachusetts by members of the Class.
- (k) Mich. Comp. Laws Ann. §§ 445.771, et seq., with respect to payments in Michigan by members of the Class.

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

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

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

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

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

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

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

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

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

(u) 10 L.P.R.A. §§ 260, et seq., with respect to payments in Puerto Rico by members of the Class.

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

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

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

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

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

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

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

**COUNT VII**  
**Violation of State Consumer Protection Laws**  
**(Against All Defendants)**

485. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

486. Defendants engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below.

487. As a direct and proximate result of Defendants' unfair, unconscionable, deceptive, and fraudulent conduct in violation of the state consumer protection statutes listed below,

Plaintiff's assignors 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.

488. There was a gross disparity between the price that Plaintiff's assignors 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.

489. 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 payments in Arizona by members of the Class.

(b) Arkansas Code Annotated, § 4-88-101, et seq., with respect to payments in Arkansas by members of the Class.

(c) Cal. Bus. & Prof. Code §§ 17200, et seq., with respect to payments in the U.S. by members of the Class.

(d) D.C. Code §§ 28-3901, et seq., with respect to payments in the District of Columbia by members of the Class.

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

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



(g) Iowa Code §§ 714.16, et seq., with respect to payments in Iowa by members of the Class.

(h) Idaho Code Ann. §§ 48-601, et seq., with respect to payments in Idaho by members of the Class.

(i) 815 Ill. Comp. Stat. Ann. §§ 505/1, et seq., with respect to payments in Illinois by members of the Class.

(j) Kan. Stat. Ann. §§ 50-623, et seq., with respect to payments in Kansas by members of the Class.

(k) Me. Rev. Stat. tit. 5 §§ 207, et seq., with respect to payments in Maine by members of the Class.

(l) Mass. Gen. Laws ch. 93A, et seq., with respect to payments in Massachusetts by members of the Class.

(m) Mich. Comp. Laws Ann. §§ 445.901, et seq., with respect to payments in Michigan by members of the Class.

(n) Mo. Ann. Stat. §§ 407.010, et seq., with respect to payments in Missouri by members of the Class.

(o) Mont. Code Ann. §§ 30-14-101, et seq., with respect to payments in Montana by members of the Class.

(p) Neb. Rev. Stat. §§ 59-1601, et seq., with respect to payments in Nebraska by members of the Class.

(q) Nev. Rev. Stat. §§ 598.0903, et seq., with respect to payments in Nevada by members of the Class.

(r) N.H. Rev. Stat. Ann. §§ 358-A:1, et seq., with respect to payments in New Hampshire by members of the Class.

(s) N.M. Stat. Ann. §§ 57-12-1, et seq., with respect to payments in New Mexico by members of the Class.

(t) N.Y. Gen. Bus. Law §§ 349, et seq., with respect to payments in New York by members of the Class.

(u) N.C. Gen. Stat. §§ 75-1.1, et seq., with respect to payments in North Carolina by members of the Class.

(v) R.I. Gen. Laws §§ 6-13.1-1, et seq., with respect to payments in Rhode Island by members of the Class.

(w) Tenn. Code Ann. §§ 47-18-101, et seq., with respect to payments in Tennessee by members of the Class.

(x) Utah Code Ann. §§ 13-11-1, et seq., with respect to payments in Utah by members of the Class.

(y) Vt. Stat. Ann. tit. 9 §§ 2451 et seq., with respect to payments in Vermont by members of the Class.

(z) W. Va. Code §§ 46A-6-101, et seq. with respect to payments in West Virginia by members of the Class.

490. Plaintiff 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 directly results from Defendants' unlawful conduct.

**COUNT VIII**  
**Conspiracy in Violation of Section 1 of the**  
**Sherman Antitrust Act**  
**(Against Gilead and Janssen)**

491. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

492. 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; and (c) agreeing to and abiding by mutual No-Generics Restraints with respect to Symtuza. 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.

493. Plaintiff's assignors and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff's assignors 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.

494. As a result of Defendants' unlawful conduct, Plaintiff's assignors 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.

495. If Gilead and Janssen had competed in a full and timely fashion, Plaintiff's assignors 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.

496. During the relevant period, Plaintiff's assignors and the other Class members purchased substantial amounts of the products. As a result of Gilead and Janssen's unlawful conduct, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff's assignors 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) Plaintiff's assignors and Class members were deprived of the opportunity to purchase lower-priced generic and comparable products instead of expensive brand products; (2) Plaintiff's assignors 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.

497. Plaintiff 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 IX**  
**Conspiracy in Violation of State Antitrust Laws**  
**(Against Gilead and Janssen)**

498. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

499. 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 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.

500. 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 payments in Alabama by members of the Class.
- (b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to payments in Arizona by members of the Class.
- (c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to payments in the U.S. by members of the Class.
- (d) Conn. Gen. Stat. § 35-24, et seq., with respect to payments in Connecticut by members of the Class.

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

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

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

(h) 740 Ill. Comp. Stat. 10/3, et seq., with respect to payments in Illinois by members of the Class.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(x) 10 L.P.R.A. § 251, et seq., with respect to payments in Puerto Rico by members of the Class.

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

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

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

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

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

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

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

501. Plaintiff's assignors and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff's assignors 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.

502. As a result of Defendants' unlawful conduct, Plaintiff's assignors 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.

503. If Gilead and Janssen had competed in a full and timely fashion, Plaintiff's assignors 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.

504. During the relevant period, Plaintiff's assignors 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, Plaintiff's assignors and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff's assignors 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) Plaintiff's assignors and Class members were deprived of the opportunity to purchase lower-priced generic or comparable products instead of expensive brand products; (2) Plaintiff's assignors 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.

505. Plaintiff 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 X**  
**Conspiracy in Violation of Section 1 of the Sherman Antitrust Act**  
**(Against Gilead and Japan Tobacco)**

506. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

507. Gilead and Japan Tobacco have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by agreeing to and abiding by the No-Generics Restraints with respect to Stribild and Genvoya, the purpose and effect of which was to impair competition. By entering into these unlawful agreements, Gilead and Japan Tobacco unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Gilead and Japan Tobacco 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.

508. Plaintiff's assignors and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff's assignors 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.

509. As a result of Defendants' unlawful conduct, Plaintiff's assignors and the Class paid more than they would have paid for Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Stribild, Genvoya, and competing cART drugs absent that unlawful conduct. But for Gilead and Japan Tobacco'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.

510. If Gilead and Japan Tobacco had competed in a full and timely fashion, Plaintiff's assignors 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.

511. During the relevant period, Plaintiff's assignors and the other Class members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and Japan Tobacco's unlawful conduct, Plaintiff's assignors and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff's assignors 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) Plaintiff's assignors and Class members were deprived of the opportunity to purchase lower-priced generic or comparable products instead of expensive brand products; (2) Plaintiff's assignors 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 Japan Tobacco's conduct.

512. Plaintiff's assignors 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 Japan Tobacco's continuing conspiracy in violation of Section 1 of the Sherman Act.

**COUNT XI**  
**Conspiracy in Violation of State Antitrust Laws**  
**(Against Gilead and Japan Tobacco)**

513. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

514. Gilead and Japan Tobacco have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by agreeing to and abiding by the No-Generics

Restraints with respect to Stribild and Genvoya, the purpose and effect of which was to impair competition. The agreements between Gilead and Japan Tobacco 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.

515. By entering into these unlawful agreements, Gilead and Japan Tobacco unlawfully conspired in restraint of trade and violated the following state laws:

- (a) Ala. Code §8-10-3 with respect to payments in Alabama by members of the Class.
- (b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to payments in Arizona by members of the Class.
- (c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to payments in the U.S. by members of the Class.
- (d) Conn. Gen. Stat. § 35-24, et seq., with respect to payments in Connecticut by members of the Class.
- (e) D.C. Code Ann. §§ 28-4501, et seq., with respect to payments in the District of Columbia by members of the Class.
- (f) Fla. Stat. §§ 501.201, et seq., with respect to payments in Florida by members of the Class.
- (g) Hawaii Rev. Stat. §§ 480-1, et seq., with respect to payments in Hawaii by members of the Class.
- (h) 740 Ill. Comp. Stat. 10/3, et seq., with respect to payments in Illinois by members of the Class.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(x) 10 L.P.R.A. § 251, et seq., with respect to payments in Puerto Rico by members of the Class.

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

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

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

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

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

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

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

516. Plaintiff and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff's assignors 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.

517. 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, Stribild, Genvoya, and competing cART drugs absent that unlawful conduct. But for Gilead and Japan Tobacco'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.

518. If Gilead and Japan Tobacco had competed in a full and timely fashion, Plaintiff's assignors 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.

519. During the relevant period, Plaintiff's assignors and the other Class members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and

Japan Tobacco's unlawful conduct, Plaintiff's assignors and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff's assignors 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) Plaintiff's assignors and Class members were deprived of the opportunity to purchase lower-priced generic or comparable products instead of expensive brand products; (2) Plaintiff's assignors 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 Japan Tobacco's conduct.

520. Plaintiff 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 Japan Tobacco's continuing conspiracy.

**COUNT XII**  
**Conspiracy Violation of Section 1 of the**  
**Sherman Antitrust Act**  
**(Against Gilead and BMS)**

521. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

522. 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 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.



523. Plaintiff and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff's assignors and members of 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 alternative for their purchases of the more expensive brand and/or the more expensive generic products.

524. As a result of Defendants' unlawful conduct, Plaintiff's assignors 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.

525. If Gilead and BMS had competed in a full and timely fashion, Plaintiff's assignors 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.

526. During the relevant period, Plaintiff's assignors 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, Plaintiff's assignors and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff's assignors 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) Plaintiff's assignors and Class members were deprived of the opportunity to

purchase lower-priced generic products instead of expensive brand products; (2) Plaintiff's assignors 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.

527. Plaintiff 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 XIII**  
**Conspiracy in Violation of State Antitrust Laws**  
**(Against Gilead and BMS)**

528. Plaintiff incorporates by reference paragraphs 1 to 429 of the Complaint.

529. 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 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.

530. By entering into these unlawful agreements, Gilead and BMS unlawfully conspired in restraint of trade and violated the following state laws:

- (a) Ala. Code §8-10-3 with respect to payments in Alabama by members of the Class.
- (b) Arizona Rev. Stat. §§ 44-1401, et seq., with respect to payments in Arizona by members of the Class.
- (c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to Medicare payments in the U.S. by members of the Class.

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

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

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

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

(h) 740 Ill. Comp. Stat. 10/3, et seq., with respect to payments in Illinois by members of the Class.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(x) 10 L.P.R.A. § 251, et seq., with respect to payments in Puerto Rico by members of the Class.

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

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

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

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

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

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

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

531. Plaintiff and all members of the Class have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff's assignors 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 alternative for their purchases of the more expensive brand and/or the more expensive generic products.

532. As a result of Defendants' unlawful conduct, Plaintiff's assignors 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.

533. If Gilead and BMS had competed in a full and timely fashion, Plaintiff's assignors 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.

534. During the relevant period, Plaintiff's assignors 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, Plaintiff's assignors and the other Class members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff's assignors 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) Plaintiff's assignors and Class members were deprived of the opportunity to purchase lower-priced generic products instead of expensive brand products; (2) Plaintiff's assignors 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.

535. Plaintiff 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.

**JURY DEMAND**

536. Under Fed. Civ. P. 38, Plaintiff, individually and on behalf of the Class, demands a trial by jury on all issues so triable.

**DEMAND FOR JUDGMENT**

537. WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that the Court:

- a. Determine that this action may be maintained as a class action under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), 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 Plaintiff the representative of the Class;
- b. Enter judgment against each Defendant in favor of Plaintiff and the Class;
- c. Adjudge and decree the acts alleged herein, under 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 under 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:
  - i. 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;
  - ii. 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;
  - iii. Defendants shall not enforce the No-Generics Restraints that would otherwise prohibit Janssen, Japan Tobacco, or BMS from making or marketing competing FDCs after the expiration of Gilead's relevant patents;
  - iv. 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;

- v. 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;
  - vi. 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;
  - vii. Each of Janssen, Japan Tobacco, and BMS shall issue licenses to their third agents to any willing licensee on terms to be determined by the Court;
  - viii. Gilead shall issue licenses to TDF, TAF, and FTC to any willing licensee on terms to be determined by the Court;
  - ix. 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;
  - x. 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 Plaintiff and the Class damages (and multiple damages as provided by law) in amounts to be determined at trial;
  - f. Award to Plaintiff 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.

Dated: January 15, 2020

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