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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CENTENE CORPORATION, Plaintiff, v. GILEAD SCIENCES, INC.; GILEAD HOLDINGS, LLC; GILEAD SCIENCES, LLC (f/k/a BRISTOL-MYERS SQUIBB & GILEAD SCIENCES, LLC); GILEAD SCIENCES IRELAND UC (f/k/a GILEAD SCIENCES LIMITED); JANSSEN PRODUCTS, L.P.; and JANSSEN R&D IRELAND (f/k/a TIBOTEC PHARMACEUTICALS), Defendants.	Case No. **COMPLAINT AND DEMAND FOR JURY TRIAL**

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Plaintiff Centene Corporation ("Plaintiff") brings this civil action against Defendants Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC (f/k/a Bristol-Myers Squibb & Gilead Sciences, LLC), Gilead Sciences Ireland UC (f/k/a Gilead Sciences Limited) (collectively, "Gilead"), Janssen Products, L.P., and Janssen R&D Ireland (f/k/a Tibotec Pharmaceuticals) (collectively, "Janssen") (collectively, "Defendants") under United States antitrust laws and the laws of various states. Plaintiff alleges as follows:

INTRODUCTION

1. Since 1981, more than 35 million people worldwide and 700,000 people in the U.S. have died from Human Immunodeficiency Virus ("HIV") infection. Despite the advent of numerous drugs over the past twenty years, the disease continues to affect millions of Americans. As of 2017, more than 1.1 million people in the U.S. were living with HIV and nearly 40,000 new patients are diagnosed with the disease each year.

2. Gilead dominates the market for antiretroviral drugs, which are essential to effective HIV treatment. It manufactures three of the four best-selling HIV drugs on the market, as well as many other drugs that are used in HIV combination antiretroviral therapy ("cART"). Presently, more than 80% of U.S. patients starting an HIV drug treatment regimen take one or more of Gilead's products every day.

3. Several of Gilead's HIV medications cost less than $10 to produce; yet for nearly 20 years, Gilead has charged health plans like Plaintiff thousands of dollars for a 30-day supply. With yearly sales in the U.S. exceeding $13 billion, Gilead has extracted enormous profits from its HIV drugs.

4. Gilead's ability to sustain supracompetitive profits in its multi-billion-dollar HIV treatment franchise has been engineered through a comprehensive, illegal scheme to blockade competition. Beginning in 2004, Gilead entered into a series of anticompetitive agreements with competing cART drug makers to:

- Create branded combination drugs, with express bans on using generic components to create competitive drugs even after patents on the combination drugs expired; and

- Delay market entry by competing generic manufacturers for years beyond the date that Gilead's patents would have been invalidated, in exchange for protecting the generic manufacturers from competition at the point of delayed entry.

5. In addition, Gilead engaged in an array of improper, anticompetitive actions to preserve and extend its monopoly cART franchise, including:

- Intentionally delaying the introduction of safer cART drugs it had developed, so it could fully monetize its less-safe drugs while they were insulated from competition via Gilead's anticompetitive agreements;
- Switching prescribers and patients away from patent-vulnerable drugs while Gilead's delayed generic entry agreements were in effect, leaving prescribers and patients with no generic alternatives;
- Degrading the efficacy of certain of its products that were more vulnerable to competition to induce patients to switch to Gilead's monopoly products; and
- Otherwise using false and misleading marketing and treatment indications to impede competition and perpetuate Gilead's monopoly positions.

6. All of these anticompetitive agreements and actions combined to insulate Gilead's product portfolio from the drastic price erosion that would have occurred with effective competition, and resulted in billions of dollars in annual excess profits that accrued (and continue to accrue) to Gilead and its co-conspirators.

7. As further explained below, Gilead and its co-conspirators' anticompetitive schemes involved unlawful contracts, combinations and restraints of trade in the markets for cART regimen drugs and unlawful monopolization in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. Sections 1 and 2, and various states' laws.

8. As a result of Gilead and its co-conspirators' anticompetitive conduct, Plaintiff paid more for cART regimen drugs than it otherwise would have paid in the absence of Gilead and its co-conspirators' unlawful conduct and has sustained, and continues to sustain, damages in the form of overcharges paid for its members' prescriptions of cART regimen drugs.

9. Plaintiff seeks redress for the economic harm it has sustained as a result of Gilead and its co-conspirators' violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. Sections 1 and 2, and various states' laws. Plaintiff also seeks injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. Section 26.

NATURE OF THE ACTION

10. Combination antiretroviral therapy regimen drugs are commonly used to treat patients with HIV. HIV can result in Acquired Immunodeficiency Syndrome ("AIDS") and death. Modern antiretroviral cART drug regimens comprise a combination or "cocktail" of drugs, most often consisting of two nucleotide/nucleoside analogue reverse transcriptase inhibitors ("NRTIs") taken with at least one antiretroviral drug of another class, such as an integrase inhibitor, commonly referred to as "third agents." Tenofovir, one of the principal NRTIs used in cART regimens, was discovered more than 30 years ago and has long since lost any patent protection.

11. In 2001, Gilead began marketing tenofovir disoproxil ("TDF") as Viread. TDF is a "prodrug" of tenofovir, meaning that TDF has slight alterations from tenofovir, and, in the body, TDF metabolizes into tenofovir. Considering these slight alterations, Gilead's patents on TDF were weak and vulnerable to attack by generic competitors. In light of that threat, Gilead entered into a series of agreements with co-conspirators Janssen and "BMS" (Bristol-Myers Squibb Co., and E.R. Squibb & Sons, L.L.C., collectively) to combine their drugs and insulate them and their component parts from generic competition. These agreements unlawfully restricted competition in ways unnecessary to achieve any legitimate business purpose.

12. In 2003 and 2004, Gilead began marketing emtricitabine (commonly, "FTC") as Emtriva. It then launched a fixed-dose combination ("FDC") drug comprised of TDF and FTC called Truvada. Like TDF, FTC became a principal NRTI, and the two together were described as the "[r]ecommended NRTI backbone for most initial [cART] regimens."[1] However, also like TDF, Gilead's patent protection on FTC was weak, as Gilead obtained its rights to FTC from others who had publicly disclosed FTC over ten years earlier.

13. In December 2004, Gilead entered into an agreement with BMS to combine Gilead's Truvada (TDF/FTC) and BMS's Sustiva (efavirenz, "EFV") into an FDC named Atripla (TDF/FTC/EFV). At the time, Gilead expected imminent challenges to its patents covering

[1] HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (Nov. 13, 2014), https://clinicalinfo.hiv.gov/en/guidelines/archived-guidelines/adult-and-adolescent-guidelines.

Truvada and sought to combine Truvada with Sustiva so that the resulting combination would be protected by BMS's patents. Gilead and BMS aggressively promoted Atripla and induced prescribers and patients to switch their prescriptions from other TDF-based drugs to Atripla, knowing that those prescribers and patients would be reluctant to switch back to their earlier, standalone drugs when generic versions of those drugs became available. As a result, Gilead and BMS could continue to charge supracompetitive prices for Atripla even after standalone generic versions of the Atripla components launched.

14. The Gilead-BMS Atripla agreement included a "No-Generics Restraint" clause, which barred both parties from using generic versions of each other's standalone drugs to make partially-generic versions of Atripla, even after the patents on their standalone drugs expired. For example, BMS could not make a combination drug that would compete with Atripla consisting of generic Truvada (TDF/FTC) and Sustiva (EFV).

15. In 2009, Gilead entered into an agreement with Janssen to combine Gilead's Truvada (TDF/FTC) and Janssen's Edurant (rilpivirine, "RPV") into an FDC named Complera (TDF/FTC/RPV). As with Atripla, Gilead and Janssen aggressively sought to switch prescribers and patients from other TDF-based drugs to Complera knowing that they could continue to charge supracompetitive prices for Complera even after generic versions of Truvada and other drugs were launched.

16. The Gilead-Janssen Complera agreement included a No-Generics Restraint clause that was broader than the No-Generics Restraint clause in the Atripla agreement. This No-Generics Restraint provision not only barred Janssen from making a partially-generic version of Complera using generic Truvada (TDF/FTC) and branded Edurant (RPV), but also barred Janssen from developing a competitor to Complera consisting of generic Viread (TDF), generic lamivudine ("3TC") — a substitute for FTC that entered the market around January 2012 — and branded Edurant (RPV).

17. Gilead subsequently entered into an additional agreement with Janssen to combine Janssen's Prezista (darunavir, "DRV") with Gilead's Tybost (cobicistat, "COBI") into a drug named Prezcobix (DRV/COBI) so that Janssen could take advantage of Gilead's longer-lived

patents for COBI. Gilead then entered into a similar agreement with BMS to combine BMS's Reyataz (atazanavir, "ATV") with Tybost into a drug named Evotaz (ATV/COBI). Both agreements contained No-Generics Restraint clauses.

18. In 2009, Teva Pharmaceuticals USA, Inc. ("Teva") challenged Gilead's TDF patents. Gilead responded by suing Teva and then entering into an unlawful reverse payment settlement agreement with Teva, with the intent and effect of eliminating Teva's patent challenges to Gilead's core group of TDF-based drugs: Viread, Truvada, and Atripla.

19. In February 2013, the day before trial, Gilead and Teva announced a settlement that delayed the introduction of generic Viread by more than 4.5 years until December 15, 2017, only six weeks before Gilead's TDF patents were set to expire. In exchange, Gilead granted Teva six weeks of exclusivity as the only seller of generic Viread — a deal that was worth over $100 million to Teva.

20. Then, in February 2014, the day before closing arguments in a trial concerning Gilead's FTC patents, Gilead and Teva announced another settlement. This one delayed the introduction of generic Truvada and Atripla by more than 6.5 years until September 30, 2020, one year before the expiration of Gilead's patents. In return, Gilead granted Teva six months of exclusivity as the only seller of generic Truvada and Atripla — a deal that was worth more than $1 billion to Teva.

21. Gilead entered into separate conspiracies with BMS, Janssen, and Teva to impede and delay competition for its TDF products so that Gilead could delay bringing its safer and more effective tenofovir alafenamide ("TAF") products to market, further extending its cART regimen monopoly. Gilead had known since at least 2001 that TAF had significantly fewer risks of side effects than TDF. The company had conducted studies on toxicity that demonstrated that TAF was far more effective than TDF and could be administered at much lower doses to reduce the risk that users would suffer bone loss or kidney damage. Despite this knowledge, once Gilead entered into its separate No-Generics Restraint agreements with BMS and Janssen, and conspired with Teva to delay competition from Teva's generic TDF, Gilead intentionally delayed

introducing its safer, more effective TAF products for years in order to extend its monopoly on TDF-based products.

22. When Gilead finally began introducing its TAF drugs, it did so in ways that both endangered patients and further impeded competition. In 2014, Gilead entered into two additional No-Generics Restraint agreements with Janssen, expanding their prior relationship to include Gilead's new TAF platform. The parties agreed to develop Odefsey, a TAF-based successor to Complera, and Symtuza, a combination of TAF, FTC, and Prezcobix (DRV/COBI). These drugs ultimately launched in 2016 (Odefsey) and 2018 (Symtuza). Gilead also launched Stribild (TDF/FTC/EVG/COBI), including elvitegravir ("EVG"), which contained TDF in a boosted form, and thus had greater risks for patients. Gilead then highlighted these risks to prescribers and patients in order to facilitate a switch from Gilead's TDF-based products to its TAF-based products.

23. Gilead next declined to apply for FDA approval of standalone TAF, forcing patients who sought the safer formulation of tenofovir to take TAF-based FDCs. Then, when Gilead finally did seek approval for standalone TAF, it only sought approval for its use in treating Hepatitis B, not HIV, despite concurrently seeking approval of a TAF-based combination product to treat HIV. Because Gilead did not pursue FDA approval of standalone TAF as an HIV treatment, potential generic competitors were impeded in their efforts to bring competing standalone TAF products to market. Prescribers also could not prescribe standalone TAF to HIV patients for "off label" use with other generic component cART drugs (such as 3TC or generic Emtriva) because the dosage of TAF in its standalone form was much higher than in Gilead's TAF-based FDCs.

24. In November 2015, Gilead launched its first TAF-based drug, Genvoya (TAF/FTC/EVG/COBI), a TAF-based successor to Stribild. Gilead then exploited the illegal agreements it had separately reached with BMS, Janssen, and Teva — which, among other things, had created a several year delay in the onset of generic TDF competition — by using that window to aggressively shift prescribers and patients from TDF-based drugs to TAF-based drugs.

25. This "product hop" scheme was wildly successful for Gilead. By September 2020, when generic Truvada finally came to market, 91% of Gilead's U.S. prescription base had been converted to TAF-based regimens. And even though by this time generic TDF drugs had finally entered the market, they were not easily substitutable for the TAF drugs prescribers and patients were now prescribing and taking. Gilead thus succeeded in further extending its cART monopoly franchise.

26. The separate horizontal agreements between Gilead and each of its co-conspirators 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 boosted drugs for use in a cART regimen in the U.S.

27. In the absence of Gilead's and its co-conspirators' unlawful conduct, generic versions of cART regimen drugs would have launched years earlier. Competition from TDF-based generics would have driven prices down to competitive levels. Gilead also would have brought its safer, more effective TAF drugs to market years earlier, and those products would have faced earlier generic competition.

28. Plaintiff has sustained, and continues to sustain, injuries to its business and property as a result of Gilead's and its co-conspirators' conduct.

JURISDICTION AND VENUE

29. This Court has subject-matter jurisdiction over this action pursuant to 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337, as Plaintiff asserts claims for violations of Sections 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and seeks injunctive relief under Section 4 and Section 16 of the Clayton Act, 15 U.S.C. § 15(a) and § 26. This Court has subject-matter jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1367 because its state law claims are so related as to form part of the same case or controversy as its federal claims. Exercising supplemental jurisdiction over Plaintiff's state law claims will avoid unnecessary duplication and multiplicity of actions and, therefore, promotes judicial economy, fairness, and convenience.

30. Venue in this District is proper pursuant to 15 U.S.C. §§ 15 and 22, 28 U.S.C. §§ 1391(b)-(d), and 28 U.S.C. § 1407. At all relevant times, Defendants transacted business within this District, carried out interstate trade and commerce in substantial part in this District,

and/or have an agent and/or can be found in this District. Defendants sold and distributed the relevant drugs in a continuous and interrupted flow of interstate commerce, which included sales of relevant HIV cART drugs in the U.S. (including in this District). Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the U.S. (including in this District).

31. This Court has personal jurisdiction over Defendants because each Defendant transacted business throughout the U.S. (including in this District); sold and distributed cART market drugs, including one or more of the relevant drugs, throughout the U.S. (including in this District); engaged in an unlawful conspiracy to restrain trade for cART market drugs, including one or more of the relevant drugs, that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the U.S. (including in this District); entered into agreements for the development and manufacture of cART market drugs, including the relevant drugs in the U.S. (including in this District); has registered agents in the U.S. (including in this District); may be found in the U.S. (including in this District); and is otherwise subject to the service of process provisions of 15 U.S.C. § 22.

PARTIES

32. Plaintiff Centene Corporation[2] is a Delaware corporation with its principal place of business at Centene Plaza, 7700 Forsyth Boulevard, St. Louis, Missouri 63105. Centene and its subsidiaries are providers of healthcare related services, including insuring risk for prescription drug costs for more than 15.2 million insureds in all 50 States, the District of Columbia, and Puerto Rico. At all times relevant to this Complaint, Centene and its subsidiaries were (and are) contractually responsible under various prescription drug benefit plans for making payments for branded and generic HIV cART drugs dispensed to their members across the United States and, as a result, spent billions of dollars on these drugs. Centene seeks recovery of all overcharges incurred in connection with those purchases.

[2] Centene operates its insurance business through a variety of wholly owned subsidiaries all of whom have assigned their claims in this action to Centene.

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

34. Defendant Gilead Holdings, LLC is a Delaware limited liability company 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.

35. Defendant Gilead Sciences, LLC (f/k/a Bristol-Myers Squibb & Gilead Sciences, LLC) is a Delaware limited liability company with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Sciences, LLC is now a wholly owned subsidiary of Gilead Sciences, Inc.

36. Defendant Gilead Sciences Ireland UC (f/k/a Gilead Sciences Limited) is an Irish unlimited liability company with a principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland. Gilead Sciences Ireland UC is a wholly-owned subsidiary of Gilead Sciences, Inc.

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

38. Defendant Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals) is a private Irish company 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.

39. Other persons and entities not named as Defendants, including Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C. and Teva Pharmaceuticals USA, Inc. joined and participated in conspiracies with Gilead related to cART drugs.

REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs.

40. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers seeking to market a pharmaceutical product must obtain FDA approval by filing a New Drug Application ("NDA"). 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). The products based on these NDAs are generally referred to as "brand-name drugs" or "branded drugs."

41. When the FDA approves an NDA, the drug product is listed in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The FDA lists in the Orange Book any patents which, according to the information supplied to the FDA by the brand manufacturer: (1) claim the approved drug or its approved uses; and (2) the manufacturer believes could reasonably be asserted against another manufacturer that makes, uses, or sells a generic version of the brand drug. 21 U.S.C. § 355(b)(1). A manufacturer must submit this patent information within thirty days of NDA approval, or, for any later-issued patent, within thirty days of issuance of the patent. 21 U.S.C. § 355(c)(2).

42. The FDA relies completely on a brand manufacturer's truthfulness and representations in submitting patents to be listed, as it does not have the resources or authority to verify the validity or relevance of the manufacturer's patents. Therefore, in listing patents in the Orange Book, the FDA merely performs a ministerial act.

43. A drug that receives NDA approval may be entitled to regulatory exclusivity for a limited period of time — in other words, the FDA cannot approve any generic drug applications during this period.

B. The Hatch-Waxman Amendments.

44. When a branded drug's regulatory exclusivity is about to expire, a manufacturer seeking approval to sell a generic version of a branded drug may file an Abbreviated New Drug

Application ("ANDA") that demonstrates that a generic version of the drug is essentially the same as the branded version: i.e., has the same active ingredients, dosage form, safety, strength, absorption, route of administration, quality, performance characteristics, and intended use. 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).

45. An ANDA relies on the scientific findings of safety and effectiveness included in a brand manufacturer's original NDA and must further show that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to a generic drug that is therapeutically equivalent to a brand-name counterpart, indicating the drugs may be substituted for one another. 21 U.S.C. § 355(j)(8)(B).

46. Congress had two goals in enacting the Hatch-Waxman Amendments. First, it sought to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Second, it sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

47. To incentivize the development of new drugs, the Hatch-Waxman Amendments created a 5-year period of new chemical entity ("NCE") exclusivity. Following the approval of an NDA for a drug that has not been approved in any other application, no ANDA may be submitted for that drug for 5 years (or 4 years if the ANDA contains a paragraph IV certification, as discussed in the next section). *See* 21 U.S.C. § 355(j)(5)(F)(ii).

48. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had soared to $300 billion.

C. Paragraph IV Certifications.

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

i. that no patent for the brand drug has been filed with the FDA;

ii. that the patent for the brand drug has expired;

iii. that 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; or

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

50. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA by suing the ANDA applicant for patent infringement. If the brand manufacturer sues the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will 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. Before then, the FDA may grant only a "tentative approval" to an ANDA if it determines that the ANDA would otherwise be ready for final approval.

51. As an incentive to spur generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a paragraph IV certification typically gets 180 days of market exclusivity (unless a forfeiture event occurs, as discussed below). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. When there is only one generic on the market, the generic price is lower than the branded price, but much higher than the price after multiple generic competitors enter the market.

52. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. In a 2019 report, the FDA stated that products with a single generic producer yield a generic average manufacturer price that is 39% lower than the brand before generic competition; with two competitors, generic prices are 54% lower than the brand before generic competition; and with four competitors, generic prices are 79% less than the brand before generic competition.[3] Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

53. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a paragraph IV certification (even if the generic competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers sue generic manufacturers under Hatch-Waxman simply to delay generic competition — as opposed to enforcing a valid patent that is actually infringed by the generic — is demonstrated by the fact that generic manufacturers prevail 73% of the time by either obtaining a favorable judgment or the brand manufacturer's voluntary dismissal.

54. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry but also the market entry of all other generic manufacturers. By agreeing not to begin marketing its generic drug, the first generic applicant delays the start of the 180-day period of generic market exclusivity. This tactic is called exclusivity "parking." It creates a bottleneck because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

55. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire to delay the start of the first filer's 180-day period of

[3] U.S. Food & Drug Administration, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, at 2-3 (Dec. 2019), https://www.fda.gov/media/133509/download.

generic market exclusivity. Specifically, the law now provides six mechanisms by which first ANDA filers may forfeit their exclusivity rights, thus allowing second (or later) filers to enter the market before, or at the same time as, first filers.

56. First, under the "failure to obtain tentative approval" provision, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months of filing a substantially complete ANDA, unless the failure is caused by either a change in or review of the approval requirements. 21 U.S.C.§ 505(j)(5)(D)(i)(IV).

57. Second, under the "failure to market" provision, forfeiture occurs if the first ANDA applicant fails to timely market its generic drug. 21 U.S.C. § 505(j)(5)(D)(i)(I). Forfeiture occurs if the ANDA applicant fails to market its drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity, unenforceability, or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid, unenforceable, or not infringed; or (iii) the NDA holder delists the patent from the Orange Book.

58. In addition, a first filer may forfeit its exclusivity rights by (1) withdrawing its ANDA, (2) withdrawing its paragraph IV certifications, or (3) entering into an agreement with another generic, the brand drug application holder, or the patent owner that the Federal Trade Commission decides violates antitrust laws. Finally, first filers may forfeit their exclusivity rights upon expiration of all patents with which exclusivity is associated. *See* 21 U.S.C. § 355(j)(5)(D).

59. Despite these legal reforms, however, brand manufacturers and first-filing generics can structure their settlements to skirt these forfeiture provisions. For example, brand manufacturers can convince generic manufacturers to settle before the patents are held invalid, unenforceable, or not infringed. The brand manufacturer prolongs its monopoly and the generic manufacturer keeps its 180-day exclusivity. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants (with no 180-day exclusivity to entice

them) must obtain a judgment that all patents for which the first filing generic company filed paragraph IV certifications are invalid, unenforceable, or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a paragraph IV litigation.

60. In addition, brand and generic manufacturers can structure their settlements to provide the generic with 180 days of *de facto* exclusivity even when it is likely that the generic has forfeited that exclusivity under one of the applicable MMA forfeiture provisions, *e.g*., the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. The brand can provide such exclusivity by agreeing not to license any other generic to enter the market any earlier than six months after the generic that has forfeited exclusivity has entered. Unless a subsequent generic is itself able to overcome applicable patent and regulatory exclusivities, such an agreement effectively restores the first generic filer's lost statutory exclusivity. This results in a windfall to the generic manufacturer and a subversion of the regulatory scheme. Because the FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that confer *de facto* exclusivity — even where *de jure* exclusivity has been forfeited under the MMA — dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180-day period. And, because the lion's share of the generic revenues will perceivably go to the first filer, subsequent filers have less incentive to litigate to judgment.

D. The Benefits of Generic Drugs.

61. Generic versions of branded drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective as their branded counterparts. The only material difference between generic and branded drugs is their price: generics are usually at least 25% less expensive than their branded counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission estimates that about

one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the branded product.[4] As a result, competition from generic drugs is viewed by brand-name drug companies such as Gilead as a grave threat to their bottom lines.

62. Due to the price differentials between branded and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

63. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers, like Plaintiff, and patients also benefit from the lower prices that result from generic competition.

64. Until a generic version of a branded drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the branded drug, and therefore, the brand manufacturer can continue to charge supracompetitive prices without losing substantial sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their branded drug sales, have a strong incentive to delay the introduction of generic competition into the market, including through tactics such as those alleged here. Moreover, inhibiting generic competition is also harmful to innovation, as brand manufacturers are incentivized to delay generic competition for existing products, instead of innovating better products in a procompetitive manner.

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[4] Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

E. The Impact of Authorized Generics.

65. The 180-day marketing exclusivity to which first filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day exclusivity period. Such a generic is called an "authorized generic" and is chemically identical to the branded drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first filer's revenue, and substantially reduces drug prices for consumers.

66. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission found that authorized generics capture a significant portion of sales and reduce the first filer generic's revenues by approximately 50% on average during the 180-day exclusivity period.[5] The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

67. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiff benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

68. As a practical matter, authorized generics are the only means by which brand manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand manufacturers generally do not reduce the price of their branded drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the

[5] Federal Trade Commission, Authorized Generic Drugs: Short-term Effects and Long-Term Impact, at 139 (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

branded drugs at the same intervals and at the same rate at which they raised the price of the drugs prior to generic entry.

69. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to a generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first filer to delay entering the market. Such agreements deprive drug purchasers such as Plaintiff of the lower prices resulting from two forms of competition. During the initial period of delay agreed to by the ANDA filer, they effectively eliminate all competition from AB-rated generic products and allow the brand manufacturer to preserve its monopoly. And, during the period in which the branded company has agreed not to sell an authorized generic, they eliminate competition between the ANDA filer's generic and the authorized generic, giving the ANDA filer a monopoly on generic sales.

70. As a means of compensating first-filing generic manufacturers, brand manufacturers prefer No-Authorized Generics agreements ("No-AG agreements") to cash payments because, in the case of No-AG agreements, a portion of the compensation is paid by purchasers of the drug in the form of higher generic drug prices. The generic manufacturer receives not only the profits that the brand manufacturer would have made by launching an authorized generic in competition with the ANDA filer's product, but also the higher prices that result from the absence of that competition. Thus, the payment to the generic manufacturer is shared between the brand manufacturer and the generic manufacturer's customers.

DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. The Origin of Gilead's cART Franchise.

71. In 2001, Gilead began marketing and selling Viread (TDF, 300 mg), and in 2003, it began marketing and selling Emtriva (FTC, 200 mg). Viread and Emtriva are both NRTIs indicated for treating HIV-1 infection in adults and certain pediatric patients. These NRTIs quickly became two of Gilead's best-selling products, generating billions of dollars in sales per year. However, Gilead knew the patents covering both of these drugs were weak and vulnerable.

72. As Gilead's new chemical entity ("NCE") exclusivity on Viread (TDF) was nearing expiration, Gilead needed a way to protect its monopoly. Instead of innovating, Gilead made Truvada (TDF/FTC), a single pill that combines Viread (TDF, 300 mg) and Emtriva (FTC, 200 mg) — at the same doses as the standalone versions of each drug.

73. Gilead submitted its Truvada NDA as a "priority" submission of "Type 4 — New Combination" in March 2004, and it was approved by the FDA less than five months later on August 2, 2004 for use in combination antiretroviral treatments for HIV-1 infection in adults.

74. Unlike typical NDA submissions, which require lengthy and costly clinical trials and research, Gilead's Truvada NDA was approved based on a showing that Truvada (TDF/FTC) was bioequivalent to an administration of its separate components (TDF and FTC). Gilead offered no evidence that Truvada (TDF/FTC) provided a pharmacological benefit over standalone Viread (TDF) plus standalone Emtriva (FTC).

75. Gilead began selling Truvada in August 2004. Truvada quickly became a blockbuster drug and has been one of Gilead's top selling HIV products, historically accounting for approximately one-quarter of its HIV sales and almost 12% of its total sales. Within two years of its launch, Truvada became a billion-dollar earner for Gilead.

76. Moreover, in July 2012, Truvada (TDF/FTC) became the first drug approved for use as a pre-exposure prophylaxis ("PrEP") — one of the most effective ways to prevent HIV infections in HIV-negative individuals. Even now, Truvada is one of only two drugs approved for PrEP — the other being Gilead's Descovy (TAF/FTC).[6] The use of PrEP is a priority for public health, and PrEP medications are indispensable in terms of ending the HIV/AIDS epidemic in the U.S. As a result, "Truvada for PrEP" is now covered in all state Medicaid programs. Reduced pricing of Truvada for PrEP would have greatly benefited efforts to end the public health AIDS/HIV epidemic.

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[6] *See* U.S. Food & Drug Administration, FDA Approves Second Drug to Prevent HIV Infection as Part of Ongoing Efforts to End the HIV Epidemic (Oct. 3, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-second-drugprevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic.

77. Following the approval of Truvada for PrEP, Truvada sales skyrocketed even further. In 2016, there were 77,120 PrEP users in the U.S. compared to just over 8,000 in 2012. Gilead acknowledges this increase was "primarily due to a higher average net selling price and higher sales volume in the United States, as a result of the increased usage of Truvada for PrEP."[7] Without generic competition in the U.S. market until only recently, Gilead has been able to raise prices year after year, consistently earning in excess of $2 billion annually for Truvada sales.

B. Gilead and BMS Enter into a No-Generics Restraint Agreement Related to Atripla.

78. Truvada was successful, so Gilead knew that it could dominate the market even further by combining its drugs with others and protecting them with anticompetitive agreements.

79. In December 2004, Gilead entered into a product combination agreement with BMS to develop and commercialize Atripla (TDF/FTC/EFV). Atripla was to be a combination of Gilead's Viread (TDF) and Emtriva (FTC), along with BMS's standalone Sustiva (EFV) — a third agent. Gilead and BMS structured their arrangement as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC (n/k/a Gilead Sciences, LLC) headquartered in Foster City, CA. Pursuant to the collaboration agreement between Gilead, BMS and Bristol-Myers Squibb & Gilead Sciences, LLC — Gilead and BMS supplied the company with quantities of their respective drug components for the company to manufacture and sell Atripla from California. In return, the company made payments from California to Gilead and BMS for the supply as well as a percentage of revenue from the net sales of Atripla. Gilead and BMS granted royalty-free sublicenses to the company for the use of the companies' respective technologies and, in return, were granted a license by the company to use intellectual property resulting from the collaboration.

80. The agreement included a No-Generics Restraint provision that expressly prohibited either party from marketing an alternative TDF/FTC/EFV product using a generic version of any of its three components. By ensuring that only one version of Atripla would be

[7] Gilead Sciences, Inc., 2016 Form 10-K Annual Report.

marketed using branded components at inflated prices, Gilead and BMS unreasonably restrained trade and protected their drug from competition.

81. This No-Generics Restraint was neither necessary nor reasonably ancillary to achieving the objective of the product combination agreement. By prohibiting the marketing of generic versions of any of the three components, Gilead and BMS hindered competition and innovation of additional products for consumers.

82. This No-Generics Restraint was neither necessary nor reasonably ancillary to achieving the objective of the product combination agreement. By prohibiting the marketing of generic versions of any of the three components, Gilead and BMS hindered competition and innovation of additional products for consumers.

83. The No-Generics Restraint only benefitted Gilead and BMS by impairing competition. Before they lost patent or regulatory exclusivity, neither Gilead nor BMS received any benefit from the No-Generics Restraint because no generic was available. The No Generics Restraint produced benefits only after the relevant statutory exclusivities expired. Such contractual relief from competition is anticompetitive.

84. Absent the No-Generics Restraint, BMS or a reasonable company in its position would have been motivated to market a competing version of Atripla comprised of generic TDF, generic FTC (once available), and EFV, or alternatively generic TDF, generic 3TC, and EFV, while Gilead sold the original version of Atripla. The price of Atripla would plummet due to competition that should have ensued with the availability of generic TDF.

85. The agreement included a termination provision, but the provision actually discouraged termination. If one of the parties sought to terminate the agreement, the terminating party was required to pay the non-terminating party three years of royalty payments, and the terminating party would then become the sole member of the company. This substantial penalty discouraged either party from terminating the agreement in the event that generic versions of TDF, FTC, and/or EFV became available and discouraged the marketing of a competitive form of Atripla with lower-priced generic components, even after the relevant patents had expired. Further, if either party terminated the agreement, the other’s ability to continue making and

selling Atripla would terminate. As a result, even if a generic version of a component drug entered the market, a competitive version of Atripla using that generic component could not come to market. 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 terminated, then the other would no longer have access to the terminating party's composition and could no longer make any version of Atripla.

86. Absent Gilead's illegal generic delay agreement with Teva, generic TDF would have become available as early as 2014, and purchasers of Atripla should have benefitted from multiple competitive versions of Atripla. Even when generic TDF finally became available in December of 2017, Atripla purchasers were denied competitive alternatives because Gilead (not BMS) then terminated the joint venture to insulate its generic component from competition. The venture's name changed to Gilead Sciences, LLC, a wholly owned subsidiary of Gilead Sciences, Inc.

87. Gilead and BMS further engaged in an aggressive co-promotional marketing campaign to induce prescription switches from standalone Viread (TDF), Emtriva (FTC), and Sustiva (EFV) (which would soon be facing generic competition) to Atripla, which was insulated from generic competition under the Gilead-BMS agreement.

88. The Gilead-BMS agreement substantially increased Gilead's incentive to move sales and market share from TDF and/or FTC to Atripla. The switched sales resulted in BMS selling significantly more EFV than it would have otherwise. The agreement allowed Gilead and BMS to maintain a monopoly in the Atripla market, generating higher than normal prices for not only Atripla but the individual standalone components as well.

89. Absent Gilead and BMS's agreement to forgo use of generic components in Atripla FDC formulation(s), an unrestrained competitor in BMS's position would have challenged Gilead's patents one year before expiration of NCE exclusivity on July 2, 2008, and could have entered the market as early as January 2011.

90. In 2004, when Gilead and BMS entered into their non-compete agreement, Gilead expected generic competition for TDF and FTC years before the January 2018 (for TDF) and

September 2021 (for FTC) expiration of patents listed in the Orange Book. BMS likewise expected generic competition years before the July and August 2018 expiration of the Orange Book-listed patents covering EFV. Gilead and BMS's agreement to combine their branded TDF, FTC, and EFV components into an FDC while agreeing not to market any other Atripla FDC with generic components substantially extended their expected exclusivity, particularly in view of the weakness of the patents covering these components, as discussed below.

91. Atripla (TDF/FTC/EFV) was approved by the FDA on July 12, 2006, roughly two years after Truvada (TDF/FTC), for use alone or in combination antiretroviral treatment of HIV-1 infection in adults. As in the case of Truvada, Gilead was not required to conduct lengthy clinical trials and investigations to support its Atripla NDA, because the three components had previously been tested and proven safe and effective on their own. For approval of its Atripla NDA, Gilead merely had to establish bioequivalence to concurrent administration of the individual components. The FDA approved the Atripla NDA less than three months after its submission.

92. At least part of Atripla's success is due to Gilead and BMS's aggressive marketing efforts. Knowing that the NCE exclusivity on TDF was set to expire in October 2006, and that the NCE exclusivity on FTC was set to expire in July 2008, Gilead and BMS engaged in marketing to induce and/or reward switching prescriptions to Atripla. Gilead and BMS shared these marketing and sales efforts, co-promoting Atripla in the U.S. from July 2006 through at least 2010.

93. Gilead and BMS's No-Generics Restraint agreement and joint promotion of Atripla exploited substantial imperfections in the HIV prescription drug marketplace: (1) that HIV prescription drug sales are "sticky," and (2) that once a doctor switches a patient from one HIV drug to another, s/he is very reluctant to switch the patient back, even if a generic or lower cost product becomes available. Brand manufacturers take advantage of this stickiness by using their robust sales forces to move a prescription base from products facing imminent generic competition to products expecting a longer monopoly. Timing is critical. If the new product beats the generic version of the old product to the market, it makes as much as 10 times more in sales than it otherwise would have made.

94. Knowing this, Gilead and BMS agreed to join sales forces to co-promote Atripla, employing various marketing schemes to exploit this market defect. Gilead and BMS were able to switch much of the prescription base from Viread (TDF), Emtriva (FTC), and Truvada (TDF/FTC) to more-expensive Atripla (TDF/FTC/EFV), which was insulated from competition under Gilead and BMS's agreement.

95. The marketing campaign was successful. Like Truvada, Atripla became a top earner for Gilead. In 2008 (just two years after its July 2006 launch), Atripla's sales reached approximately $1.6 billion. And in 2010, Atripla's sales surpassed $2.9 billion. Without generic competition in the U.S. market until only recently, Atripla sales have consistently been at or above $1 billion, making Atripla was one of Gilead's best-selling drugs.

C. Gilead Announces TAF.

96. Even before the FDA approved Viread (TDF) in October 2001, Gilead had discovered TAF, and Gilead published research on TAF in April 2001. TDF and TAF are both prodrugs from the same parent drug tenofovir. However, TAF is superior because it only requires a fraction of the dose TDF requires to achieve the same therapeutic effect. The lower plasma concentrations required for TAF results in correspondingly reduced toxicities compared to TDF, making TAF safer to use.

97. Gilead knew as early as 2001 that TAF created significantly fewer side effects than TDF because TAF is more potent in smaller concentrations than TDF (*e.g.*, a 25 mg dose of TAF has the same therapeutic effect as a 300 mg dose of TDF). More specifically, TAF presented a much lower risk of toxicity — especially kidney toxicity. As early as 2002, Gilead had realized the benefits of TAF's smaller doses and lowered plasma concentrations compared to TDF. Indeed, 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[.]"[8]

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[8] Relias Media, Special coverage: 9th Conference on Retroviruses - New drugs, new data hold promise for next decade of HIV treatment (May 1, 2002), https://www.reliasmedia.com/articles/76107-special-coverage-9th-conference-on-retroviruses-new-drugs-new-data-hold-promise-for-next-decade-of-hiv-treatment.

98. In 2003, Gilead reported to investors about the TAF clinical trials that the "initial data … looks promising," and that Gilead was "excited" about TAF's prospects.[9] In January 2004, Gilead issued a press release from Foster City, CA, indicating again the promising TAF results by reporting to investors that it was "continuing the clinical development of [TAF] … based on favorable Phase I/II results."[10] In February 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[.]"[11] In May 2004, Gilead reported that 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 adverse side effects. Gilead represented to investors that smaller TAF doses could "give greater antiviral response .... [s]o, the theory holds that you can target and treat HIV differently using these kinds of prodrug and targeting technologies." Gilead continued to praise the advantages of TAF and its potential for HIV treatment for years to investors through at least June 2004, shortly before receiving FDA approval for Truvada in July of 2004.

99. A few months later, on October 21, 2004, Gilead abruptly changed course, announcing that it had decided to shelve further development of promising TAF treatments. Gilead made the announcement in a 2004 Q3 Earnings Call conducted from Foster City, California, and attributed the decision to shelve TAF to an "internal business review and ongoing review of the scientific data for [TAF]" that supposedly led Gilead to conclude that "it would be unlikely that [TAF] would emerge as a product that could be highly differentiated from Viread [TDF]."[12] This pretextual statement that TAF was "unlikely" to "be highly differentiated" from TDF directly contradicted earlier statements made by Gilead that TAF is absorbed by the blood more effectively than TDF, leading to possible efficacy and safety advantages.

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[9] Gilead Sciences Q3 2003 Earnings Conference Call (Oct. 28, 2003); Gilead Sciences Q4 2003 Year End Earnings Conference Call (Jan. 29, 2004).
[10] Gilead Press Release, Gilead Sciences Announces Fourth Quarter and Full Year 2003 Financial Results (Jan. 29, 2004), https://www.gilead.com/news-and-press/press-room/press-releases/2004/1/gilead-sciences-announces-fourth-quarter-and-full-year-2003-financial-results.
[11] Gilead Sciences, Inc., 2003 Form 10-K Annual Report.
[12] Gilead Sciences Q3 2004 Earnings Conference Call (Oct. 21, 2004).

100. Gilead's abandoned development of TAF coincided with Gilead's agreement with BMS to market TDF-based Atripla without generic components. Gilead and BMS formally entered into the agreement on December 17, 2004 and Gilead's December 2004 press release issued from Foster City, California, concerning the agreement noted that Gilead and BMS's joint work on developing the project had "been ongoing throughout most of 2004."[13]

101. Gilead abandoned its development of TAF because it concluded that instead of continuing to innovate, it could use the No-Generics Restraints to shield its TDF-based HIV medications and franchise from competition for years. With the BMS deal in place, Gilead was able to shelve its TAF product for later use as part of its product-hopping strategy once generic competition to its TDF-based HIV medications became imminent. It no longer made economic sense for Gilead to do what competition would otherwise have forced it to do — introduce the safer, more effective, TAF as soon as possible and transition patients before rival TDF products entered the market. With its BMS deal in place, Gilead could extract greater profits by continuing to market and sell its less effective, less safe, TDF products and then rolling out TAF much later.

102. Gilead itself eventually made explicit the connection between its anticompetitive deal with BMS and the shelving of TAF. At an investor conference called the Barclays Capital Global Healthcare 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 …."[14] Gilead never amended the BMS joint venture agreement to provide BMS with the opportunity to commercialize a TAF-based successor to Atripla. Nor at that time did Gilead file an NDA to market a TAF-based successor product to Atripla.

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[13] Gilead Press Release, Bristol-Myers Squibb and Gilead Sciences Establish U.S. Joint Venture to Develop and Commercialize Fixed-Dose Combination of Three HIV Medicines (Dec. 20, 2004), https://www.gilead.com/news-and-press/press-room/press-releases/2004/12/bristolmyers-squibb-and-gilead-sciences-establish-us-joint-venture-to-develop-and-commercialize-fixeddose-combination-of-three-hiv-medicines.

[14] Gilead Sciences, Inc. at Barclays Capital Global Healthcare Conference (Mar. 15, 2011).

103. Further, on May 3, 2011, at the Deutsche Bank Securities Inc. Health Care Conference, another Gilead executive, John Milligan, confirmed why Gilead sat on TAF for over a decade. Holding TAF in reserve to later reformulate TDF-based FDCs would "bring quite a bit of longevity to the Gilead portfolio," securing an "important opportunity for Gilead long-term." [15] It allowed Gilead to have another line extension and TAF-based franchise.

D. Gilead Enters into a Pay-for-Delay and No-AG agreement with Teva Related to Viread.

104. Having delayed the market introduction of its safer and more effective TAF products, Gilead next went to work asserting its weak patents and settling with prospective generic competitors to prolong its existing monopoly over TDF products.

105. Viread (TDF) is a prodrug formulation of tenofovir. Prodrugs are pharmacologically inactive compounds that, once administered, undergo a conversion by the body's metabolic processes to become an active pharmacological agent. Prodrugs were not new or novel at the time Gilead obtained its patents. And, the process for converting a compound like tenofovir into the TDF prodrug would have been obvious to a person of ordinary skill in the art.

106. Gilead did not invent tenofovir. Tenofovir was first invented and patented in the 1980s by Czech scientists of the Institute of Organic Chemistry and Biochemistry (part of the Academy of the Sciences of the Czech Republic) and Rega Stichting v.z.w (together, "IOCB/REGA"). The patents covering tenofovir expired long ago.

107. Gilead obtained an exclusive license to manufacture and use TDF from the Czech institutions that invented it. In 1991 and 1992, Gilead entered into agreements with IOCB/REGA for the exclusive right to manufacture, use and sell Viread in exchange for payment of a percentage of net revenues received "subject to minimum royalty payments."[16] In 2000, in anticipation of Viread's launch, the agreements were amended to provide for a "reduced royalty rate on future sales" of products incorporating tenofovir in return for an up-front payment from Gilead. In 2004, in anticipation of the launches of Truvada and Atripla, Gilead again amended

[15] Gilead Sciences, Inc. at Deutsche Bank Securities Inc. Health Care Conference (May 3, 2011).
[16] Gilead Sciences, Inc., 2006 Form 10-K Annual Report.

the agreements to include Truvada and “any future fixed-dose combination products that contain the licensed technology.” At the same time, the Czech institutions, understanding the need for accessible and affordable medications to end the HIV epidemic, agreed to waive any right to royalty payments for Viread or Truvada in developing countries where products are sold at or near cost.

108. Patents are intended to encourage innovation by offering protection from competition for inventions that are novel, useful, and non-obvious. A 2003 report by the Federal Trade Commission found that the average patent application gets approximately 15-20 hours of review time by the U.S. Patent and Trademark Office’s (“Patent Office”) assigned examiner.[17] Despite receiving hundreds of thousands of patent applications each year, the Patent Office grants the vast majority of patent applications that it receives.

109. Brand pharmaceutical companies have increasingly engaged in a patent procurement strategy sometimes referred to as “evergreening.” “Evergreened” patents include later-filed patents that do not cover the active pharmaceutical ingredient (“API”), but rather claim some ancillary aspect of the drug, such as its delivery method, dosage, minor chemical differences, or release mechanism. These patents — if litigated to judgment — have a high rate of being found invalid or not infringed.

110. Gilead never had any patents on the parent molecule tenofovir. Instead, Gilead’s Viread patent portfolio attempted to claim the minor differences reflected in the prodrug as novel. Three of the patents — U.S. Patents Nos. 5,922,695 (“the ’695 patent”), 5,977,089 (“the ’089 patent”), and 6,043,230 (“the ’230 patent”) — all derived from the same patent application and cover the tenofovir disoproxil prodrug. The fourth — 5,935,946 (“the ’946 patent”) — claimed the fumarate salt of tenofovir disoproxil. The four TDF patents (the ’695, ’089, ’230, and ’946 patents) were set to expire on January 25, 2018.

111. Knowing its patents were weak and likely to be invalidated, Gilead filed meritless patent infringement lawsuits against generic challengers of the TDF patents. And Gilead entered

[17] Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (Oct. 2003).

into settlement agreements with these challengers before issuance of a final court decision rendering the TDF patents invalid and/or not infringed. Gilead's goal was simple: to delay generic competition for multi-billion-dollar blockbuster drugs as long as possible.

112. Viread's 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. Therefore, if a generic manufacturer had brought a successful patent challenge (or launched during the pendency of the patent litigation which is sometimes referred to as launching "at risk"), it could have launched a generic version of TDF as early as 2009. Even in the best of circumstances for Gilead, the Orange Book-listed patents for Viread expired by January 2018.

113. On or about July 1, 2009, Teva filed a substantially complete ANDA with the FDA to manufacture and sell a generic formulation of Viread 300 mg tablets. The 300 mg strength of Viread constituted the lion's share of all Viread sales.

114. Teva's ANDA included paragraph IV certifications as to all four patents listed in the Orange Book for TDF — *i.e.*, declarations by the ANDA filer that the patents were invalid, unenforceable, or would not be infringed by the proposed ANDA product.

115. Teva's ANDA, as the first-filed ANDA with paragraph IV certifications for the 300 mg strength, entitled Teva to a lucrative 180-day Hatch-Waxman exclusivity. The vast majority of generic drug profits occur during the 180-day exclusivity period.

116. Gilead initiated Hatch-Waxman patent litigation against Teva by filing a patent infringement lawsuit within the statutory forty-five (45) days. Gilead's filing of the lawsuit triggered a stay preventing the FDA from approving Teva's ANDA until the earlier of either: (1) thirty (30) months had elapsed, or (2) the issuance of a "court decision" finding the patents invalid or not infringed by the ANDA product. *See, e.g.*, 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

117. The issue presented was a relatively simple obviousness patent analysis. As characterized by Teva in its pretrial pleadings:

> This is a straightforward obviousness case. Three of the patents in suit are directed to a prodrug of the known drug tenofovir (PMPA). The prior art made clear that PMPA is a highly potent anti-HIV drug with poor oral bioavailability. The prior art also disclosed improving PMPA's bioavailability by making a prodrug of it. The particular

> prodrug disclosed in the prior art, called bis(POM)PMPA, was known to exhibit a manageable but undesirable side effect, whose cause was well understood. ***The person of ordinary skill in the art ("POSA") would therefore have sought an alternative prodrug form*** that would not exhibit that side effect, and would have selected the carbonate prodrug (bis(POC)PMPA) claimed in three of the patents in suit.
>
> The fourth patent relates to a fumarate salt of the bis(POC)PMPA prodrug claimed in the other three patents. As in *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1362 (Fed. Cir. 2007), the prior art disclosed salts of bis(POC)PMPA and identified a motivation to make others, including the fumarate salt. Just as in *Pfizer v. Apotex*, the ***selection of the fumarate salt from the limited number of available pharmaceutically acceptable salts would have been routine.***[18]

118. The court set a bench trial for February 20, 2013. Although Teva received tentative approval of its generic Viread (TDF) ANDA on December 23, 2011, Teva first agreed not to launch at risk until May 1, 2013 (Dkt. 19), and later not until June 1, 2013 (Dkt. 86). Accordingly, Teva could have launched its generic at any point if the court found Gilead's patents invalid, not infringed, or unenforceable, or at least on June 1, 2013, if the court had not issued its judgment by then.

119. An outcome in Teva's favor would have been devastating to Gilead, costing the company billions of dollars in Viread revenues and profits. And Teva had a decided litigation advantage given the weakness of Gilead's patents.

120. The day before trial, February 19, 2013, the parties notified the court they had reached a settlement in principle. Gilead's announcement — issued the same day — stated that Teva would not be allowed to launch a generic version of Viread (TDF) until December 15, 2017 — only one and a half months prior to expiration of the TDF patents.[19] Gilead thus bought itself another four and a half years of exclusivity and supracompetitive pricing and profits for Viread. The agreement was finalized in April 2013.

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[18] *Gilead Scis., Inc. v. Teva Pharms. USA, Inc.*, No. 1:10-cv-1796, Dkt. No. 112, at 1 (S.D.N.Y. Jan. 28, 2013)) (emphasis added).

[19] Gilead Press Release, Gilead and Teva Reach Settlement Agreement in Viread Patent Litigation (Feb. 19, 2013), https://www.gilead.com/news-and-press/press-room/press-releases/2013/2/gilead-and-teva-reach-settlement-agreement-in-viread-patent-litigation.

121. Further, the Gilead-Teva settlement did not just regard Viread (TDF). Because TDF is also a component of Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV), the litigation and the settlement addressed all of those products. In other words, Gilead's settlement with Teva extended far beyond the specific TDF patent dispute being litigated, successfully delaying, impairing and/or suppressing potential generic competition for three of its blockbuster HIV drugs in one fell swoop.

122. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act"), the parties to such patent litigation settlements are required to disclose the terms of the settlements to the Federal Trade Commission and the U.S. Department of Justice ("DOJ"), which are afforded an opportunity to review the terms of such settlements.

123. On or about June 28, 2013, the Federal Trade Commission sent Gilead and Teva a letter objecting to and/or expressing concerns relating to the terms of the settlement agreement, which prompted the parties to request that the court extend the automatic dismissal deadline for the case.[20]

124. As a result, the court ordered a telephonic status conference for August 29, 2013. At the status conference, which was transcribed but originally redacted in certain relevant places, the parties described the Federal Trade Commission's objection to the court in response to the court's question about the "offending provision" of the agreement:

> **THE COURT**: OK. That sounds pretty good. Maybe the upside is I don't have to do a darn thing. All right.
>
> Do you mind my asking what is the offending provision?
>
> **[GILEAD COUNSEL OF RECORD]**: Not at all, your Honor. Just a little bit of background, if I may. The Federal Trade Commission has historically taken issue with settlements between brand companies and generics when those settlements have what are called reverse payments in them where the brand name company pays a sum of money to the generic company, allegedly in exchange for the generic company's agreement to stay off the market longer than the generic company might otherwise have done so.

[20] *See Gilead v. Teva*, No. 1:10-cv-1796, Dkt. No. 132 (June 28, 2013)).

> Not too long ago, your Honor may be aware, the Supreme Court addressed such provisions in a very split court five-three and they found that … such provisions could potentially violate antitrust laws that had to be evaluated under the rule of reason. That has emboldened the [Federal Trade Commission] and has breathed new life into its enforcement efforts.
>
> So now they have reached out in our agreement, and, as I understand it, in some others, to challenge the agreements even though there is no reverse payment provision. No money was to change hands under our agreement. ***There was, however, a provision in which Gilead agreed that if it were to independently and unilaterally determine that it would launch a generic, an authorized generic of its own, it would do so but only if it gave Teva six weeks head start on the Gilead authorized generic. This so-called, in the [Federal Trade Commission's] view, "no authorized generic clause," they have now tried to analogize, in our case and others, to a reverse payment.*** That song, quite frankly, has never had too many folks singing in its choir.[21]

125. Since the August 29, 2013 hearing, numerous courts have agreed with the Federal Trade Commission and found that "no authorized generic" ("No-AG") clauses can and indeed do constitute anticompetitive reverse payments to ANDA filers.

126. Gilead's counsel continued by assuring the court that the parties had simply removed the "no authorized generic" agreement from the settlement:

> **[GILEAD COUNSEL OF RECORD]**: … as of late yesterday afternoon, the parties have determined that they will drop the "offending" provision from the agreement. So we simply now have to prepare and execute a simple amendment to the underlying settlement agreement, send that down to the Federal Trade Commission, and then your Honor will be able to dismiss the case.
>
> …
>
> **[GILEAD COUNSEL OF RECORD]:** … Fortunately, for all concerned, we have resolved it, but we have eliminated the so-called "no AG clause" from the agreement so it is truly inconceivable to us that the [Federal Trade Commission] can have any other complaints …."[22]

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[21] *Gilead v. Teva*, No. 1:10-cv-1796, Dkt. No. 134, at 4:17-5:21 (Aug. 29, 2013) (emphasis added).
[22] *Id*. at 3:22-4:3 & 6:5-9.

127. Thus, counsel for Gilead represented to the court that the No-AG clause was dropped from the patent settlement agreement and no other changes were made to reflect the supposed elimination of the No-AG provision. However, what Gilead and Teva did not disclose was that even though they removed the "No-AG" language from the agreement, they still had an agreement preventing Gilead from launching an AG at the point of Teva's delayed generic entry. That secret agreement did not become apparent until Gilead did ***not*** launch a competing AG when Teva launched its generic on December 15, 2017, and Teva issued a press release announcing its "exclusive" generic Viread launch.[23]

128. Teva's ability to launch its generic without facing competition from Gilead's AG was of great economic benefit to Teva. According to the Federal Trade Commission, in a scenario without a competing authorized generic, the first filer generic immediately gains a substantial share within days of launch, and ultimately will capture up to 90% of the total molecule market. The greater the market share the first filer is able to secure, the greater the long-term advantages, as the first filer usually retains the majority of its exclusive market share even with the presence of multiple generics.

129. Applying these observed market dynamics to this case, Gilead earned annual revenues on Viread of approximately $1 billion before the launch of generic equivalents (or $115 million during the six-week exclusivity period). Teva, as the first filer, claimed at least half of that revenue during the exclusivity period and retained a significantly higher portion of the overall market even beyond the exclusivity period. In such a situation, Teva could expect revenues over $50 million during the six-week exclusivity period without a competing AG.

130. Teva's profits would have been significantly lower had Gilead launched a competing AG. According to the Federal Trade Commission, in that event, Teva would obtain only approximately 30% of the market during the six-week exclusivity period.[24] And, Teva's market share would not have increased much higher thereafter.

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[23] Teva Press Release, Teva Announces Exclusive Launch of Generic Viread in the United States (Dec. 15, 2017), https://www.tevapharm.com/news-and-media/latest-news/teva-announces-exclusive-launch-of-generic-viread-in-the-united-states/.

[24] *See, e.g.*, Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (Aug. 2011).

131. Greater price erosion also cuts into the first filer's revenues. In the above $1 billion drug example, instead of launching at a 10% discount to the brand and making over $50 million in revenues during the six-week exclusivity period, the first filer must launch at a greater discount to compete with the authorized generic. Assuming Teva launched at a 25% discount to the brand and maintained an average 30% market share during the six-week exclusivity period, Teva would only earn revenues of approximately $28 million during the six-week exclusivity period. Gilead's launch of an AG would thus cost Teva over $20 million in revenues during the six-week exclusivity period, and additional hundreds of millions of dollars beyond the exclusivity period as Teva's market share would not recover.

132. Gilead's decision not to launch a competing AG defies rational business logic, as such a move could have offset the expected generic erosion. Moreover, a No-AG agreement runs contrary to Gilead's decision to recognize such profits and launch AGs with respect to multiple other products in its portfolio, including its blockbuster hepatitis C drugs Harvoni and Epclusa, through its subsidiary Asegua Therapeutics.[25] Yet, Gilead never launched a Viread AG.

133. The purpose of the settlement agreement was clear: in exchange for delayed generic entry, Teva would be granted exclusive entry into the market without competition from a Gilead AG. This No-AG agreement was a payment from Gilead to Teva worth substantially more than what Teva could have earned if it had prevailed in the patent litigation and come to market with a generic Viread in competition with Gilead's AG. This reverse payment from Gilead to Teva exceeded Gilead's anticipated litigation costs to continue pursuing the patent litigation.

134. Gilead also included "most-favored entry" ("MFE") and "most-favored-entry-plus" ("MFEP") provisions in its patent settlements with Teva and other generic manufacturers. MFE clauses benefit first filers but can also be used to incentivize later filers. MFE clauses provide that if any subsequent generic ANDA filer succeeds in entering the market before the

[25] *See, e.g.*, Gilead Press Release, Gilead Subsidiary to Launch Authorized Generics of Epclusa and Harvoni for the Treatment of Chronic Hepatitis C (Sept. 24, 2018), https://www.gilead.com/news-and-press/press-room/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-epclusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvirsofosbuvir-for-the-treatment-of-chronic.

agreed-upon date for the first filer, the first filer's entrance will be accelerated and it may enter at the same time as that subsequent filer. A first filer may agree to an MFE in exchange for delayed entry because it knows the MFE will dramatically reduce a second filer's incentive to file an ANDA and challenge the patents. If second filers are aware that they will face immediate competition from a first filer, they are less likely to pursue costly litigation against the brand company. Two entrants inevitably result in reduced market share and lower pricing for both generics.

135. The anticompetitive effects of MFEs may be compounded by increasing the number of generic manufacturers to which the clauses apply. When a second filer is deciding whether to initiate or continue a patent challenge, knowing that the brand manufacturer has already granted an MFE to the first filer and has offered to grant one to the second filer, it could reasonably conclude that the brand manufacturer will also likely grant MFEs to subsequent filers (*i.e.*, the third, fourth, and fifth filers). 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 possibly additional generics. Simultaneous entry of multiple manufacturers would quickly push prices down close to marginal cost.

136. MFEP clauses primarily benefit first filers as well. MFEP clauses provide that the brand manufacturer will not grant a license to any second (or subsequent) filer to enter the market until a defined period of time after the first filer enters. Like MFE clauses, MFEP clauses dramatically reduce a later filer's incentive to challenge the patents, because they ensure the first filer's exclusivity for a set period of time. Absent an MFEP, a second filer could use its challenge to the patents as leverage to negotiate with the brand manufacturer for a license to enter the market before the first filer. This is particularly significant where the first filer has forfeited its 180-day exclusivity by failing to get tentative FDA approval within 30 months. Absent the 180-day exclusivity period, the second filer could enjoy a substantial period of *de facto* exclusivity in the generic sector of the market. The MFEP would eliminate that possibility by ensuring that the second filer could not successfully negotiate for an earlier licensed entry date.

137. By February 2013, the time that Gilead and Teva reached their patent settlement, approximately six other generic drug manufacturers — Lupin, Cipla, Hetero, Aurobindo, Strides Pharma, and Macleods Pharmaceuticals — had filed ANDAs seeking FDA approval to sell generic Viread. The first two of those manufacturers included paragraph IV certifications with respect to the TDF patents, and Gilead had filed suit. Gilead and Teva fully 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.

138. In view of this potential competition, Gilead used MFE and MFEP clauses to incentivize Teva to push back its generic entry date. Under the MFE clause, Teva received assurances that no other generic manufacturer would enter the Viread market before Teva. And under the MFEP clause, Teva would be protected from competition from any other generic until the expiration of the TDF patents on January 26, 2018. So Teva received six weeks as the exclusive Viread generic. This reduction in generic competition was enormously valuable to Teva and amounted to a payment. For every week that Teva was on the market as the only generic manufacturer of a standalone Viread (TDF) generic, it could expect to sell all of the TDF units at about 90% of the brand price. Entry of multiple generics would swiftly cause Teva's unit sales and profits per unit sale to decrease. Without MFE and MFEP clauses, Teva faced a substantial risk that it would be stuck on the sidelines while later filers entered the market years in advance and reaped the corresponding gains of being the first generic TDF standalones.

139. Moreover, Teva's competitive advantage was not limited to just the period when no other manufacturer was selling the product. With a certain, single-entrant launch date, Teva could ramp up its production and negotiate contracts with its customers to effectively flood the distribution channel with product before the second filers entered the market, and lock in high prices with long-term sales contracts. The difference between the single-generic price and the price with multiple generic competitors represented a significant additional cost to purchasers of the drug.

140. The MFE and MFEP clauses also benefitted Gilead. They allowed Gilead to extract an exceedingly favorable entry date — just six weeks before the end of the patent term in mid-January 2018. Such agreements also provided Gilead control over when generic entry would occur and allowed it to further impede competition. Having information as to the timing of generic TDF was essential to Gilead's multi-layered product-hopping schemes and compounded the anticompetitive effects of Gilead's and its co-conspirators' concerted plans to delay and suppress generic competition in the markets for these critical HIV drugs. And Gilead used these clauses to reduce the likelihood of substantive patent challenges, by discouraging later filers from litigating. These anticompetitive clauses proved to be effective tools for Gilead to maintain and extend its market dominance.

141. Gilead also included MFE clauses in its settlement agreements with other generic Viread manufacturers. Those MFE clauses persuaded subsequent filers to agree to delay entry until at least six weeks after Teva's entrance into the Viread market, or until January 26, 2018. This meant that Lupin and Cipla, who each litigated the patents for nearly two years, ultimately agreed to delay their generic launch until the patents expired (*i.e.*, they received no advantage over generics that did not litigate). These subsequent filers were made aware of the MFEs in the Gilead/Teva agreement.

142. When agreeing to the delayed December 15, 2017 entry date, Teva knew that: (a) Gilead was willing to include anticompetitive MFEs in settlement agreements with subsequent filers; (b) it was in Gilead's financial interest to include such clauses in agreements with all subsequent filers; (c) the subsequent filers would have known that the Gilead/Teva agreement included an MFE; (d) no subsequent filer after the adoption of the MFEs would have an interest in incurring the costs of patent litigation to try to enter the market before Teva; and (e) the MFEs' deterrent effect would grow with every additional MFE that Gilead granted in settlement.

143. Just as Gilead intended, the MFEs in the Teva agreement (and others) deterred subsequent ANDA filers and deterred substantive patent challenges. Lupin and Cipla settled their litigations in exchange for no benefit over other ANDA filers. And the other ANDA filers — at least Hetero, Aurobindo, Strides, and Macleods — chose not to amend their ANDAs to include

paragraph IV certifications. Absent Gilead's anticompetitive conduct, at least Hetero and Aurobindo would have made such certifications as they made paragraph IV certifications with respect to Truvada.

144. On January 26, 2018, six weeks to the day after Teva entered the market, and the day after the TDF patents expired, five generic manufacturers (Cipla, Hetero, Aurobindo, Strides, and Macleods) received final FDA approval, and four immediately began marketing generic Viread. At least four more ANDAs were finally approved over the next year. Many had received tentative approval years earlier.

145. Viread has been an enormously successful drug for Gilead. After launching in late 2001, Viread quickly became a blockbuster drug. In 2003, Gilead earned $566.5 million in sales and royalty revenues from Viread worldwide. In 2004, that number jumped to $782.9 million. After many years of stable sales of approximately $650-$950 million per year, Viread crossed the $1 billion plateau in 2014. Viread earned $1 billion per year worldwide thereafter through 2017. Teva launched generic Viread on December 15, 2017.

146. In 2017, the year that Teva eventually entered the market, Viread had U.S. sales of $591 million, or about $11 million per week. Generic manufacturers (however many there were) could expect to take at least 80% of Viread's unit sales. As the sole generic on the market, Teva could expect to price its generic at 90% of the brand price and make at least $7.9 million for every week of sales, while as one of seven generics on the market Teva could expect to price its generic at about 20% of the brand price and make a seventh of the total generic sales or about $250,000 for every week of sales. Thus, Gilead and Teva's efforts to forestall generic competition increased Teva's sales by $7.65 million for every week in which it was the only seller of generic Viread — an increase of $45.9 million over the six weeks secured by the MFEs and MFEPs.

147. During the six weeks secured by the MFEs and MFEPs, Teva was the only seller of generic Viread on the market, and it stuffed the supply chain with its generic Viread product, locking in high prices through long-term sales contracts. Thus, Teva made millions more than it would have absent the MFEs and MFEPs. Absent Gilead and Teva's anticompetitive conduct,

Teva and the second filers would have entered the market much sooner than they did. The delay in generic entry protected more than $2 billion in Gilead's Viread branded sales, and the insulation from competition facilitated Gilead's delayed introduction of its TAF products, all at the expense of Plaintiff and others.

E. Gilead and BMS Enter into Pay-for-Delay Agreements Related to Truvada and Atripla.

148. Gilead and Teva's anticompetitive TDF patent settlement established that generic competition to Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV) would be precluded at least until December 2017 — when Teva could launch its generic Viread (TDF). However, litigation regarding the other components of these FDCs pushed their generic entry dates back even further.

149. On or about September 26, 2008, Teva filed substantially complete ANDAs with the FDA to manufacture and sell generic formulations of Truvada and Atripla. For both of these ANDAs, Teva ultimately included paragraph IV certifications as to the four TDF patents (which were litigated alongside Viread, discussed above), the FTC patents, and, for Atripla, the EFV patents. Thus, Teva asserted these patents were invalid, unenforceable, or not infringed by its proposed ANDA products.

150. The Orange Book-listed patents for Truvada and Atripla for the four TDF patents (the '695, '089, '230, and '946 patents) expired on January 25, 2018. The FTC patents expired on May 4, 2021 and September 9, 2021. For Atripla, the patents covering EFV expired July 20, 2018 and August 14, 2018.

151. Like Teva's ANDA for Viread, Teva's ANDAs for Truvada and Atripla were each the first substantially complete applications to be filed, entitling Teva to first filer status for statutory ANDA exclusivity, subject to any forfeiture.

1) BMS and Teva enter into a Pay-for-Delay agreement related to Atripla.

152. BMS contributed EFV for the Gilead-BMS joint development of Atripla (TDF/FTC/EFV). After Teva filed the first Atripla ANDA, BMS filed suit against Teva in March of 2010, accusing it of infringing U.S. Patent Nos. 6,639,071 (the "'071 patent") and

6,939,964 (the "'964 patent"). BMS was initially represented by the same counsel who represented Gilead in its Viread patent infringement litigation against Teva. Merck, Sharp & Dohme Corp., owner of the patents, joined BMS as co-plaintiff. *See Merck, Sharp & Dohme Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 1:10-cv-01851 (S.D.N.Y. filed Mar. 9, 2010). The asserted EFV patents expired on August 14, 2018 and July 20, 2018, respectively.

153. The patents BMS asserted against Teva covered particular crystalline forms of EFV — they did not claim the compound itself, but merely particular ways the molecules may arrange themselves in a crystal. These were weak, and susceptible to invalidity challenges. BMS did not assert the purported composition of matter patent for EFV (which expired in 2013) or the method of use patent for treatment of HIV infection (which expired in 2014). Moreover, BMS specifically chose not to assert the '071 or the '964 patents in an earlier case against Mylan Pharmaceuticals regarding the Sustiva (EFV) standalone drug. There, BMS stated that defendants' Notice Letter "provided a detailed statement of the factual and legal basis for [their] paragraph IV certification regarding" these patents. *Bristol Myers Squibb Co. v. Mylan Pharms. Inc.*, No. 1:09-cv-00651, Dkt. 183, ¶ 20 (D. Del. June 18, 2012). BMS thus believed that Mylan had established — just based on its letter — that its ANDA product did not infringe these patents and/or that they were invalid or unenforceable.

154. In addition to Teva and Mylan, multiple other generics challenged BMS's EFV patents, reflecting the weakness of these patents.

155. Like Gilead, BMS filed the Atripla EFV patent infringement lawsuit without regard to the merits, knowing the EFV patents it asserted were weak and likely to be invalidated and fully anticipating imminent generic competition. BMS knew that there was a substantial probability that it would lose the patent litigation given the weakness of its EFV patents and that it would likely face generic competition years prior to the expiration of its patents.

156. In its Pretrial Memorandum, Teva presented facts that the asserted patents were invalid because they were inherently anticipated and/or obvious. Teva showed that the claimed crystalline structure, "Form I," is inevitably formed by practicing the processes described in either of two different prior art references, rendering the asserted patents invalid. Teva further showed

that the "Background of the Invention" sections of the '071 and '964 patents expressly admit that Form I was in the prior art, and state that the novelty of the patents is the use of a different crystallization process (not the discovery of a new crystal form). Yet, the claims of the '071 and '964 cover only the final crystallized forms (i.e., "Form I"), without any reference to the processes used to make them, despite first stating that "[t]he instant invention describes a method for crystallizing [EFV]."

157. On June 5, 2013, less than three weeks before the scheduled trial concerning the EFV patents, the parties had "reached a settlement in principle." The case was officially closed on August 16, 2013.

158. On October 8, 2014, BMS issued a press release announcing the resolution of all its EFV and Atripla patent infringement litigation. It stated: "we believe that loss of exclusivity in the U.S. for efavirenz should not occur until December 2017."[26] Thus, BMS's announcement indicated that it expected to lose exclusivity for EFV on about the same date that Teva had accepted for the launch of its generic TDF.

159. There are now several versions of generic EFV on the market. Mylan, the first filer for EFV, received tentative FDA approval in 2011 and final approval in 2016. However, Mylan did not launch generic EFV until February 1, 2018, just six months before the last-expiring asserted EFV patent was set to expire. The terms of the parties' settlement were never fully disclosed.

2) Gilead and Teva enter into a Pay-for-Delay agreement related to Truvada and Atripla.

160. Shortly after the TDF patent settlement and the EFV patent settlement, Gilead entered into a similar anticompetitive settlement agreement with Teva in regard to FTC to further delay the entry of generic Truvada (TDF/FTC) and Atripla (TDF/FTC/EFV). This agreement was a highly effective impediment to generic competition. Until recently, Teva marketed the

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[26] Bristol-Myers Squibb Press Release, Bristol-Myers Squibb Statement on Sustiva (efavirenz) in the U.S. (Oct. 8, 2014), https://news.bms.com/news/details/2014/Bristol-Myers-Squibb-Statement-on-Sustiva-efavirenz-in-the-US/default.aspx.

only generic versions of both drugs. Additional generic manufacturers recently entered both markets, causing prices of generic Truvada and Atripla to plummet.

161. As in the case of Viread, generic erosion of Truvada and Atripla sales would have occurred swiftly. Introduction of generic Truvada and Atripla would have drastically reduced pricing and made these crucial HIV medications more affordable and accessible to those living with HIV.

162. Gilead did not invent FTC. Instead, like for TDF, Gilead obtained rights to it from others. The Orange Book-listed patents for Truvada and Atripla purportedly covering the FTC component include U.S. Patent Nos. 6,642,245 ("the '245 patent") and 6,703,396 ("the '396 patent"). The FTC patents were set to expire on May 4, 2021 and September 9, 2021, respectively.

163. At different times, in an attempt to extend its flagship TDF-based product line, Gilead also listed other patents in the Orange Book for Truvada and Atripla — all of dubious validity. For many of the listed patents, Gilead never asserted them against any prospective generic competitors. Others merely purport to claim the non-inventive pairing of drugs, where such combinations would have been obvious to a skilled artisan. And none of them cover the API, but rather some ancillary aspect of the drug product. As such, these later-listed Orange Book patents were obvious and not novel, and would have likely been found invalid.

164. Like for TDF, Gilead acquired the rights to FTC from the real inventors. In 1990, scientists at Emory University filed the first of a family of patents that disclosed FTC — or, more precisely, the specific enantiomer (*i.e.*, orientation) of FTC used in Emtriva, Truvada, and Atripla, which is called "(–)-β-FTC." For example, U.S. Patent No. 5,814,639 ("the '639 patent") issued in September 1998 and claimed β-FTC, claimed using β-FTC for HIV treatment, disclosed its two enantiomers (the (+) and (–) enantiomers), and disclosed a technique for separating them.

165. Gilead listed Emory's patents (the '639, '245, and '396 patents), along with Emory's related U.S. Patent No. 5,210,085 ("the '085 patent"), in the Orange Book for Truvada and Atripla. The '245 and '396 patents were the two patents Gilead was asserting against Teva at the time the parties settled their litigation.

166. In April 1996, Triangle Pharmaceuticals, Inc., obtained an exclusive license to purified forms of FTC for use in HIV and HBV indications. Gilead acquired Triangle in January 2003, including the exclusive rights. Upon that acquisition, Gilead rushed standalone Emtriva (FTC) and Truvada (TDF/FTC) to market. The FDA approved standalone Emtriva (FTC) in July 2003, roughly six months after Gilead acquired the license to FTC. In March 2004, less than a year later, Gilead filed its NDA for Truvada (TDF/FTC), which the FDA approved in August 2004 (less than five months after Gilead's initial submission).

167. The NCE exclusivities for FTC as a component of Truvada and Atripla expired on July 2, 2008. As a result, any 30-month stay blocking FDA approval of a competing generic could have expired as early as January 2, 2011. That means that a generic manufacturer bringing a successful patent challenge against Truvada or Atripla could have launched a generic version of Truvada or Atripla as early as 2011. Even in the best of circumstances for Gilead, the Orange Book-listed patents were to expire by their own terms in January of 2018 for TDF and in September of 2021 for FTC.

168. Gilead sued for patent infringement within forty-five (45) days of receiving Teva's paragraph IV certifications. Gilead's filing triggered a stay preventing the FDA from approving Teva's ANDAs for Truvada and Atripla until the earlier of thirty (30) months or the issuance of a court decision finding the patents at issue invalid, unenforceable, or not infringed.

169. Gilead filed suit against Teva on December 12, 2008, alleging its generic Truvada would infringe the '245 and '396 FTC patents. On September 25, 2009, Gilead amended its patent infringement complaint, adding allegations that Teva's generic Atripla would also infringe these patents.

170. Gilead filed its FTC patent infringement lawsuits without regard to the merits of those cases. It knew that the patents were weak, fully anticipated that generic manufacturer(s) would successfully challenge the patent claims, and expected to face imminent generic competition. When it sued Teva in December of 2008, Gilead knew there was a substantial probability that it would lose the patent infringement litigation because of the weakness of its patents. Gilead's 2008 SEC Form 10-K reported:

> Teva alleges that two of the patents associated with [FTC], owned by Emory University and licensed exclusively to [Gilead], are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two [FTC] patents. We cannot predict the ultimate outcome of the action, and we may spend significant resources defending these patents. If we are unsuccessful in the lawsuit, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada in the United States would be shortened to expire in 2017 instead of 2021.[27]

171. In September 2013, the parties filed pretrial memoranda, and the four-day bench trial began on October 8, 2013. It focused on one of Teva's strongest contentions: that the patents were invalid for obviousness-type double patenting because the (–)-enantiomer claimed in the '245 and '396 patents was claimed by the earlier-expiring '639 and '085 patents described above. Teva argued that the specific (–)-β-FTC enantiomer was anticipated or rendered obvious by the earlier-expiring patents, because the earlier patents claimed the FTC compound broadly (without regard to its orientation), and further disclosed its two enantiomers and a separation technique.

172. More specifically, Teva maintained that the asserted FTC patents were invalid and an improper attempt to extend Gilead's monopoly beyond the scope of previously-issued patents. As explained in Teva's Pretrial Memorandum, Gilead was trying to parlay the earlier invention and associated patent rights into additional patents (and exclusivities) for uses that were not novel or new and would have been obvious to person skilled in the art at the time. The claims disclosed in the earlier FTC patents (the '639 and '085 patents) relating to the discovery of FTC for HIV treatment rendered the later-obtained FTC patents (the '245 and '396 patents) invalid as obvious and/or anticipated:

> What is relevant is that [Gilead et al.] are entitled only to a single patent term for [FTC], irrespective of the value or properties of that drug. Plaintiffs received the complete protection the law allows when they received the '639 and '085 patents, which claim emtricitabine and its only use. ***[Gilead et al.] are not entitled to an extra six-year monopoly simply for recycling those patents and again claiming emtricitabine and that use***. Upon the expiration of

[27] Gilead Sciences, Inc., 2008 Form 10-K Annual Report.

> the ’639 and ’085 patents, the population that suffers from AIDS is entitled to obtain that drug, and the generic drug industry is entitled to offer it to that population, at a non-monopoly price. That is the promise of the Hatch-Waxman Act, Congress’s expression of the public policy that favors the introduction and distribution of generic drugs not protected by valid patents.[28]

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

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

> That’s just a mathematical proposition, right? I mean if there’s billions or millions, hundreds of millions of molecules, then I guess you might have one or two and then the balance all one [*sic*] and then everything in between. It’s hard for me to see why that’s a compelling argument, but we’ll come to that.[29]

175. Gilead’s counsel tried to explain further, but the court interrupted again:

> That’s a mathematical proposition that basically there is infinity between point A and point B, so there will be an infinite number of stops along that chain. But I don’t think — it seems to me that’s not really scientific argument that there are an infinite number of ratios

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[28] *Gilead Scis., Inc. v. Teva Pharms. USA, Inc.*, No. 08-cv-10838, Defs’ Mem. in Opp. to Pltfs’ Pretrial Mem., Dkt. 152, at 1 (S.D.N.Y. Sept. 23, 2013) (emphasis added).
[29] *Gilead v. Teva*, No. 08-cv-10838, Trial Transcript — Day 1, Dkt. 162 at 42-45 (S.D.N.Y. filed Oct. 21, 2013).

> that a scientist of ordinary skill in the art would be looking to experiment to see whether a ratio of 49.6 percent was better than a ratio of 49.7 percent, which might be better or worse than 47.2 percent. That just strikes me as illogical.

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

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

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

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

179. On the other element of its anticipation sub-theory — whether a person of skill in the art could obtain (–)-β-FTC without undue experimentation — Teva elicited powerful evidence

that put the lie to a narrative Gilead had promoted throughout the case. Before trial, Gilead claimed that real-world experience had shown that separating the enantiomers of β-FTC required a very high amount of time and ingenuity. Gilead's pretrial brief asserted that "the inventors themselves attempted five of those methods [of separation] during their research (all but one of which failed) before settling on enzymatic resolution."[30] But one of the inventors admitted at trial that enzymatic resolution was the first method he tried, and he was able to separate the enantiomers with the very first enzyme he tried, pig liver esterase. This was not just an amazing coincidence; the evidence showed that enzymatic resolution was a commonly used method at the time, and the inventor was sure enough that it would work that in the patent application for β-FTC, he listed it as a method for separation even before trying it.[31] Gilead also claimed before trial that the company BioChem took more than a year to separate the enantiomers of BCH-189, a compound similar to β-FTC. That was incorrect. In fact, a technician at BioChem, who had never before attempted to separate enantiomers, testified that she successfully did so with BCH-189 in "less than 15 days of laboratory time."[32] Based on the evidence at trial, and the judge's view of Gilead's "infinite mixtures" argument, Gilead was very likely to lose.

180. Gilead's arguments against the obviousness sub-theory fared no better. Here, the parties contested whether in light of the patents for β-FTC and its use, it would be obvious to a person of ordinary skill in the art to try to obtain (–)-β-FTC, and whether doing so would involve undue experimentation. As described above, Teva would have prevailed on the second element, as the inventors of β-FTC obtained (–)-β-FTC on their first try, using well-known methods, and a technician at BioChem did the same with a β-FTC analog in less than 15 days. Gilead claimed, however, that the person of ordinary skill in the art would not have been motivated to obtain (–)-β-FTC for various reasons. This was highly implausible because in 1987, three years before (–)-

[30] *Gilead v. Teva*, No. 08-cv-10838, Gilead Pretrial Mem., Dkt. 137 at 34 (S.D.N.Y. Sept. 9, 2013).
[31] *Gilead v. Teva*, No. 08-cv-10838, Trial Transcript — Day 2, Dkt. 164 at 300-01 (S.D.N.Y. filed Oct. 21, 2013).
[32] *Gilead v. Teva*, No. 08-cv-10838, Trial Transcript — Day 2, Dkt. 164 at 377-80 (S.D.N.Y. filed Oct. 21, 2013).

β-FTC was obtained, the FDA issued guidance stating that enantiomers should be separated and may need to be tested:

> When the NDS [*i.e.*, new drug substance] is asymmetric (e.g., contains one or more chiral centers, or has cis-trans or other types of isomers), the sponsor should ideally (and prior to the submission of an IND [*i.e.*, investigational new drug]) have either separated the various potential stereoisomers of the NDS or synthesized them independently. Physical/chemical information about each stereoisomer should be provided (in detail), or may be requested. Individual stereoisomers may need to be studied for pharmacological and toxicological properties (and/or for safety and efficacy).[33]

(Stereoisomers are molecules that have the same sequence of atoms but differ in their three-dimensional structure. Enantiomers are a type of stereoisomer.) Gilead had no real response to this evidence. Moreover, the evidence at trial showed that the separation and study of enantiomers was a regular practice as early as the 1970s, and the development of single-enantiomer drugs was standard practice in the pharmaceutical industry by 1990. And while Gilead had claimed that a person of ordinary skill in the art would have viewed (+)-β-FTC as the more obvious candidate for development (instead of (–)-β-FTC), Gilead's own expert and fact witnesses agreed that such a person would have tested both before rejecting either of them.

181. Other generic manufacturers, well aware of the inherent weaknesses of the FTC patents, similarly challenged the patent protection of Truvada and Atripla. In response, Gilead filed lawsuits against nearly each and every potential generic rival, alleging infringement of its duplicitous and ancillary patent portfolios.

182. Gilead and Teva settled the FTC patent case in February 2014 while awaiting the trial court's decision. Notably, Gilead and Teva's settlement of the FTC patent infringement case came shortly after their settlement in mid-2013 of the TDF patent infringement litigation as to Viread, Truvada and Atripla and shortly before Gilead's July 2014 settlement with Cipla, which resolved patent litigations involving both FTC and TDF patents.

[33] U.S. Food & Drug Administration, Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances (Feb. 1987).

183. Having successfully settled the TDF patent case using MFE and MFEP provisions, Gilead and Teva used the same clauses in the FTC case to guarantee a future date certain for Teva's generic entry for Truvada and Atripla in exchange for assurances to Teva that no generic manufacturer would enter the market prior to Teva.

184. The settlement agreements set a date certain for Teva's initial generic entry and further provided that Teva, as the first filer, could enter sooner should a second filer gain entry into the market by, for example, proving that Gilead patents were invalid.

185. Gilead's settlement agreements with other generic manufacturers challenging the FTC patents reinforced and compounded the anticompetitive effects of these MFE and MFEP provisions by including promises that Gilead would not authorize further generic entry for a defined period after Teva's initial entry and delaying other generics from entering the market for an additional 6 months after Teva's initial entry.

186. The MFE and MFEP clauses in the Truvada and Atripla settlement agreements were extremely effective at delaying and suppressing generic competition. Each generic manufacturer ultimately agreed to stay out of the market for the period of time that Gilead granted to Teva in the MFEPs, and, in exchange, Teva agreed to delay generic Truvada and Atripla until September 30, 2020, just one year before expiration of the FTC patents.

187. After Gilead and Teva entered into the settlement agreements delaying generic competition for Truvada and Atripla until September 30, 2020, Gilead struck another anticompetitive settlement with Cipla. The settlement agreement with Cipla contained additional anticompetitive provisions, creating another roadblock to generic entry of Truvada and Atripla. Cipla agreed to substantially delay the launch of its standalone generic Emtriva (FTC) product until August 2020 (approximately one month before the agreed-upon date certain for generic entry of Truvada and Atripla) in exchange for undisclosed payments and assurances of exclusivities with respect to Gilead's and its co-conspirators' HIV medications, despite having received final FDA approval for its generic in July 2018. Further, less than two months after the

case settled, Gilead announced it would license Cipla, among others, to sell cheaper versions of new hepatitis C drugs, a potentially very lucrative opportunity for Cipla.[34]

188. As with Viread, a number of second filers lined up behind first-filer Teva challenging Gilead's FTC patents. At the time of Teva's and Gilead's February 2014 settlement, Gilead had already filed patent infringement lawsuits relating to the FTC patents against at least Lupin and Cipla. And with the success of Truvada and Atripla, Teva could anticipate others.

189. Teva and these subsequent filers faced the same economic dynamics as in the case of Viread: the MFEs and MFEPs granted to Teva dissuaded the second filers from continuing to litigate and provided Teva a period of exclusivity. Significantly, at the time of the settlement, 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. *See* 21 U.S.C. § 355 (j)(5)(D)(i)(I)(aa)(BB).

190. The MFEPs 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. This was of particular importance to Teva because it had either forfeited its eligibility for the 180-day statutory exclusivity period or at the very least was uncertain of that eligibility. The MFEs and MFEPs provided Teva with assurances of 180-day exclusivity that it was not entitled to by statute or regulation. Teva traded its delay of generic Truvada and Atripla for the guarantee of 180 days of exclusivity.

191. The MFEs further provided that, if any subsequent filer entered the market before Teva's agreed entry date, Teva's permitted entry date would be accelerated correspondingly. No generic manufacturer introduced generic Truvada or Atripla prior to Teva.

192. Gilead succeeded in delaying entry of generic Truvada and Atripla just as it did with respect to Viread. Gilead settled the FTC patent litigations with Cipla and Lupin in 2014; with Mylan in 2015; with Aurobindo and Hetero in 2016; and with Amneal in 2017. Gilead

[34] Manufacturing Chemist, Gilead announces generic licensing agreements with Indian companies (Sept. 16, 2014), https://bit.ly/2lTQvqO.

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.

193. The reduction in generic competition provided by the MFE and MFEP provisions had enormous value to Teva. At the time of settlement in 2014, annual combined U.S. sales for Atripla and Truvada were approximately $4 billion. As the only generic manufacturer of Truvada and/or Atripla, Teva could expect to sell all of its units at about 90% of the brand price. Entry of multiple generics, however, would swiftly reduce Teva's unit sales and profits per sale. Using the methodology described above in connection with Viread, six months of exclusive sales of those generic products was worth almost $1.5 billion to Teva. Absent the reverse payment to Teva, Teva and subsequent filers would have entered the market sooner than they did. The delay in generic competition protected billions of dollars in Truvada and Atripla branded sales, all at the expense of Plaintiff and other purchasers of those drugs.

194. Moreover, Teva's competitive advantage was not limited to its period of exclusivity. With a guaranteed single-entrant launch date, Teva could ramp up its production and negotiate contracts with its customers to flood the distribution channel with generic products before any second filer entered the market and lock in high prices with long-term sales contracts. The difference between the single-generic price and the multiple-generic price represented a significant cost to purchasers of the drugs.

F. Gilead and Janssen Enter into No-Generics Restraint Agreement Related to Complera.

195. Effective July 16, 2009, Gilead entered into a No-Generics Restraint agreement with Janssen Products, L.P. to develop and commercialize a fixed dose combination drug to be known as Complera. It contained Gilead's Truvada (TDF/FTC) and Janssen's rilpivirine (RPV).

196. Janssen submitted an NDA for its standalone RPV product, Edurant (RPV), on July 23, 2010. On May 20, 2011, the FDA approved the NDA.

197. Gilead submitted an NDA for Complera (TDF/FTC/RPV) on February 10, 2011. On August 10, 2011, the FDA approved that NDA.

198. In the parties' July 16, 2009 License and Collaboration Agreement, Janssen granted Gilead a No-Generics Restraint for the use of RPV in a fixed dose combination drug comprised of TDF, FTC and RPV. Janssen agreed that it "will not import, sell or offer to sell" a fixed dose combination drug comprised of generic TDF, generic FTC, and RPV. The agreement also prohibited Janssen from selling any "Derivative Combination Product" comparable to TDF/FTC/RPV.

199. On December 23, 2014, Gilead and Janssen entered into an Amended & Restated Collaboration Agreement (discussed further below in regard to Odefsey), in which Janssen again agreed to a No-Generics Restraint in regard to Complera (TDF/FTC/RPV). Janssen agreed that it "shall not … make, have made, use, sell, have sold, offer for sale, or import" a fixed dose combination drug comprised of generic TDF, generic FTC, and RPV. It also prohibited Janssen from selling any "Other Combination Product," precluding Janssen from selling a product made with generic TDF, 3TC (rather than FTC), and RPV.

200. Similar to the No-Generics Restraint included in Gilead and BMS's joint venture, Gilead and Janssen's No-Generics Restraint is also neither necessary nor reasonably ancillary to a presumptive objective of innovating and releasing an improved product. Gilead and Janssen's only real goal in creating this joint venture as indicated by the presence of the No-Generics Restraint was to avoid and delay generic competition.

201. Pursuant to the terms of Gilead and Janssen's collaboration agreement, Gilead was responsible for all of the manufacturing of Complera from its manufacturing facilities in California. To accomplish this, in addition to Janssen's granting of RPV license rights to Gilead, the agreement also obligated Janssen to supply quantities of RPV to Gilead as promptly as practicable for Gilead to manufacture and sell Complera from California. Gilead stated that it is responsible for manufacturing Complera, and distributing Complera in the U.S. and much of the rest of the world. Gilead further stated that the price of Complera is the sum of the prices of Truvada (TDF/FTC) and rilpivirine components. "The cost of rilpivirine purchased by us from

Janssen for the combination product approximates the market price of rilpivirine, less a specified percentage of up to 30% in major markets."[35]

202. Janssen is not permitted to terminate the agreement until after expiration of the last patent covering RPV.

203. When Gilead and Janssen entered into their No-Generics Restraint in 2009, two things were happening that would have motivated Gilead to lock in the development of a new combination drug like Complera. First, Gilead had recently sued Teva regarding the FTC patents in connection with Teva's first-to-file ANDA for Truvada. Gilead expected to face generic competition for Truvada as early as May 2011, when Teva's 30-month stay expired. Second, on the same date in 2009 as the agreement, BMS received a Notice Letter from Matrix and Mylan in regard to Sustiva (EFV) — the third component of Atripla (TDF/FTC/EFV). BMS filed suit a month later, but conceded in its complaint that Matrix/Mylan's paragraph IV certifications in regard to both of its Orange-Book listed patents were sufficient, so BMS only sued Matrix/Mylan on another patent that would not trigger a 30-month stay. Thus, any additional exclusivity for Atripla (TDF/FTC/EFV) based on EFV was also in serious doubt. By comparison, Janssen's principal patents protecting RPV have expiration dates in the time period 2019 to 2025.

204. As contemplated by the No-Generics scheme, Gilead cannibalized TDF and FTC sales, encouraging prescribers to switch their patients from those products to Complera.

205. As with Gilead's prior agreement with BMS regarding Atripla, the effects of the agreement between Gilead and Janssen would continue even after expiration or invalidation of the relevant patents.

206. The agreement confirmed that the license from Janssen to Gilead was "exclusive" even as to Janssen, *i.e.*, it prohibited Janssen from commercializing its own fixed dose combination drug containing 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 fixed dose combination drugs with those ingredients, even after generic versions of TDF, FTC and/or TAF become available.

[35] Gilead Sciences, Inc., 2012 Form 10-K Annual Report.

207. When generic versions of TDF became available in 2017, purchasers should have benefited because a competitor in Janssen's position would have competed with Gilead by marketing a competing version of Complera comprised of generic TDF, 3TC, and RPV. The combined price of those products would have dropped due to the competition resulting from the availability of generic TDF.

208. Absent the No-Generics Restraint, Janssen or a reasonable company in Janssen's position would have offered a competing version of Complera long before December 2017 and would have challenged Gilead's patents. No NCE exclusivity would have barred Janssen from timely seeking FDA approval for a competing fixed dose combination drug because Janssen controlled the NCE exclusivity. The only NCE-protected ingredient in Complera at the time of its approval was Janssen's RPV.

209. A 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, a competitor in Janssen's position would have competed against Gilead with a fixed dose combination drug comprised of RPV and generic versions of TDF and FTC as early as February 2014.

210. The No-Generics Restraint prevents Janssen from competing until at least 2025, as Janssen cannot terminate its collaboration agreement with Gilead until then.

211. The No-Generics Restraints with respect to Atripla and Complera artificially inflated prices of their individual components, the fixed dose combination drugs themselves and other cART products. Fixed dose combination drugs that are formulated with a generic component and a brand component sell for about 40% to 50% less than the combined prices of the brand versions of the two components. As a result of the No-Generics Restraints, Gilead's and its conspirators' products continue to sell for about the same price as the combined prices of the brand components, even after the relevant patents expired and generic components have become available.

212. Similarly, when an alternative version of a fixed dose combination drug is introduced using a recognized but not identical substitute for one of the components, its price will

be about 40% to 50% less than the incumbent's price. As a result of the No-Generics Restraints, however, only one alternative version of the affected fixed dose combination drugs is available. Complera (TDF/FTC/RPV) sells for $35,000 for a yearly course of treatment. A comparable version made with generic or comparable versions of TDF or 3TC would sell for half that.

213. Gilead, Janssen, and BMS moved sales from their standalone products to the fixed dose combination drugs that they had unlawfully protected by means of the No-Generics Restraints.

G. Gilead Introduces Stribild.

214. Despite Gilead's clear intent to introduce a line of TAF-based products and its undisputed knowledge that Vemlidy (TAF) was markedly safer than Viread (TDF), in August of 2012 Gilead introduced Stribild (TDF/FTC/EVG/COBI), another TDF-based fixed-dose combination pill comprised of its own component drugs: Viread (TDF), Emtriva (FTC), Vitekta (EVG), and Tybost (COBI). The launch of Stribild was part of Gilead's long-running scheme to move TDF-based fixed dose combination drugs to TAF-based fixed dose combination drugs.

215. By introducing Stribild, a product that Gilead knew contained a dosage of TDF that was much higher than necessary, Gilead recklessly and unnecessarily subjected patients to dangerous side effects to further augment its profits. Gilead anticipated that by intentionally making Stribild less safe than other TDF products, it would help Gilead move prescriptions later on from TDF-based Stribild to TAF-based Genvoya. Because Gilead refused to reduce the dosage of TDF in Stribild, it was able to strategically drive patients to the similar TAF-based product a few years later by focusing on the safety differences between these two of its own products.

216. Gilead's clinical trials on Stribild showed that it was more toxic than unboosted TDF and resulted in more adverse events and treatment discontinuations. Gilead formulated Stribild with 300 mg of TDF together with the pharmacokinetic booster cobicistat. This is the same dosage in which Gilead sold TDF as a standalone product, *i.e.*, for use without a booster. Gilead purposefully did not reduce the dose of TDF to reduce the toxicity of Stribild.

217. Gilead made the mercenary decision to put a product on the market that it knew was more toxic than necessary instead of a product that it knew was safer and more effective. There was no procompetitive reason for Gilead to continue shelving TAF and introduce a less-safe product, and Gilead's only intention in doing so was to maintain its market power and profits through its product switching scheme.

218. Having artificially created two separate, elongated exclusivity periods for TDF and TAF, Gilead knew it would earn higher total revenues and profits by first protecting, and then transitioning, its TDF-based franchise to a newly introduced TAF-based franchise, just as generic competition on TDF was imminent. After launching Stribild, Gilead knew it had a limited amount of time to introduce the second-generation drugs for its entire TDF product line in order to switch the market. Accordingly, it took several steps to facilitate this process.

H. Gilead and BMS Enter into No-Generics Restraint Agreement Related to Evotaz.

219. Effective October 25, 2011, Gilead announced in a press release issued from Foster City, CA that it had entered into another unlawful No-Generics Restraint agreement with BMS to develop a fixed-dose combination product that would become Evotaz (ATV/COBI). Evotaz consists of atazanavir (ATV), a protease inhibitor that BMS markets in standalone form as Reyataz (ATV), and cobicistat (COBI), then an investigational drug developed by Gilead. Gilead provided BMS with an exclusive license (exclusive even as to Gilead) to use COBI in combination with BMS's ATV.

220. BMS has marketed Reyataz (ATV) since 2003. Indeed, back in Gilead's 2004 Atripla agreement with BMS (discussed above), Gilead and BMS agreed, for nine months, to pursue development of a TDF/FTC and ATV product. That agreement also precluded Gilead from pursuing development of a combination of TDF/FTC with any third-party protease inhibitor during that time.

221. On or about October 19, 2009, BMS received notice that Teva had submitted an ANDA with paragraph IV certifications that the patents purportedly covering ATV were invalid, unenforceable, and/or would not be infringed by Teva's proposed generic product. Consequently,

BMS could expect to encounter generic competition to Reyataz as early as April 2012 if Teva received approval and launched at the conclusion of the 30-month stay.

222. On October 26, 2011, after BMS received notice of Teva's ANDA but before Teva could enter the market, BMS and Gilead announced the unlawful No-Generics Restraint agreement to combine BMS's vulnerable ATV with Gilead's investigational COBI. On January 29, 2015, the FDA approved the drug, which BMS markets as Evotaz.

223. The license permitting BMS to use Gilead's COBI in Evotaz prohibits Gilead from commercializing and marketing its own fixed dose combination drug containing COBI and a generic version of ATV (such as the one for which Teva was seeking approval) even after the vulnerable patents on ATV expired. This No-Generics Restraint does not terminate until expiration of the last of Gilead's cobicistat patents in 2029.

224. Generic ATV became available in the U.S. in December 2017. At that time, purchasers should have benefited because: (1) patients could take generic ATV in combination with Gilead's COBI or another booster; and (2) Gilead or a reasonable company in its position would have competed with BMS by marketing a fixed dose combination drug consisting of generic ATV and COBI. The combined price of the two drugs would have plummeted due to competition. Instead, the Evotaz No-Generics Restraint was intended to, and did, prevent purchasers from obtaining those procompetitive benefits.

225. As contemplated by the agreement, BMS encouraged prescribers to switch prescriptions from Reyataz to Evotaz.

I. Gilead Orchestrates an Unlawful Product Hop from TDF-based Products to TAF-based Products Before Generic TDF-based Products Can Enter.

226. In November 2015, after conspiring with Teva to delay launching its generic Viread (TDF) until December 2017, and after launching Stribild with dangerous TDF levels — Gilead finally introduced its first TAF-based product marketed as Genvoya (TAF/FTC/EVG/COBI). Gilead created an artificial window, insulated from competition, to carry out its unlawful switching campaign from TDF-based to TAF-based drugs. Gilead

immediately began cannibalizing its own sales of Stribild (TDF/FTC/EVG/COBI) (among others) by switching patients to its new TAF-based analog, Genvoya.

227. Gilead used its aggressive marketing campaign to switch prescribers and patients from TDF-based drugs — including Viread (TDF), Truvada (TDF/FTC), Atripla (TDF/FTC/EFV), and Complera (TDF/FTC/RPV) — to patent-protected TAF-based drugs, including Odefsey (TAF/FTC/RPV) (launched March 2016) and Descovy (TAF/FTC) (launched April 2016).

228. Gilead disparaged TDF-based products in favor of TAF-based products via TAF-based product websites, scientific conferences, investors calls, promotional materials, and scientific studies. As early as 2013, Gilead started signaling to its investors its need to switch patients from TDF products to TAF products.[36] In its Annual Report, Gilead claimed that "[i]f we are not successful in encouraging prescribers to change patients' regimens to include our HIV products, the sales of our HIV products will be limited. As generic HIV products are introduced into major markets, our ability to maintain pricing and market share may be affected."[37]

229. In furtherance of the scheme, Gilead's sales force used data showing the superior safety profile of TAF over TDF to convince prescribers to switch patients from TDF-based to TAF-based products.

230. Prior to TAF's release, Gilead President and COO Milligan told analysts during a November 10, 2015 Credit Suisse Healthcare Conference that he expected Gilead's sales representatives to be successful in switching the market from TDF to Genvoya based on favorable data showing the benefits of TAF over TDF.[38] Milligan viewed switching patients from Stribild to Genvoya as "the most likely thing to happen very commonly, because it's very seamless for a patient. You're not really changing much; you're just getting a better version of Stribild." Milligan also touted the benefit of switching Atripla patients, who, at that point, had a decade of TDF toxicity buildup, to Genvoya, which, he said, gives patients the benefits of TDF with a better safety profile.

[36] Gilead Sciences, Inc., 2012 Form 10-K Annual Report.
[37] Gilead Sciences, Inc., 2012 Form 10-K Annual Report.
[38] Gilead Sciences at Credit Suisse Healthcare Conference (Nov. 10, 2015).

231. Consistent with Gilead's plan of launching an intentionally inferior and less-safe product, Stribild, before commercializing its TAF-based products — Gilead artificially increased Stribild's price at the same time that it launched Genvoya. Since launching Stribild in 2012, Gilead had consistently raised its price annually, approximately 5% to 7%. In connection with the switch to TAF-based Genvoya in 2016, however, Gilead took its normal annual increase on Stribild plus another mid-year increase of 7%. That price increase boosted the wholesale price of a 12-month supply of Stribild to $34,686, substantially higher than the $30,930 price of Genvoya. This price increase only made economic sense to Gilead because it encouraged switching from Stribild to Genvoya and thereby avoided generic competition.

232. Industry analysts took note of Gilead's scheme, with one writing that "[d]espite the potential of larger revenues associated with a premium price, Gilead chose to price Genvoya and Odefsey slightly lower than Stribild and Complera in the US to encourage switching onto the TAF-based regimens, which are under patent protection for the foreseeable future."[39]

233. In Gilead's Q2 2016 investor call conducted from Foster City, California, the company touted Genvoya, the first TAF-based drug to launch (in November 2015) as the "most successful HIV launch since [the] introduction of Atripla." Gilead stated that almost 40% of Genvoya prescriptions were switches from Stribild, Genvoya's TDF-based predecessor, and 78% of all prescriptions were switches from Gilead drugs.[40]

234. Unlike Gilead's other launches, Gilead chose not to launch standalone TAF. But it could have. Gilead's NDA for Genvoya (TAF/FTC/EVG/COBI) included studies demonstrating the efficacy of both standalone TAF and TAF/FTC in the treatment of HIV. Nonetheless, Gilead strategically launched a TAF-based combination product first to make TAF only available as a component of an FDC. Gilead did so to ensure that prescribers could not pair TAF with other component drugs on the market as part of an overall cART. During that critical time, while Gilead aggressively moved prescriptions from the TDF-based products to TAF-based products,

[39] Pharmaceutical Technology, Gilead's aggressive promotion of its TAF-based HIV portfolio already yielding results (May 23, 2017), https://www.pharmaceutical-technology.com/comment/commentgileads-aggressive-promotion-of-its-taf-based-hiv-portfolio-already-yielding-results-5771127/.
[40] Gilead Sciences Event Brief of Q2 2016 Earnings Call (July 25, 2016).

standalone TAF was not available. Any patient who wanted TAF could get it only by switching to a Gilead FDC. Gilead used its control over tenofovir to impair competition and maintain a dominant position in the cART market.

J. Gilead Amends Its No-Generics Restraint Agreement with Janssen to Include Odefsey.

235. In 2014, Gilead entered into two agreements with Janssen expanding their prior relationship to Gilead's new TAF platform. The parties agreed to develop Odefsey, a TAF-based successor to Complera. Gilead and Janssen amended their joint development agreement on December 29, 2014 to include the development of Odefsey, another fixed dose combination pill containing TAF, FTC, and Janssen's RPV. Similar to Gilead's other joint development agreements, Gilead was responsible for manufacturing Odefsey in its manufacturing facilities in California under the terms of the agreement, and Gilead took the lead role in registration, distribution, and commercialization of the drug from California.

236. Gilead submitted an NDA for Odefsey in July 2015, and the FDA approved Odefsey on March 1, 2016.

237. Gilead and Janssen also entered into mutual No-Generics Restraints for Odefsey, and under the terms of the agreement, Janssen agreed that it would not sell any drug that would be similar to Odefsey (i.e., a drug that contains generic TAF/generic FTC/RPV or comparable generic TAF/3TC/RPV). The agreement states: each party agrees that it "shall not, and shall cause its Affiliates not to, make, have made, use, sell, have sold, offer for sale, or import … (A) a Combination Product other than pursuant to this Agreement or (B) any Other Combination Product[.]" The Agreement defines a "Combination Product" as each of Complera and "the fixed-dose co-formulated product in oral dosage form containing, as its only APIs per single daily dose, TAF, FTC, and RPV[.]" The Agreement defines an "Other Combination Product" as "any fixed-dose, co-formulated combination product (other than a Combination Product) in oral dosage form that contains, as its sole APIs, all three (3) of (a) TAF or TDF, (b) FTC or 3TC, and (c) RPV." Under that No-Generics Restraint, Janssen cannot develop an FDC combining its branded RPV with generic TAF or TDF and generic FTC or 3TC.

238. The No-Generics Restraint in the agreement for Odefsey expressly broadens the parties' earlier No-Generics Restraint concerning Complera. Under the No-Generics Restraint in the Odefsey agreement, Janssen is expressly prohibited from developing an FDC combining generic TDF, 3TC, and branded RPV. The agreement 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.

239. Gilead and Janssen also entered into mutual No-Generics Restraints relating to Janssen's drugs Prezcobix and Symtuza. Janssen and Gilead announced a tentative agreement on June 28, 2011 to jointly develop a fixed dose combination drug combining Janssen's vulnerable Prezista with Gilead's then-investigational drug cobicistat. The FDA approved the drug on January 29, 2015, and Janssen markets the drug as Prezcobix (DRV/COBI). Gilead and Janssen made the Prezcobix deal contingent on concluding a further agreement to coformulate Janssen's darunavir with Gilead's TAF, FTC and cobicistat. The FDA approved that drug on July 17, 2018, and Janssen now markets it as Symtuza (TAF/FTC/DRV/COBI).

240. Each agreement prohibits either party from making comparable fixed-dose combination drugs using generic versions of the other party's components, even after the relevant patents have expired. Absent those agreements, one of the two parties would have competed with the other by launching a comparable version of the drug using generic versions of the other party's components as soon as the relevant patent or patents expired, or would have challenged those patents and entered the market even earlier. Without mutual No-Generics Restraints, competitors like Gilead and Janssen would have been vulnerable to generic-component-based competition from the other and would challenge each other's patents to incorporate generic or comparable components to produce competitors to Odefsey and Symtuza.

241. Absent the Restraints, a competitor in Gilead's position would have marketed competing versions of Prezcobix and Symtuza using generic versions of darunavir in combination with its own components (cobicistat in the case of Prezcobix, and TAF, FTC, and cobicistat in the case of Symtuza). Moreover, a competitor in Janssen's position would have marketed a competing version of Odefsey using generic versions of TAF and FTC as soon as those products

became available, or would have used comparable components. An untainted competitor in Janssen's position would have challenged Gilead's patents one year before the expiration of that exclusivity and could enter the market as early as the expiration of the 30-month stay, in September 2022. However, Janssen is barred from developing that product by the No-Generics Restraint in the Odefsey Agreement, which Janssen cannot terminate until 2026.

242. As a result of the mutual No-Generics Restraints, those competitive benefits were lost. The three agreements relating to Complera/Odefsey, Prezcobix, and Symtuza are part of a decade long conspiracy in which both Gilead and Janssen mutually agreed to refrain from competing against the other's vulnerable compositions, even after the relevant patents expire.

243. As contemplated by the No-Generics scheme, Gilead and Janssen encouraged prescribers and patients to switch from TDF-based treatments to Odefsey and Symtuza. In doing so, Gilead and Janssen knew that once switched, prescribers and patients would be reluctant to switch back to their earlier treatments when generic versions of Viread, Emtriva, and Truvada (and other components of Odefsey and Symtuza) became available. As a result, Gilead and Janssen could continue to charge supracompetitive prices for Odefsey and Symtuza even after the launch of generic versions of Viread, Emtriva, Truvada, and/or other components of Odefsey and Symtuza.

K. Gilead Further Expands Its TAF-based Product Line with Descovy and Reaps the Profits of Its Product-Hopping Scheme.

244. On April 4, 2016, the FDA approved Descovy (TAF/FTC), another TAF-based product that Gilead released that became exceptionally successful as the only other product besides Truvada to have a PrEP indication. Switching patients from Truvada to Descovy was one of Gilead's most lucrative product-hopping schemes. Indeed, by September 2020, 46% of patients taking Truvada for PrEP had been converted to TAF-based Descovy.

245. Gilead's 2019 Annual Report acknowledged the market dynamics and likely impact of Gilead's marketing efforts and product-hopping schemes to switch prescriptions from Truvada (soon to be facing generic competition and reduced pricing) to patent and exclusivity-protected Descovy for PrEP:

> Truvada (FTC/TDF)-based product sales decreased in the United States … in 2019 compared to 2018. The decrease in U.S. sales was primarily due to lower sales volume as a result of patients switching to newer regimens containing FTC/TAF, partially offset by the increased usage of Truvada for PrEP. The decrease in Europe sales was primarily due to lower sales volumes of Truvada and Atripla as a result of broader availability of generic versions and patients switching to newer regimes containing FTC/TAF. We expect a decline in our sales of Truvada in the United States as patients ***switch to Descovy for PrEP from Truvada for PrEP and expected entry of generic versions in late 2020***.

246. As part of its scheme, Gilead's launch of an aggressive product-hopping scheme aimed to switch the prescription base from TDF-based Truvada to its patent-protected and higher priced TAF-based Descovy. The timing of Gilead's plan was crucial: it needed to induce switches to Descovy prior to the anticipated entry of Teva's generic Truvada. To accomplish this, Gilead actively promoted TAF-based Descovy as preferable to Truvada. Gilead disseminated misleading propaganda mischaracterizing the inappropriateness of Truvada and its associated adverse events and risk profiles while touting the alleged benefits of Descovy. The goal of Gilead's deceptive marketing was to switch as many prescriptions as possible from Truvada to Descovy.

247. In a series of investor calls conducted from Gilead's headquarters in Foster City, CA, Gilead continuously indicated the success of its product switching scheme. According to Gilead's Q3 2016 investor call, "[t]he uptick of Genvoya, Odefsey and Descovy have largely been driven by the switch from Gilead's old STRs[.]"[41] Subsequently, in Gilead's Q4 2016 investor call, the company then stated that as of the end of 2016, "TAF-based regimens made up 37% of Gilead's HIV prescription volume," and that "[m]ost patients on these products switch from Gilead's older regimens[.]"[42] Moreover, in Gilead's Q1 2017 investor call, the company reported "quarter-on-quarter growth of 47%" for its TAF portfolio, which it stated "continue[d] to drive the year-on-year growth of the Gilead HIV franchise." The company stated that its "TAF-

[41] Gilead Sciences Q3 2016 Earnings Call (Nov. 1, 2016).
[42] Gilead Sciences Q4 2016 Earnings Call (Feb. 7, 2017).

based regimens now represent 42% of total Gilead HIV prescription volume just 17 months after the launch of Genvoya and less than a year after the launches of Odefsey and Descovy."[43]

248. Gilead's product hop continued to be very successful. By December 2017, when generic Viread (TDF) finally entered the market, Gilead had switched more than 60% of its HIV product sales to its TAF-based products. Gilead boasted about its better-than-expected success in specifically switching 10% of Truvada patients to Descovy in just the first few months after Descovy's launch.[44] By the end of Q2 2020, Gilead had reportedly switched 38% of Truvada PrEP patients to Descovy, and was well on its way to reaching its 40-45% switching goal. Gilead persisted in its profit-driven switching campaign even though studies suggested that Descovy offers no advantages over branded or generic Truvada.[45] In Gilead's Q3 2020 investor call conducted from Foster City, CA — reporting on the time period ending with Teva's launch of generic Truvada in September 2020 — the company reported that 91% of Gilead's U.S. patients had "converted to TAF-based regimens." The company also told investors that it had beaten its 40-45% switching goal and had converted 46% of "clinically appropriate at-risk individuals" from Truvada for PrEP to TAF-based Descovy.[46]

249. Gilead's delay in developing and launching Vemlidy (TAF) and of the clinical research for PrEP HIV medications, together with Gilead's other unlawful business practices — entering into anticompetitive reverse payment settlement agreements and No-Generics Restraints agreements with BMS and Janssen — manipulated the markets for both TDF-based and TAF-based HIV medications and substantially diminished the competitive pressures that force manufacturers to innovate and introduce better and safer products sooner.

250. Gilead's collusive collaboration with BMS to market Atripla and its numerous patent infringement settlement agreements impeding generic competition for Atripla's subcomponents (Viread (TDF), Emtriva (FTC) and Truvada (TDF/FTC)) shielded Gilead from

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[43] Gilead Sciences Q1 2017 Earnings Call (May 2, 2017).
[44] Kyle Blankenship, Gilead's Truvada Faces Teva Generics Assault Amid Descovy Switching Campaign, Fierce Pharma (Oct. 2, 2020), https://www.fiercepharma.com/manufacturing/gilead-sciences-truvada-will-face-teva-generic-challenger-amid-descovy-switching.
[45] *Id.*
[46] Gilead Sciences Q3 2020 Earnings Call (Oct. 28, 2020).

competitive pressures. Gilead was able to raise prices year after year for inferior TDF-based HIV medications, allowing it to delay improved TAF until it had generated as much revenue as possible from its TDF-based franchise, propped up by dubious patent portfolios and further supported by calculated and unfair business arrangements that effectively restrained generic competition and prevented price erosion. Gilead sought to maximize profits from the exclusivities and higher-pricing of its TDF-based franchise before transitioning to its newly introduced TAF-based franchise, despite having recognized the safety and efficacy benefits of TAF for years.

251. Gilead knew that if it could successfully orchestrate the product hops, it could maintain its stranglehold on the market for HIV drugs. For example, Gilead knew that once patients were taking Odefsey (TAF/FTC/RPV), Gilead would likely be insulated from competition on that drug until at least March 2026, because of its No-Generics Restraint agreement with Janssen. And, Gilead's own patents on Tybost (COBI) and Vemlidy (TAF) precluded generic competition on Genvoya (TAF/FTC/EVG/COBI) and Descovy (TAF/FTC) until at least 2025.

252. Gilead's unlawful conduct has resulted in years of artificially overpriced TDF-based HIV medications, unfairly restrained competition, and reduced incentives to innovate and bring safer, more effective products to the market. Absent Gilead's product-hopping and anticompetitive marketing schemes, Plaintiff would have purchased TDF-based and TAF-based HIV medications at substantially reduced pricing sooner. This conduct has also resulted in limited access and affordability of PrEP medications.

253. Gilead and its co-conspirators' collective actions reduced innovation and effectively prevented safer, more effective and/or more affordable preventative HIV medications from entering the market. Most importantly, it created cost barriers and limited access to life-saving HIV medications necessary to prevent and treat the spread of HIV infections and impaired efforts to end the HIV public health epidemic.

L. Gilead Finally Launches Standalone TAF (Vemlidy) but Strategically Elects to Forego Approval for an HIV Indication in Continuing to Impair Competition.

254. Gilead intentionally delayed seeking FDA approval to market standalone TAF (Vemlidy), and altogether withheld it from the market from November 2015 to November 2016. During that window, TAF was only available as a component of Gilead's FDCs. As Gilead knew and intended, the FDA did not approve standalone TAF (Vemlidy) until November 10, 2016, just over a year after approving its first TAF-based product, the FDC Genvoya. By the time of the release of Vemlidy, Gilead had already succeeded in converting more than half of all TDF-based Stribild prescriptions to Genvoya, and its TDF-based Complera prescriptions to TAF-based Odefsey. That pattern of rapid cannibalization continued through 2018.

255. When Gilead did ultimately seek FDA approval of standalone TAF, it did so at what it knew to be a less safe level of 25 mg, when it had sought and received approval for the safer 10 mg level only for use in Gilead's FDCs. Consistent with its same anticompetitive scheme, Gilead refused to make Vemlidy (standalone TAF) or the TAF in Descovy available in 10 mg strength — and still refuses through the present day. Gilead did this with the knowledge that if Vemlidy and Descovy were available with a dosage of 10 mg of TAF, many prescribers and patients would prefer to prescribe or take Vemlidy or Descovy together with a non-Gilead third agent, rather than Gilead's FDC Genvoya (and, later, Symtuza).

256. In furtherance of its anticompetitive scheme, Gilead also refused to seek FDA approval of standalone TAF for use in the treatment of HIV. It instead only sought approval of standalone TAF for use in the treatment of chronic Hepatitis B. Gilead 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, such as Gilead's application for approval of Genvoya where it included studies demonstrating the efficacy of standalone TAF. Additionally, obtaining FDA approval of an HIV indication for standalone TAF would have been economically rational for Gilead, absent its anticompetitive motivations and objectives. 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.

257. Despite the procompetitive rationale for, benefits from, and ease in obtaining an HIV indication for standalone TAF, Gilead nevertheless chose to forego doing so. 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 10 mg 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 was to force patients to purchase Gilead's FDCs rather than standalone TAF plus a competing HIV drug.

258. By not seeking approval for Vemlidy for HIV treatment, Gilead further limited the potential for earlier substitution of TAF (in combination with Gilead's competitors' generic and/or comparable standalone components). For example, by refusing to seek an HIV indication, prescribers were dissuaded from writing prescriptions for standalone TAF in combination with other standalone components for HIV treatment, because to do so would have required an "off-label" course of therapy. Moreover, by steering the market away from standalone TAF for HIV treatment, Gilead also effectively prevented the production of TAF-based versions of Atripla consisting of TAF/generic EFV/generic 3TC or TAF/generic EFV/FTC, which would have reduced pricing. Withholding an HIV indication made economic sense for Gilead only because it impaired competition.

259. Accordingly, Gilead's delay in marketing TAF-based HIV medications dramatically delayed the date on which generic manufacturers could challenge the Vemlidy and Descovy patents. Earlier generic entry would have significantly reduced pricing for these products.

260. Absent Gilead and BMS's agreement, these generic entry dates would have been much earlier. A reasonable manufacturer in Gilead's position would have begun marketing TAF and TAF-based FDCs like Descovy no later than 2007.

261. Thus, instead of NCE protection on TAF-based products, like Descovy, expiring in November 2020, and the Hatch-Waxman 30-month stays expiring in May 2023, NCE exclusivity would have expired in November 2011, and the Hatch-Waxman 30-month stays would have

expired in May 2013. And those living with HIV or at risk for infection of HIV would already have generic versions of TAF-based products.

262. Forgoing introduction of TAF caused Gilead to lose millions of dollars in TAF-based HIV medications sales every year. But impairing competitors' entry into the marketplace with TAF-based products and lower priced generic and/or comparable products was far more lucrative and valuable to Gilead. Delaying TAF only made economic sense for Gilead because of its anticompetitive effects. As a result of Gilead's unfair and anticompetitive business tactics, purchasers have paid for overpriced TAF-based HIV medications.

INTERSTATE COMMERCE

263. Defendants' and Gilead's other co-conspirators' conduct, including the marketing and sale of cART regimen drugs, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the U.S. During the relevant time period, the Gilead and its co-conspirators used various devices to effectuate the illegal acts alleged herein, including the U.S. mail, interstate and foreign travel, and interstate and foreign wire commerce.

264. The actions alleged in this Complaint have directly and substantially affected interstate commerce as Defendants and Gilead's other co-conspirators deprived Plaintiff of the benefits of free and open competition in the purchase of cART regimen drugs within the U.S.

MARKET POWER

265. The relevant geographic market is the U.S. and its territories and possessions.

266. At all relevant times, Gilead had market power in the cART market and in the markets for each of Viread, Emtriva, Truvada, Vemlidy, Descovy, Tybost, Stribild, Genvoya, and their generic equivalents; Gilead and BMS had market power over Atripla and Evotaz and their generic equivalents; Gilead and Janssen had market power over each of Complera, Odefsey, Prezcobix, and Symtuza and their generic equivalents; BMS had market power over Reyataz and its generic equivalents; and Janssen had market power over Edurant and Prezista and their generic equivalents. Gilead and its co-conspirators had the power to maintain the price of their drugs from these markets at supracompetitive levels without losing sufficient sales to other products.

267. Small but significant, permanent increases in the drugs' prices above competitive levels did not cause a loss of sales sufficient to make the price increases unprofitable. At competitive prices, none of the drugs exhibit significant, positive cross-elasticity of demand with respect to price with any product other than generic versions of the brand drugs.

268. Each of the brand drugs is differentiated from all drug products other than generic versions. Due to its use, 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 generic versions.

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

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

271. Brand manufacturers, including Gilead, BMS, and Janssen, exploit this price disconnect by employing large sales forces that visit prescribers' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise prescribers of the cost of the branded products. Moreover, studies show that prescribers 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.

272. The relative unimportance of price in the pharmaceutical marketplace reduces the price elasticity of demand or 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. Thus, brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including the cART drugs at issue here.

273. At all relevant times, Gilead's product gross margin, which is dominated by cART drugs, has been 74% or higher, and has reached as high as 88%. These margins indicate substantial market power.

274. To the extent that Plaintiff is required to prove market power through circumstantial evidence by first defining a relevant product market, at least two types of markets are relevant here: (a) the market for Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, and Symtuza and their respective AB-rated generic equivalents; and (b) the cART Market.

A. The Markets for Specific cART Drugs.

275. One purpose and effect of the No-Generics Restraints described herein was to impair competition from generic versions of each of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, and Symtuza.

276. Similarly, a purpose and effect of Gilead's delay in the improvement of Stribild and standalone TAF, and its regulatory gaming with respect to standalone TAF, was to impair competition from generic versions of Stribild and standalone TAF and generic versions of TAF-containing fixed dose combination drugs.

277. A purpose of Gilead's delay in the entry of generic versions of Viread, Truvada, and Atripla was to impair competition from generic versions of those products.

278. 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:

a. From October 26, 2001 until at least December 15, 2017, Gilead had market power in the market for Viread and its AB-rated generic equivalents, and during that time had 100% share of that market;

b. 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% share of that market;

c. 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% share of that market;

d. from July 2, 2003 to August 31, 2020, Gilead had market power in the market for Emtriva and its AB-rated generic equivalents, and during that time had 100% share of that market;

e. from September 24, 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% share of that market;

f. from August 2, 2004 to October 2, 2020, Gilead had market power in the market for Truvada and its AB-rated generic equivalents, and during that time had 100% share of that market;

g. from July 12, 2006 to October 2, 2020, Gilead and BMS had market power in the market for Atripla and its AB-rated generic equivalents, and during that time had 100% share of that market;

h. 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% share of that market;

i. 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% share of that market;

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

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

l. 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% share of that market;

m. from January 29, 2015 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% share of that market;

n. 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% share of that market;

o. from January 29, 2015 to the present, Gilead and Janssen have had market power in the market for Prezcobix and its AB-rated generic equivalents, and during that time have had 100% share of that market;

p. 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% share of that market; and

q. from July 17, 2018 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% share of that market.

279. Gilead and its co-conspirators 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 generic TDF/3TC/RPV and have market power in the market for Symtuza and comparable versions made of generic TAF/generic FTC (or 3TC)/ritonavir/darunavir.

B. The cART Market and Narrower Markets Therein.

280. Another purpose and effect of the No-Generics Restraints described herein was to impair competition among drugs used in the cART regimen. Similarly, this was also one of the purposes and effects of Gilead's delay in the improvement of Stribild (and supra-profit-maximizing pricing) along with: its delay in the improvement of standalone TAF; its regulatory gaming with respect to standalone TAF; its delay in the entry of generic versions of Viread, Truvada, and Atripla; and its unlawful TAF patent delay-and-extend. 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.

281. As noted in detail above, a cART regimen is a course of treatment distinct from other drugs and regimens that might be used to treat HIV. The term "cART drugs" refers to all antiretroviral drugs used in the treatment of HIV as part of a combination therapy.

282. Demand for cART drugs is a function of demand for combination therapies that can effectively treat HIV. APIs used to treat HIV may be available in standalone form and/or as

fixed dose combination drugs, but they are inputs into combination treatment and not treatments by themselves. The cART drugs that comprise the cART market include Agenerase, Aptivus, Atripla, Biktarvy, Cabenuva, Cimduo, Combivir, Complera, Crixivan, Delstrigo, Descovy, Dovato, Edurant, Emtriva, Epivir, Epzicom, Evotaz, Fortovase, Fuzeon, Genvoya, Hivid, Intelence, Invirase, Isentress, Isentress HD, Juluca, Kaletra, Lexiva, Norvir, Odefsey, Pifeltro, Prezcobix, Prezista, Rescriptor, Retrovir, Retrovir IV Inf, Reyataz, Rukobia, Selzentry, Stribild, Sustiva, Symfi, Symfi Lo, Symtuza, Temixys, Tivicay, Triumeq, Trizivir, Trogarzo, Truvada, Tybost, Videx, Videx EC, Viracept, Viramune, Viread, Vitekta, Vocabria, Zerit, Ziagen, and their AB-rated generic substitutes.

283. Effective cART reduces the concentration of HIV virus in treated patients to undetectable levels. Patients on effective cART regimens 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 U.S. Department of Health and Human Services ("HHS"), the World Health Organization ("WHO"), and all major HIV-treatment organizations, every HIV treatment regimen, with inconsequential exceptions, is a cART regimen.

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

285. In addition to interchangeability of use, price competition exists among drugs within the cART market. However, for the reasons noted in detail above, price competition in many prescription drug therapeutic classes tends to be weak. This is especially true in the cART market, with prescribers and patients selecting among brand-drug antiretrovirals based principally on clinical criteria rather than prices, but price competition among brand cART drugs is not altogether absent.

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

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

288. In this case, many of these "viable alternatives" also are controlled by Gilead. Gilead sells not just one but a whole portfolio of cART products. When reacting to substitution to other products, the monopolist will limit the price rise if the substituting products belong to competitors. If consumers respond to a price increase on a particular drug by moving to another of the monopolist's products, the monopolist will feel no harm, and neither will this form of substitution constrain its pricing power.

289. In economics, it is well established that a monopolist selling two substitute products will raise prices higher than would two firms, each with a monopoly on the products individually. With a portfolio of cART drugs, Gilead has another layer of market power over and above the typical brand manufacturer's ability to price its product above the generic-level price.

290. Defining a broad relevant market for this purpose is consistent with decades of antitrust jurisprudence and analysis. For example, when antitrust authorities examine the likely effect of mergers between brand-drug manufacturers, they often define broad markets to include all or many of the drugs within a therapeutic class.

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

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

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

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

295. NRTIs (Nucleoside/Nucleotide Reverse Transcriptase Inhibitors) work by preventing other nucleosides from being incorporated into the HIV DNA that the virion is trying to build up. Essentially, they disrupt and terminate the DNA chain. Modern cART regimens usually include two of the following NRTIs: TDF, TAF, 3TC, FTC, or abacavir. Compared to other leading antiretrovirals, NRTIs have significant advantages, including a long history of success when co-administered with a third agent. During the relevant period, they have been

recommended as part of nearly all of the HHS-recommended first-line cART regimens. The principal NRTIs are Gilead's TDF, TAF, and FTC, which were APIs in more than 79% of prescriptions containing one or more NRTIs from 2014-19.

296. Prescribers and patients using a cART regimen almost always choose two NRTIs. For very substantial medical reasons, prescribers 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, and tenofovir, by contrast, needs to be phosphorylated only twice by host kinases into its active form, tenofovir diphosphate ("TFV-DP").

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

Available NRTIs	
DRUG NAME AND MANUFACTURER	**DATE OF APPROVAL**
Zidovudine (Retrovir) AZT • Manufactured by ViiV (Burroughs Wellcome) • Used less commonly due to side effects	3/19/87
Didanosine (Videx) ddl • Manufactured by BMS • Not used commonly due to side effects/inferiority	10/9/91
Zalcitabine (Hivid) ddC • Manufactured by Roche • Discontinued in 2006 due to toxicity	6/22/92
Stavudine (Zerit) d4T • Manufactured by BMS • Usage strongly discouraged by WHO	6/24/94
Lamuvidine (Epivir) 3TC • Manufactured by ViiV (Glaxo) • Interchangeable with FTC if used as HIV treatment	11/17/95
Abacavir (Ziagen) ABC • Manufactured by ViiV (Glaxo) • Cannot be used in patients in HLA-B*5701 + pts	12/17/98
Tenofovir Disoproxil Fumarate TDF • Manufactured by Gilead	10/26/01

Emtricitabine FTC • Manufactured by Gilead • Interchangeable with 3TC if used as HIV treatment	7/2/03
Tenofovir Alafenamide Fumarate TAF • Manufactured by Gilead • First approved as a single tablet regimen (Genvoya)	11/5/15

298. 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.

299. 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.

300. In 2006, all U.S. sales of Zalcitabine were halted due to toxicity side effects.

301. The WHO strongly discourages prescribers 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.

302. For many prescribers and patients, Abacavir is not a realistic substitute for tenofovir in a cART regimen. Gilead noted at a 2017 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." 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, prescribers 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 prescribers 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 HIV treatment

programs are based on the "test and treat" approach, in which prescribers encourage patients to begin HIV treatment on the day they are diagnosed, as there is a higher chance the patient will begin and stick with treatment if started immediately after diagnosis.

303. 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 U.S. sales of tenofovir. Even after the entry of generic TDF in December 2017, Gilead's and its co-conspirators' unlawful conduct has allowed Gilead to maintain at least 93% of all unit sales of tenofovir in the U.S. Further, Gilead's and its conspirators' unlawful conduct has allowed Gilead to maintain its share of prescriptions containing NRTIs in the U.S. at an average of more than 79%, and never less than 76%, from 2014 to 2019.

304. Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) also attack the HIV virus. Unlike NRTIs, NNRTIs interfere with reverse transcription by directly binding to the reverse transcriptase enzyme and retarding its function. Compared to other leading antiretrovirals, NNRTIs have significant disadvantages, including significant side effects and a relatively low genetic barrier for the development of resistance. The principal NNRTIs include EFV, which is the sole API in BMS's Sustiva and is also an API in Gilead/BMS's Atripla, and RPV, which is the sole API in Janssen's Edurant and is also an API in Gilead/Janssen's Complera and Odefsey. Gilead's and its co-conspirators' unlawful conduct allowed Gilead to maintain its share of prescriptions containing NNRTIs in the U.S. at an average of more than 80%, and never less than 77%, in the period from 2014 to 2019.

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

306. Integrase Strand Transfer Inhibitors ("INSTIs") prevent HIV integrase from incorporating viral DNA into the human host cell, thereby halting the HIV strand transfer. Compared to other leading antiretrovirals, INSTIs have significant advantages because they have no human homolog, allowing the drug to precisely target the HIV virion, leading to superior

efficacy and minimal toxicity. Today, they are recommended as part of all four of the HHS-recommended first-line cART regimens. The principal INSTIs are elvitegravir, which is the sole API in Gilead's Vitekta and is an API in Gilead's Stribild and Genvoya; bictegravir, which is an API in Gilead's Biktarvy; dolutegravir, which is the sole API in Viiv's Tivicay and is an API in ViiV's Triumeq and Dovato; and raltegravir, which is the sole API in Merck's Isentress. Gilead's and its co-conspirators' unlawful conduct allowed Gilead to grow its share of prescriptions containing INSTIs in the U.S. from 30% in 2014 to 55% in 2019.

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

308. Protease Inhibitors ("PIs") act as competitive inhibitors that directly bind to HIV protease and prevent it from subsequently breaking up the initially translated polyproteins, thus preventing the secondary virions from being infectious. Compared to other leading antiretrovirals, PIs have significant disadvantages, including the fact that in long-term treatment they tend to have side effects such as inducing metabolic syndromes (e.g., dyslipidemia, insulin-resistance, and lipodystrophy/lipoatrophy) and cardiovascular and cerebrovascular diseases. There are currently 10 PIs, including atazanavir, which is the sole API in BMS's Reyataz and is an API in Gilead/BMS's Evotaz; and darunavir, which is the sole API in Janssen's Prezista and is an API in Gilead/Janssen's Prezcobix and Symtuza. The unlawful conduct of Gilead and its co-conspirators allowed Gilead to grow its share of prescriptions containing PIs in the U.S. from 45% in 2014 to 65% in 2019.

309. As noted above, HHS prescribing Guidelines often play a role in the doctor's drug-product selection. Confirming the interchangeability of use of the principal cART drugs throughout the relevant period, the HHS Guidelines included among their preferred or alternative regimens NRTIs, NNRTIs, PIs, and INSTIs. Throughout the relevant period, almost all of the

preferred regimens included two NRTIs, and Gilead's products dominated the NRTIs in the preferred regimens. Moreover, Gilead almost always controlled at least one of the preferred third agents. The following table summarizes much of the relevant information in the HHS Guidelines:

HHS Guidelines: 2012-2019

Month/Year	Number of Preferred Regimens	Number of Preferred Regimens Requiring Two NRTIs	Gilead Control of Recommended NRTIs in Preferred Regimens	Preferred or Alternative Regimen Includes All Four ARV Types*	Gilead Controls at Least One Preferred Third Agent
March 2012	4	4	100%	Yes	No
Feb. 2013	4	4	100%	Yes	Yes
May 2014	7	7	87.5%	Yes	Yes
Nov. 2014	7	7	87.5%	Yes	Yes
July 2016	5	5	80%	Yes	Yes
Oct. 2017	4	4	75%	Yes	Yes
Oct. 2018	4	4	75%	Yes	Yes
July 2019	4	4	75%	Yes	Yes
Dec. 2019	5	4	66%	Yes	Yes

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

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

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

313. In absolute dollars, cART is the nation's fifth costliest therapeutic class. Moreover, cART drugs cost more per prescription than those in three of the four therapeutic classes that rank above it in absolute dollars spent (that is, three of the four have greater dollars spent because there are far more prescriptions written for those drugs). Throughout the cART

market, prices are far higher than they would have been absent the anticompetitive conduct described herein.

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

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

316. At all relevant times, Gilead has maintained at least 70% of all unit sales of NRTIs in the U.S.

317. 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.

318. 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. The unlawful conduct of Gilead and its co-conspirators allowed Gilead to maintain this share of prescriptions of single-tablet regimens in the U.S. Gilead's share of single-tablet regimen prescriptions was never less than 75% between 2014 and 2019 and was more than 78% in 2019.

319. As noted above, the unlawful conduct of Gilead and its co-conspirators has similarly allowed Gilead to dominate other important subcategories of cART drugs. In 2019,

Gilead had the following shares of prescriptions in the U.S.: all cART Drugs (73%); NRTI (80%); NNRTI (71%); INSTI (55%); PI (65%); and single tablet regimen (78%). (Shares for all cART drugs are based on dollar sales; all other shares based on prescriptions.)

320. At all relevant times, Gilead and its co-conspirators were protected by high barriers to entry with respect to the above-defined relevant markets due to patent protections, 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 pharmacists' ability to swap in other drugs. 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. The unlawful No-Generics Restraints and other unlawful conduct described herein 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 higher prices or reductions in output by Gilead and its co-conspirators.

MARKET EFFECTS

321. By impeding competition, Gilead's and its co-conspirators' anticompetitive conduct caused Plaintiff to pay more than it would have paid for branded and generic versions of each relevant drug. Earlier entry of generic versions of each drug would have given purchasers the choice between the branded drug and its generic equivalents, which would have been priced substantially below the brand. This is particularly true with regard to AB-rated generics. Every state's pharmacy substitution laws require or encourage pharmacies to substitute AB-rated generics for branded prescription pharmaceuticals whenever possible. Absent Gilead's and its co-conspirators' anticompetitive conduct, Plaintiff would have saved hundreds of millions of dollars by purchasing generic versions of each relevant drug earlier. Gilead's and its co-conspirators' anticompetitive conduct caused Plaintiff to incur overcharges on its purchases of both branded and generic versions of the relevant drugs.

322. Defendants' and Gilead's other co-conspirators' anticompetitive conduct created and extended monopolies on each relevant drug. Absent Defendants' and Gilead's other co-

conspirators' anticompetitive conduct, generic versions of each branded drug would have been sold earlier than they actually were.

323. Defendants' and Gilead's other co-conspirators' conduct also harmed Plaintiff by increasing and artificially inflating the prices charged for generic versions of the relevant drugs if and when those generic versions became or will become available. When entering a market, generic manufacturers price their products based on a percentage discount off of the then-prevailing brand price. Absent Gilead's and its co-conspirators' unlawful conduct, generic versions of the branded drugs would have entered the market sooner and would have been priced at a discount to the lower then-prevailing brand price rather than the higher brand price that prevailed at the time of actual generic entry. Thus, Gilead's and its co-conspirators' unlawful conduct has caused Plaintiff to pay substantial overcharges on its purchases of each relevant drug.

TOLLING

324. Each time Plaintiff paid an overcharge for the drugs at issue in this Complaint — i.e., each time payment was made at a higher price than would have been paid absent Gilead's and its co-conspirators' unlawful conduct — a new cause of action accrued for that overcharge.

325. Prior to the filing of this Complaint, Plaintiff was an absent member of the putative classes in *Staley v. Gilead Sciences, Inc.*, Case No. 19-cv-02573 (N.D. Cal.) and *Jacksonville Police Officers & Fire Fighters Health Insurance Trust v. Gilead Sciences, Inc.*, Case No. 20-cv-06522 (N.D. Cal.). Pursuant to the U.S. Supreme Court decision in *American Pipe Construction Co. v. Utah*, 414 U.S. 538 (1974), and its progeny, the class action complaints tolled the applicable statute of limitations as to the claims asserted by Plaintiff. Accordingly, Plaintiff is entitled to recover overcharges (and treble damages) for indirect purchases made starting at least four years prior to the filing of those class actions, i.e., May 14, 2015 and later.

326. Plaintiff is also entitled to recover damages on purchases made from at least as early as November 2014 to the present because Gilead and Teva fraudulently concealed that their settlement agreement contained an unlawful reverse payment, and Plaintiff could not have discovered the existence of Gilead's and its co-conspirators' unlawful conduct through the exercise of reasonable diligence prior to December 15, 2017, thereby tolling the relevant statute

of limitations. Gilead's payment to Teva in the form of a secret No-AG agreement was not discoverable until after Teva launched its generic Viread on December 15, 2017, and Gilead did not launch an authorized generic.

327. Gilead and Teva's scheme was self-concealing, in that, by its nature and design, it was incapable of being detected. In addition, Gilead and Teva actively concealed the terms of their agreement to avoid detection. For example, Gilead and Teva specifically represented to the court in the underlying patent litigation that their Viread settlement did not contain a No-AG agreement.

328. Because Plaintiff was not aware of Gilead and Teva's secret, unlawful reverse payment agreement, it could not have been aware that Gilead's and its co-conspirators' other conduct was also part of Gilead's and its co-conspirators' monopolistic and anticompetitive scheme and the antitrust violations alleged herein. In particular:

- The No-Generics Restraint agreements between Gilead and BMS had substantially greater anticompetitive effects when used by Gilead and its co-conspirators in conjunction with the secret Gilead-Teva generic delay agreement;
- The No-Generics Restraint agreements between Gilead and Janssen had substantially greater anticompetitive effects when used by Gilead and its co-conspirators in conjunction with the secret Gilead-Teva generic delay agreement;
- The MFE and MFEP agreements entered into by Gilead and its individual co-conspirators had substantially greater anticompetitive effects when used by Gilead and its co-conspirators in conjunction with the secret Gilead-Teva generic delay agreement.
- The efforts of Gilead and its co-conspirators to switch prescribers and patients from TDF products to other products had substantially greater anticompetitive effects when used by Gilead in conjunction with the secret Gilead-Teva generic delay agreement.

329. Plaintiff lacked the facts and information necessary to form a good faith basis for believing that legal violations had occurred prior to December 15, 2017.

IMPACT AND CONTINUING INJURY TO PLAINTIFF

330. During the relevant period, Plaintiff purchased substantial quantities of the relevant drugs (and, in some cases, generic versions of the relevant drugs) at supracompetitive prices. As a result of Gilead's and its co-conspirators' illegal conduct, Plaintiff was compelled to

pay, and did pay, artificially inflated prices for those drugs. Those prices were substantially greater than the prices that would have been paid absent the illegal conduct alleged herein, because: (a) the prices of the relevant drugs were artificially inflated by Gilead's and its co-conspirators' illegal conduct; (b) Plaintiff was deprived of the opportunity to purchase lower-priced generic versions of the relevant drugs, which it would have done had it had the opportunity; and (c) when the generic drugs ultimately became or will become available, the prices of those generic drugs were or will be higher than they would have been absent Gilead's and its co-conspirators' unlawful conduct.

331. As a direct consequence of Gilead's and its co-conspirators' antitrust violations, Plaintiff has sustained substantial loss and damage to its business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

332. As a result of Gilead's and its co-conspirators' unlawful conduct, Plaintiff continues to pay overcharges today, notwithstanding the launch of generic versions of some of the relevant drugs. The commencement of generic competition does not immediately create a competitive environment indistinguishable from the environment that would have existed had generic competition begun much earlier. In fact, it can take considerable time for the process of generic competition to eliminate the effects of prior anticompetitive conduct for several reasons, all of which apply here.

333. First, generic substitution rates do not immediately reach their maximum level when an AB-rated generic drug is launched. While generic substitution by Plaintiff typically reaches a level of 90% in approximately three months, generic substitution rates continue to increase gradually and incrementally after that time and eventually reach 95% or more, at which point they plateau. It may take a year or longer for generic substitution rates to reach this maximum level. Until they do, the actual generic substitution rate will be lower than it would have been had generic entry occurred earlier, and Plaintiff will continue to purchase units of the branded drug that would have been replaced with units of the less-expensive generic drug but for the antitrust violation.

334. Second, generic prices do not immediately drop to the level they would have achieved had generic competition begun earlier. Generic prices typically fall over time even in the absence of additional generic entrants so long as the number of generic manufacturers in the market does not decrease. In this case, generic prices were high, both because of price increases on the relevant drugs and because Teva and other generic entrants did not face competition from other generics upon launch. Even after additional generics entered the markets, generic prices have remained relatively high and continue to remain relatively high today. Had generic competition begun much earlier, as it would have absent Gilead's and its co-conspirators' unlawful conduct, intergeneric competition would have been underway for a longer period of time and generic prices would have fallen to lower levels than the generic prices Plaintiff is paying today.

335. The fact that generic substitution rates and generic prices can take considerable time to reach the equilibrium levels they would have reached had generic competition begun earlier means that Plaintiff will continue to pay overcharges on its purchases of the relevant drugs and, where available, generic equivalents for some time to come.

336. Moreover, Gilead's and its co-conspirators' unlawful No-Generics Restraints have already caused significant anticompetitive effects by depriving drug purchasers of comparable FDCs once generic TDF and generic FTC 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 Defendants' and Gilead's other co-conspirators' unlawful conduct to make substitutable or comparable versions of at least Complera, Symtuza, and Evotaz. And such competitors would have challenged the applicable patents and would already have entered the market with substitutable or comparable versions of at least Atripla, Prezcobix, and Odefsey.

337. Unless enjoined by this Court, Gilead's and co-conspirators' unlawful conduct will have additional and intensified anticompetitive effects once generic versions of any of TAF, COBI, or DRV become available. For example, absent the No-Generics Restraints, an untainted competitor in Janssen's position would make or have made a substitutable version of Complera

when generic FTC became available. In addition, 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 a generic version of TAF becomes available. Moreover, that competitor would have accelerated the availability of generic versions of those compositions by challenging Gilead's patents on them. Unless enjoined by this Court, however, the unlawful No-Generics Restraints will prevent that competition until at least March 2026.

338. 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. Unless enjoined by this Court, however, the unlawful No-Generics Restraints will prevent that competition until at least 2026.

339. Absent the No-Generics Restraints, 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 the date of 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. But the unlawful No-Generics Restraints 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.

340. 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 begin in or about May 2023.

341. Gilead's and its co-conspirators' conduct is also continuing to unlawfully delay the entry of generic TAF. As noted in detail above (see Section VII(D)(2)(b)), Gilead's and its co-conspirators' conduct resulted in Gilead's delaying the introduction of TAF and TAF-based FDCs from 2006 to 2015. Absent that delay, the NCE exclusivity for TAF would have expired by 2011, and 30-month stays on generic entry would have expired by 2013. But with Gilead's delaying the introduction of TAF to 2015, no generic has yet been able to enter the market, because the NCE exclusivity did not expire until November 5, 2020.

342. 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.

CLAIMS FOR RELIEF

COUNT I:
Conspiracy to Monopolize in Violation of Sections 1 and 2 of the Sherman Antitrust Act (15 U.S.C. §§ 1, 2)
(Gilead)

343. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

344. At all relevant times, Gilead has possessed substantial market 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 patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

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

346. As stated more fully above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS in a conspiracy to monopolize that included:

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

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

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

349. By the time it agreed to the Evotaz No-Generics Restraint with Gilead in October 2011, BMS knew that Gilead had a market share greater than 70% of the cART market. As of that date, BMS also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with Janssen in 2009 protecting Gilead's cART monopoly from competition,

and that the Gilead-Janssen No-Generics Restraint was substantially identical to BMS's No-Generics Restraint. And BMS knew that its No-Generics Restraints and Janssen's enabled Gilead, BMS, and Janssen to tie up a majority of sales of NRTIs and third agents, as well as a majority of sales of all cART drugs. BMS therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART market and the markets for specific cART drugs.

350. BMS participated in the conspiracy to monopolize with Gilead because BMS benefitted directly from it, including from: (a) the Atripla No-Generics Restraint, which incentivized Gilead to switch patients to Atripla thereby increasing BMS's sales of its third agent EFV as a component of Atripla; (b) Gilead's and BMS's unlawful deals with Teva to delay entry of generic versions of Atripla, which increased BMS's profits on the sales of Atripla; and (c) the No-Generics Restraint protecting BMS's third agent ATV and its FDC Evotaz from competition. BMS also benefitted from the other elements of Gilead's scheme, which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed BMS to charge higher prices on its other cART drugs.

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

352. Plaintiff has been injured, and unless Gilead's unlawful conduct is enjoined, will continue to be injured, in its business and property by virtue of overcharges paid for HIV cART drugs as a result of Gilead and BMS's continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT II:
Conspiracy to Monopolize in Violation of Sections 1 and 2 of the Sherman Antitrust Act (15 U.S.C. §§ 1, 2)
(Gilead and Janssen)

353. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

354. At all relevant times, Gilead has possessed substantial market 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 patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

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

356. As stated more fully above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting Janssen in a conspiracy to monopolize that included:

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

357. Janssen consciously committed to the monopolization scheme when it provided the No-Generics Restraints protecting Gilead's drugs from generic competition, received the No-

Generics Restraints from Gilead protecting its drugs from generic competition, and abided by those Restraints.

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

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

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

361. Janssen participated in the conspiracy to monopolize with Gilead because Janssen benefitted directly from it, including from: (a) the Complera and Odefsey No-Generics Restraints, which incentivized Gilead to switch patients to those drugs and thereby increased Janssen's sales of its third agent RPV as a component of Complera and Odefsey; (b) the lump-sum payments Janssen received from Gilead; (c) the degrading of standalone TAF, which increased sales of Odefsey; and (d) the No-Generics Restraints protecting Janssen's Prezcobix and Symtuza from

competition. Janssen also benefitted from the other elements of Gilead's scheme, which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed Janssen to charge higher prices on its other cART drugs.

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

363. Plaintiff has been injured, and unless Gilead and Janssen's unlawful conduct is enjoined will continue to be injured, in its business and property by virtue of overcharges paid for HIV cART drugs as a result of Gilead and Janssen's continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT III:
Conspiracy to Monopolize/Restrain Trade in Violation of California's Cartwright Act
(Gilead)

364. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

365. At all relevant times, Gilead has possessed substantial market 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 patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

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

367. As stated more fully above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;

- Entering into and abiding by the Atripla Agreement and the Evotaz Agreement, each of which was a horizontal market allocation agreement;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF in order to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

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

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

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

371. By the time it agreed to the Evotaz No-Generics Restraint with Gilead in October 2011, BMS knew that Gilead had a market share greater than 70% of the cART market. As of that date, BMS also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with Janssen in 2009 protecting Gilead's cART monopoly from competition, and that the Gilead-Janssen No-Generics Restraint was substantially identical to BMS's No-Generics Restraint. And BMS knew that its No-Generics Restraints and Janssen's enabled Gilead, BMS, and Janssen to tie up a majority of sales of NRTIs and third agents, as well as more

than 70% of sales of all cART drugs. BMS therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART market and the markets for specific cART drugs.

372. BMS participated in the conspiracy to monopolize with Gilead because BMS benefitted directly from it, including from: (a) the Atripla No-Generics Restraint, which incentivized Gilead to switch patients to Atripla thereby increasing BMS's sales of its third agent EFV as a component of Atripla; (b) Gilead's and BMS's unlawful deals with Teva to delay entry of generic versions of Atripla, which increased BMS's profits on the sales of Atripla; and (c) the No-Generics Restraint protecting BMS's third agent ATV and its FDC Evotaz from competition. BMS also benefitted from the other elements of Gilead's scheme which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed BMS to charge higher prices on its other cART drugs.

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

374. By engaging in the foregoing conduct, individually and in concert with BMS, Gilead intentionally and wrongfully violated California's Cartwright Act (Cal. Bus. & Prof. Code §§ 16700, *et seq.*).

375. Gilead's violation of the Cartwright Act was done knowingly, willingly, and flagrantly.

376. Gilead's unlawful acts, aided by BMS, had, and continue to have, a substantial and foreseeable effect on California commerce by artificially raising and fixing prices for the drugs at issue.

377. Gilead's unlawful activities, aided by BMS, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from California

and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

378. During the relevant period, through Gilead, BMS, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold each year in California. Moreover, Gilead sells all of its HIV drugs from its headquarters in California.

379. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead's illegal conduct.

380. As a direct and proximate result of Gilead's violation of the Cartwright Act, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members and suffered damages in an amount to be proven at trial.

COUNT IV:
Conspiracy to Monopolize/Restrain Trade in Violation of Various State Antitrust Laws
(Gilead)

381. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

382. This claim for relief is pleaded in the alternative to the Third Count, in the event it is determined that all of Plaintiff's claims for relief related to its reimbursements and payments for cART drugs are not governed by California law.

383. At all relevant times, Gilead has possessed substantial market 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 patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

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

385. As stated more fully above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting BMS in a conspiracy to monopolize that included:

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

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

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

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

389. By the time it agreed to the Evotaz No-Generics Restraint with Gilead in October 2011, BMS knew that Gilead had a market share greater than 70% of the cART market. As of that date, BMS also knew from Gilead's public SEC filings that Gilead had entered into a No-Generics Restraint with Janssen in 2009 protecting Gilead's cART monopoly from competition,

and that the Gilead-Janssen No-Generics Restraint was substantially identical to BMS's No-Generics Restraint. And BMS knew that its No-Generics Restraints and Janssen's enabled Gilead, BMS and Janssen to tie up a majority of sales of NRTIs and third agents, as well as more than 70% of sales of all cART drugs. BMS therefore knew that its unlawful agreements substantially contributed to Gilead's unlawful maintenance of a monopoly in the cART market and the markets for specific cART drugs.

390. BMS participated in the conspiracy to monopolize with Gilead because BMS benefitted directly from it, including from: (a) the Atripla No-Generics Restraint, which incentivized Gilead to switch patients to Atripla thereby increasing BMS's sales of its third agent EFV as a component of Atripla; (b) Gilead's and BMS's unlawful deals with Teva to delay entry of generic versions of Atripla, which increased BMS's profits on the sales of Atripla; and (c) the No-Generics Restraint protecting BMS's third agent ATV and its FDC Evotaz from competition. BMS also benefitted from the other elements of Gilead's scheme which enabled Gilead to obtain and maintain its monopoly power and supracompetitive prices for cART drugs generally, and thereby allowed BMS to charge higher prices on its other cART drugs.

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

392. By engaging in the foregoing conduct, Gilead, acting individually and in concert with BMS, intentionally and wrongfully violated antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers, including each of the following such laws:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to purchases of HIV cART drugs in Alabama;

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of HIV cART drugs in Arizona;

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of HIV cART drugs in California;

d. Conn. Gen. Stat. §§ 35-26, *et seq.*, with respect to purchases of HIV cART drugs in Connecticut;

e. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of HIV cART drugs in the District of Columbia;

f. Haw. Rev. Stat. §§ 480-2, *et seq.*, with respect to purchases of HIV cART drugs in Hawaii;

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of HIV cART drugs in Illinois;

h. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of HIV cART drugs in Iowa;

i. Kan. Stat. Ann. §§ 50-161(b), *et seq.*, with respect to purchases of HIV cART drugs in Kansas;

j. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of HIV cART drugs in Maine;

k. Md. Code Ann., Com. Law §§ 11-201, *et seq.*, with respect to purchases of HIV cART drugs in Maryland;

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of HIV cART drugs in Michigan;

m. Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of HIV cART drugs in Minnesota;

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of HIV cART drugs in Mississippi;

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of HIV cART drugs in Montana;

p. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of HIV cART drugs in Nebraska;

q. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of HIV cART drugs in Nevada;

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of HIV cART drugs in New Hampshire;

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of HIV cART drugs in New Mexico;

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of HIV cART drugs in New York;

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of HIV cART drugs in North Carolina;

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of HIV cART drugs in North Dakota;

w. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases of HIV cART drugs in Oregon;

x. P.R. Laws Ann. tit. 10 §§ 257, *et seq.*, with respect to purchases of HIV cART drugs in Puerto Rico;

y. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of HIV cART drugs in Rhode Island;

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of HIV cART drugs in South Dakota;

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of HIV cART drugs in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases of HIV cART drugs in Utah, where Plaintiff is a citizen of Utah;

cc. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of HIV cART drugs in Vermont;

dd. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of HIV cART drugs in West Virginia; and

ee. Wis. Stat. §§ 133.03, *et seq*., with respect to purchases of HIV cART drugs in Wisconsin.

393. Gilead's conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

394. Gilead's unlawful acts, aided by BMS, had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

395. Gilead's unlawful activities, aided by BMS, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from each of the

above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

396. During the relevant period, through Gilead, BMS, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

397. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead's illegal conduct.

398. As a direct and proximate result of Gilead's violation of each of the foregoing laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members in these states and territories and suffered damages in an amount to be proven at trial.

COUNT V:
Conspiracy to Monopolize/Restrain Trade in Violation of California's Cartwright Act
(Gilead and Janssen)

399. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

400. At all relevant times, Gilead has possessed substantial market 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 patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

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

402. As stated more fully above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting Janssen in a conspiracy to monopolize that included:

- Entering into and abiding by the illegal No-Generics Restraints;

- Entering into and abiding by the Complera Agreement, Prezcobix Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF in order to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

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

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

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

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

407. By December 2014 when it entered into No-Generics Restraints on Odefsey and Symtuza, Janssen knew that Gilead's scheme included switching its tenofovir-based cART

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

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

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

410. By engaging in the foregoing conduct, individually and in concert, Gilead and Janssen intentionally and wrongfully violated California's Cartwright Act (Cal. Bus. & Prof. Code §§ 16700, *et seq.*).

411. Gilead and Janssen's violation of the Cartwright Act was done knowingly, willingly, and flagrantly.

412. Gilead and Janssen's unlawful acts had, and continue to have, a substantial and foreseeable effect on California commerce by artificially raising and fixing prices for the drugs at issue.

413. Gilead and Janssen's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing in to or out from California and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

414. During the relevant period, through Gilead, Janssen, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold each year in California. Moreover, Gilead sells all of its HIV drugs from its headquarters in California.

415. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead and Janssen's illegal conduct.

416. As a direct and proximate result of Gilead and Janssen's violation of the Cartwright Act, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members and suffered damages in an amount to be proven at trial.

COUNT VI:
Conspiracy to Monopolize/Restrain Trade in Violation of Various State Antitrust Laws
(Gilead and Janssen)

417. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

418. This claim for relief is pleaded in the alternative to the Fifth Count, in the event it is determined that all of Plaintiff's claims for relief related to its payments and reimbursements for cART drugs are not governed by California law.

419. At all relevant times, Gilead has possessed substantial market 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 patients continuing on a HIV regimen, take one of Gilead's products every day. Gilead has the market shares alleged in detail above and possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART market and narrower markets therein.

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

421. As stated more fully above, Gilead willfully obtained and maintained its monopoly power in the cART market by enlisting Janssen in a conspiracy to monopolize that included:

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

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

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

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

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

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

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

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

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

429. By engaging in the foregoing conduct individually and in concert, Gilead and Janssen intentionally and wrongfully violated antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers, including each of the following such laws:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to purchases of HIV cART drugs in Alabama;

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of HIV cART drugs in Arizona;

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of HIV cART drugs in California;

d. Conn. Gen. Stat. §§ 35-26, *et seq.*, with respect to purchases of HIV cART drugs in Connecticut;

e. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of HIV cART drugs in the District of Columbia;

f. Haw. Code §§ 480-2, *et seq.*, with respect to purchases of HIV cART drugs in Hawaii;

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of HIV cART drugs in Illinois;

h. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of HIV cART drugs in Iowa;

i. Kan. Stat. Ann. §§ 50-161(b), *et seq.*, with respect to purchases of HIV cART drugs in Kansas;

j. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of HIV cART drugs in Maine;

k. Md. Code Ann., Com. Law §§ 11-201, *et seq.*, with respect to purchases of HIV cART drugs in Maryland;

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of HIV cART drugs in Michigan;

m. Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of HIV cART drugs in Minnesota;

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of HIV cART drugs in Mississippi;

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of HIV cART drugs in Montana;

p. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of HIV cART drugs in Nebraska;

q. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of HIV cART drugs in Nevada;

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of HIV cART drugs in New Hampshire;

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of HIV cART drugs in New Mexico;

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of HIV cART drugs in New York;

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of HIV cART drugs in North Carolina;

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of HIV cART drugs in North Dakota;

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of HIV cART drugs in Oregon;

x. P.R. Laws Ann. tit. 10 §§ 257, *et seq.*, with respect to purchases of HIV cART drugs in Puerto Rico;

y. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of HIV cART drugs in Rhode Island;

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of HIV cART drugs in South Dakota;

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of HIV cART drugs in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases of HIV cART drugs in Utah, where Plaintiff is a citizen of Utah;

cc. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of HIV cART drugs in Vermont;

dd. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of HIV cART drugs in West Virginia; and

ee. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of HIV cART drugs in Wisconsin.

430. Gilead and Janssen's conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

431. Gilead and Janssen's unlawful acts had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

432. Gilead and Janssen's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

433. During the relevant period, through Gilead, Janssen, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

434. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead and Janssen's illegal conduct.

435. As a direct and proximate result of Gilead and Janssen's violation of each of the foregoing laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members in these states and territories and suffered damages in an amount to be proven at trial.

COUNT VII:
Monopolization and Monopolistic Scheme in Violation of Section 2 of the Sherman Antitrust Act (15 U.S.C. § 2)
(Gilead)

436. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

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

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

439. As alleged above, Gilead willfully obtained and maintained its monopoly power in the cART market and narrower markets therein using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff thereby.

440. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

441. As stated more fully above, Gilead knowingly, willfully, and wrongfully obtained and maintained its monopoly power by engaging in a comprehensive scheme to impede, delay, and blockade competition, including through the following conduct:

- Entering into and abiding by the illegal No-Generics Restraints in its separate agreements with BMS and Janssen;
- Entering into and abiding by the Atripla Agreement, Complera Agreement, Prezcobix Agreement, Evotaz Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;

- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

442. 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.

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

444. Plaintiff has been injured, and unless Gilead's unlawful conduct is enjoined, will continue to be injured, in its business and property by virtue of overcharges paid for HIV cART drugs as a result of Gilead's continuing monopolization in violation of Section 2 of the Sherman Act.

COUNT VIII:
Monopolization and Monopolistic Scheme in Violation of California's Cartwright Act
(Gilead)

445. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

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

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

448. As alleged above, Gilead, acting individually and in concert with its co-conspirators, willfully obtained and maintained its monopoly power in the cART market and narrower markets therein using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff thereby.

449. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

450. As stated more fully above, Gilead, acting individually and aided by its co-conspirators, knowingly, willfully, and wrongfully obtained and maintained its monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints it entered into separately with Janssen and BMS;
- Entering into and abiding by the Atripla Agreement, Complera Agreement, Prezcobix Agreement, Evotaz Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

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

452. By engaging in the foregoing conduct, Gilead intentionally and wrongfully violated California's Cartwright Act (Cal. Bus. & Prof. Code §§ 16700, *et seq.*).

453. Gilead's violation of the Cartwright Act was done knowingly, willingly, and flagrantly.

454. Gilead's unlawful acts had, and continue to have, a substantial and foreseeable effect on California commerce by artificially raising and fixing prices for the drugs at issue.

455. Gilead's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from California and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

456. During the relevant period, through either Gilead or the regional and national distributors and retailers it has engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold each year in California. Moreover, Gilead sells all of its HIV cART drugs from its headquarters in California.

457. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead's illegal conduct.

458. As a direct and proximate result of Gilead's violation of the Cartwright Act, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members and suffered damages in an amount to be proven at trial.

COUNT IX:
<u>Monopolization and Monopolistic Scheme in Violation of Various State Antitrust Laws</u>
(Gilead)

459. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

460. This claim for relief is pleaded in the alternative to the Eighth Count, in the event it is determined that all of Plaintiff's claims for monetary relief related to Plaintiff's payments and reimbursements for cART drugs are not governed by California law.

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

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

463. As alleged above, Gilead, acting individually and in concert with its co-conspirators, willfully obtained and maintained its monopoly power in the cART market and narrower markets therein using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff thereby.

464. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

465. As stated more fully above, Gilead, acting individually and aided by its co-conspirators, knowingly, willfully, and wrongfully obtained and maintained its monopoly power and harmed competition by:

- Entering into and abiding by the illegal No-Generics Restraints it entered into separately with BMS and Janssen;
- Entering into and abiding by the Atripla Agreement, Complera Agreement, Prezcobix Agreement, Evotaz Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;
- Entering into and abiding by the illegal post-patent-expiration royalty provisions;
- Degrading Stribild and artificially raising its price in order to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to the TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

466. To the extent that Gilead is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that

conduct's harmful effects. Even if there were some conceivable such justification that Gilead were permitted to assert, the conduct is and was broader and more anticompetitive than necessary to achieve such a purpose.

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

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to purchases of HIV cART drugs in Alabama;

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of HIV cART drugs in Arizona;

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of HIV cART drugs in California;

d. Conn. Gen. Stat. §§ 35-26, *et seq.*, with respect to purchases of HIV cART drugs in Connecticut;

e. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of HIV cART drugs in the District of Columbia;

f. Haw. Code §§ 480-2, *et seq.*, with respect to purchases of HIV cART drugs in Hawaii;

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of HIV cART drugs in Illinois;

h. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of HIV cART drugs in Iowa;

i. Kan. Stat. Ann. §§ 50-161(b), *et seq.*, with respect to purchases of HIV cART drugs in Kansas;

j. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of HIV cART drugs in Maine;

k. Md. Code Ann., Com. Law §§ 11-201, *et seq.*, with respect to purchases of HIV cART drugs in Maryland;

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of HIV cART drugs in Michigan;

m. Minn. Stat. §§ 325D.51, et seq., and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of HIV cART drugs in Minnesota;

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of HIV cART drugs in Mississippi;

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of HIV cART drugs in Montana;

p. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of HIV cART drugs in Nebraska;

q. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of HIV cART drugs in Nevada;

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of HIV cART drugs in New Hampshire;

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of HIV cART drugs in New Mexico;

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of HIV cART drugs in New York;

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of HIV cART drugs in North Carolina;

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of HIV cART drugs in North Dakota;

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of HIV cART drugs in Oregon;

x. P.R. Laws Ann. tit. 10 §§ 257, *et seq.*, with respect to purchases of HIV cART drugs in Puerto Rico;

y. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of HIV cART drugs in Rhode Island;

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of HIV cART drugs in South Dakota;

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of HIV cART drugs in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases of HIV cART drugs in Utah, where Plaintiff is a citizen of Utah;

cc. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of HIV cART drugs in Vermont;

dd. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of HIV cART drugs in West Virginia; and

ee. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of HIV cART drugs in Wisconsin.

468. Gilead's conduct in violation of each of the foregoing laws was done knowingly, willingly, and flagrantly.

469. Gilead's unlawful acts had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

470. Gilead's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing in to or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

471. During the relevant period, through either Gilead or the regional and national distributors and retailers that it has engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

472. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead's illegal conduct.

473. As a direct and proximate result of Gilead's violation of each of the foregoing laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members in these states and territories suffered damages in an amount to be proven at trial.

COUNT X:
Attempted Monopolization in Violation of Section 2 of the Sherman Antitrust Act (15 U.S.C. § 2)
(Gilead)

474. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

475. 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.

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

477. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

478. As stated more fully above, Gilead, acting individually and in concert with its co-conspirators, knowingly, willfully, and wrongfully attempted to acquire and/or maintain monopoly power by, without limitation and as will be further developed through discovery, the following conduct:

- Entering into and abiding by the illegal No-Generics Restraints separately with Janssen and BMS;
- Entering into and abiding by the Atripla Agreement, Complera Agreement, Prezcobix Agreement, Evotaz Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;
- Degrading Stribild and artificially raising its price to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla and entering into no-AG agreements with Teva related to these drugs.

479. 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.

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

481. As a direct and proximate result of Gilead's and its co-conspirators' antitrust violation(s), Plaintiff has been injured in its business or property and will continue to suffer such injury unless the unlawful conduct is enjoined. Its injury consists of having paid and continuing to pay higher prices than it would have paid in the absence of the violation. Such overcharges are the type of injury the antitrust laws were designed to prevent and flow from that which makes Gilead's acts unlawful.

COUNT XI:
Attempted Monopolization in Violation of California's Cartwright Act
(Gilead)

482. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

483. 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.

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

485. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

486. As stated more fully above, Gilead, acting individually and in concert with its co-conspirators, knowingly, willfully, and wrongfully attempted to acquire and/or maintain monopoly power by, without limitation and as will be further developed through discovery, the following conduct:

- Entering into and abiding by the illegal No-Generics Restraints separately with BMS and Janssen;
- Entering into and abiding by the Atripla Agreement, Complera Agreement, Prezcobix Agreement, Evotaz Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;
- Degrading Stribild and artificially raising its price to drive patients to TAF-based FDCs that it had shielded from competition;
- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;
- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, to raise rivals' costs and delay their entry into the market; and
- Causing delayed entry of generic versions of Viread, Truvada, and Atripla and entering into no-AG agreements with Teva related to these drugs.

487. 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 California's Cartwright Act.

488. Gilead's unlawful acts had, and continue to have, a substantial and foreseeable effect on California commerce by artificially raising and fixing prices for the drugs at issue.

489. Gilead's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from California and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

490. During the relevant period, through either Gilead or the regional and national distributors and retailers it has engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold each year in California. Moreover, Gilead sells all of its HIV cART drugs from its headquarters in California.

491. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead's illegal conduct.

492. As a direct and proximate result of Gilead's violation of the Cartwright Act, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART drugs dispensed to its members and suffered damages in an amount to be proven at trial.

COUNT XII:
Attempted Monopolization in Violation of Various State Antitrust Laws
(Gilead)

493. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

494. This claim for relief is pleaded in the alternative to the Eleventh Count, in the event it is determined that all of Plaintiff's claims for relief related to its payments and reimbursements for cART drugs are not governed by California law.

495. 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.

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

497. Gilead's conscious objective was to further its dominance in the cART market and narrower markets therein by and through its exclusionary conduct.

498. As stated more fully above, Gilead, acting individually and in concert with its co-conspirators, knowingly, willfully, and wrongfully attempted to acquire and/or maintain monopoly power by, without limitation and as will be further developed through discovery, the following conduct:

- Entering into and abiding by the illegal No-Generics Restraints separately with BMS and Janssen;

- Entering into and abiding by the Atripla Agreement, Complera Agreement, Prezcobix Agreement, Evotaz Agreement, Odefsey Agreement, and Symtuza Agreement, each of which was a horizontal market allocation agreement;

- Degrading Stribild and artificially raising its price to drive patients to TAF-based FDCs that it had shielded from competition;

- Degrading standalone TAF, also in furtherance of the scheme to drive patients to TAF-based FDCs that it had shielded from competition;

- Abusing the regulatory process, by withholding an HIV indication from standalone TAF, to raise rivals' costs and delay their entry into the market; and

- Causing delayed entry of generic versions of Viread, Truvada, and Atripla and entering into no-AG agreements with Teva related to those drugs.

499. 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 the following state laws:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to purchases of HIV cART drugs in Alabama;

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of HIV cART drugs in Arizona;

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of HIV cART drugs in California;

d. Conn. Gen. Stat. §§ 35-26, *et seq.*, with respect to purchases of HIV cART drugs in Connecticut;

e. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of HIV cART drugs in the District of Columbia;

f. Haw. Code §§ 480-2, *et seq.*, with respect to purchases of HIV cART drugs in Hawaii;

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of HIV cART drugs in Illinois;

h. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of HIV cART drugs in Iowa;

i. Kan. Stat. Ann. §§ 50-161(b), *et seq.*, with respect to purchases of HIV cART drugs in Kansas;

j. Md. Code Ann., Com. Law §§ 11-201, *et seq.*, with respect to purchases of HIV cART drugs in Maryland;

k. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of HIV cART drugs in Maine;

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of HIV cART drugs in Michigan;

m. Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of HIV cART drugs in Minnesota;

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of HIV cART drugs in Mississippi;

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of HIV cART drugs in Montana;

p. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of HIV cART drugs in Nebraska;

q. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of HIV cART drugs in Nevada;

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of HIV cART drugs in New Hampshire;

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of HIV cART drugs in New Mexico;

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of HIV cART drugs in New York;

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of HIV cART drugs in North Carolina;

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of HIV cART drugs in North Dakota;

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of HIV cART drugs in Oregon;

x. P.R. Laws Ann. tit. 10 §§ 257, *et seq.*, with respect to purchases of HIV cART drugs in Puerto Rico;

y. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of HIV cART drugs in Rhode Island;

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases of HIV cART drugs in South Dakota;

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of HIV cART drugs in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases of HIV cART drugs in Utah, where Plaintiff is a citizen of Utah;

cc. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of HIV cART drugs in Vermont;

dd. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of HIV cART drugs in West Virginia; and

ee. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of HIV cART drugs in Wisconsin.

500. Gilead's unlawful acts had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

501. Gilead's unlawful activities, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

502. During the relevant period, through either Gilead or the regional and national distributors and retailers it has engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

503. There was and is a gross and unconscionable disparity between the price that Plaintiff paid for the drugs at issue and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Gilead's illegal conduct.

504. As a direct and proximate result of Gilead's violation of each of the foregoing laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for cART

drugs dispensed to its members in these states and territories and suffered damages in an amount to be proven at trial.

COUNT XIII:
Restraint of Trade in Violation of California's Cartwright Act
(Gilead)

505. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

506. Gilead violated California's Cartwright Act by entering into and adhering to a contract, combination, or conspiracy in unreasonable restraint of trade with Teva, namely: (a) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Viread until December 15, 2017; and (b) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Truvada and Atripla until September 30, 2020.

507. At all relevant times, Gilead had substantial market power with respect to sales of Truvada and its AB-rated generic equivalents in the U.S.

508. As alleged in detail above, on or about February 19, 2013, Gilead and Teva entered into a reverse-payment agreement, under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing a generic version of Viread to the market. The purposes and effects of that agreement were to: (a) prevent the sale of a generic version of Viread in the U.S., thereby lengthening the period of time when Viread was protected from generic competition; (b) allow Teva to earn supracompetitve profits on generic Viread due to the absence of competition from other generic manufacturers; (c) delay the date when other generic manufacturers would enter the market; and (d) maintain prices for Viread and its AB-rated generic equivalents at supracompetitive levels. This reverse payment from Gilead to Teva exceeded Gilead's anticipated litigation costs to continue pursuing the patent litigation, and was worth substantially more than what Teva could have earned if it had prevailed in the patent litigation and come to market with a generic Viread in competition with Gilead's AG.

509. Additionally, in or about February 2014, Gilead and Teva entered into another reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing its generic versions of Truvada and Atripla to market. The purposes and effects of the reverse payment were to: (a) delay generic entry of Truvada and Atripla in order to lengthen the period in which Gilead would earn supracompetitive profits on sales of Truvada and Atripla; (b) allow Teva to earn supracompetitive profits on generic Truvada and Atripla due to the absence of competition from other generic manufacturers; (c) delay the date that other generic manufacturers would enter that market; and (d) raise and maintain the prices that Plaintiff would pay for Truvada, Atripla, and their AB-rated equivalents at supracompetitive levels.

510. By entering into the unlawful agreements with Teva, Gilead unlawfully conspired to and did restrain trade, thereby violating California's Cartwright Act.

511. Gilead's unlawful acts with Teva had, and continue to have, a substantial and foreseeable effect on California commerce by artificially raising and fixing prices for the drugs at issue.

512. Gilead's unlawful activities with Teva, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from California and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in California.

513. During the relevant period, through Gilead, Teva, or the regional and national distributors and retailers they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold each year in California. Moreover, Gilead sells all of its HIV cART drugs from its headquarters in California.

514. There is and was no legitimate, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the reverse payments were not necessary to achieve such a purpose, and, in any event, such procompetitive effects

would be outweighed by the restraint's anticompetitive effects on purchasers, competition, and consumers.

515. As a direct and proximate result of Gilead's violation of the Cartwright Act, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for HIV cART drugs dispensed to its members and suffered damages in an amount to be proven at trial. Plaintiff's injury consists of having paid higher prices for Viread, Truvada, Atripla, and their generic equivalents, and continuing to pay higher prices than it would have paid in the absence of the antitrust violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Gilead's conduct unlawful.

COUNT XIV:
<u>Restraint of Trade in Violation of Various State Antitrust Laws</u>
(Gilead)

516. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

517. This claim for relief is pleaded in the alternative to the Thirteenth Count, in the event it is determined that all of Plaintiff's claims for relief related to its payments and reimbursements for cART drugs are not governed by California law.

518. Gilead violated various state antitrust laws by entering into and adhering to a contract, combination, or conspiracy in unreasonable restraint of trade with Teva, namely: (a) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Viread until December 15, 2017; and (b) Gilead's agreement to make a reverse payment to Teva in exchange for Teva's agreement to delay its launch of generic Truvada and Atripla until September 30, 2020.

519. At all relevant times, Gilead had substantial market power with respect to sales of Truvada and its AB-rated generic equivalents in the U.S.

520. As alleged in detail above, on or about February 19, 2013, Gilead and Teva entered into a reverse-payment agreement, under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing a generic version of Viread to the market. The purposes and effects of that agreement were to: (a) prevent

the sale of a generic version of Viread in the U.S., thereby lengthening the period of time when Viread was protected from generic competition; (b) allow Teva to earn supracompetitve profits on generic Viread due to the absence of competition from other generic manufacturers; (c) delay the date when other generic manufacturers would enter the market; and (d) maintain prices for Viread and its AB-rated generic equivalents at supracompetitive levels.

521. Additionally, in or about February 2014, Gilead and Teva entered into another reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Gilead agreed to pay, and Teva agreed to receive, substantial consideration in exchange for Teva's agreement to delay bringing its generic versions of Truvada and Atripla to market. The purposes and effects of the reverse payment were to: (a) delay generic entry of Truvada and Atripla in order to lengthen the period in which Gilead would earn supracompetitive profits on sales of Truvada and Atripla; (b) allow Teva to earn supracompetitive profits on generic Truvada and Atripla due to the absence of competition from other generic manufacturers; (c) delay the date that other generic manufacturers would enter that market; and (d) raise and maintain the prices that Plaintiff would pay for Truvada, Atripla and their AB-rated equivalents at supracompetitive levels.

522. By entering into the unlawful agreements with Teva, Gilead unlawfully conspired to and did restrain trade, thereby violating antitrust laws in the following states:

a. Ala. Code §§ 8-10-3, *et seq.*, with respect to purchases of HIV cART drugs in Alabama;

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of HIV cART drugs in Arizona;

c. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law, with respect to purchases of HIV cART drugs in California;

d. Conn. Gen. Stat. §§ 35-26, *et seq.*, with respect to purchases of HIV cART drugs in Connecticut;

e. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases of HIV cART drugs in the District of Columbia;

f. Haw. Code §§ 480-2, *et seq.*, with respect to purchases of HIV cART drugs in Hawaii;

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of HIV cART drugs in Illinois;

h. Iowa Code §§ 553.4, *et seq.*, with respect to purchases of HIV cART drugs in Iowa;

i. Kan. Stat. Ann. § 50-161(b), *et seq.*, with respect to purchases of HIV cART drugs in Kansas;

j. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, with respect to purchases of HIV cART drugs in Maine;

k. Md. Code Ann., Com. Law §§ 11-201, *et seq.*, with respect to purchases of HIV cART drugs in Maryland;

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of HIV cART drugs in Michigan;

m. Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of HIV cART drugs in Minnesota;

n. Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of HIV cART drugs in Mississippi;

o. Mont. Code Ann. §§ 30-14-201, *et seq.*, with respect to purchases of HIV cART drugs in Montana;

p. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases of HIV cART drugs in Nebraska;

q. Nev. Rev. Stat. §§ 598A.060, *et seq.*, with respect to purchases of HIV cART drugs in Nevada;

r. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases of HIV cART drugs in New Hampshire;

s. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of HIV cART drugs in New Mexico;

t. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases of HIV cART drugs in New York;

u. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of HIV cART drugs in North Carolina;

v. N.D. Cent. Code §§ 51-08.1-02, *et seq.*, with respect to purchases of HIV cART drugs in North Dakota;

w. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of HIV cART drugs in Oregon;

x. P.R. Laws Ann. tit. 10 §§ 257, *et seq.*, with respect to purchases of HIV cART drugs in Puerto Rico;

y. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of HIV cART drugs in Rhode Island;

z. S.D. Codified Laws §§ 37-1-3.1, *et seq.,* with respect to purchases of HIV cART drugs in South Dakota;

aa. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of HIV cART drugs in Tennessee, in that the actions and transactions alleged herein substantially affected Tennessee trade or commerce;

bb. Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases of HIV cART drugs in Utah, where Plaintiff is a citizen of Utah;

cc. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases of HIV cART drugs in Vermont;

dd. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases of HIV cART drugs in West Virginia; and

ee. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases of HIV cART drugs in Wisconsin.

523. Gilead's unlawful acts with Teva had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

524. Gilead's unlawful activities with Teva, as described in this Complaint, also affected both intrastate commerce and interstate commerce flowing into or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

525. During the relevant period, through Gilead, Teva, or the regional and national distributors and retailers they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

526. There is and was no legitimate, procompetitive justification for the anticompetitive restraint. Even if there were some conceivable and cognizable justification, the reverse payments were not necessary to achieve such a purpose, and, in any event, such procompetitive effects

would be outweighed by the restraint's anticompetitive effects on purchasers, competition, and consumers.

527. As a direct and proximate result of Gilead's violation of the various states' antitrust laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for HIV cART drugs dispensed to its members in these states and territories and suffered damages in an amount to be proven at trial. Plaintiff's injury consists of having paid higher prices for Viread, Truvada, Atripla and their generic equivalents, and continuing to pay higher prices than it would have paid in the absence of the antitrust violation. Such injury is of the type the antitrust laws were designed to prevent, and flows from that which makes Gilead's conduct unlawful.

COUNT XV:
Violation of Various State Unfair and Deceptive Trade Practices and Consumer Protection
(All Defendants)

528. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

529. By engaging in the foregoing anticompetitive conduct alleged above, Defendants have violated the unfair and deceptive trade practices and consumer protection statutes of all the states and territories, including but not limited to all of the following:

a. Ariz. Code §§ 44-1522, *et seq.*, with respect to purchases of various HIV cART drugs in Arizona;

b. Ark. Code Ann. §§ 4-88-101, *et seq.*, with respect to purchases of various HIV cART drugs in Arkansas;

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of various HIV cART drugs in California;

d. Colo. Rev. Stat §§ 6-1-105, *et seq.*, with respect to purchases of various HIV cART drugs in Colorado;

e. D.C. Code §§ 28-3901, *et seq.*, with respect to the purchases of various HIV cART drugs in the District of Columbia;

f. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of various HIV cART drugs in Florida;

g. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of various HIV cART drugs in Idaho;

h. 815 Ill. Comp. Stat. 505/1, *et seq.*, with respect to purchases of various HIV cART drugs in Illinois;

i. Ind. Code §§ 24-5-0.5-1, *et seq.*, with respect to purchases of various HIV cART drugs in Indiana;

j. La. Stat. Ann. §§ 51:1401, *et seq.*, with respect to purchases of various HIV cART drugs in Louisiana;

k. Me. Stat. tit. 5 §§ 207, *et seq.*, with respect to purchases of various HIV cART drugs in Maine;

l. Mass. Gen. Laws ch. 93A § 11, with respect to purchases of various HIV cART drugs in Massachusetts;

m. Mich. Comp. Laws §§ 445.901, *et seq.*, with respect to purchases of various HIV cART drugs in Michigan;

n. Minn. Stat. §§ 325D.43, *et seq.*, Minn. Stat. §§ 325F.69, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases of various HIV cART drugs in Minnesota;

o. Miss. Code. Ann. §§ 75-24-1, *et seq.*, with respect to purchases of various HIV cART drugs in Mississippi;

p. Mo. Rev. Stat. §§ 407.010, *et seq.*, with respect to purchases of various HIV cART drugs in Missouri;

q. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of various HIV cART drugs in Nebraska;

r. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of various HIV cART drugs in Nevada;

s. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of various HIV cART drugs in New Hampshire;

t. N.M. Stat. Ann. §§ 57-12-1, *et seq.*, with respect to purchases of various HIV cART drugs in New Mexico;

u. N.Y. Gen. Bus. Law §§ 349, *et seq.*, with respect to purchases of various HIV cART drugs in New York;

v. N.C. Gen. Stat. §§ 75-1.1, *et seq.*, with respect to purchases of various HIV cART drugs in North Carolina;

w. N.D. Cent. Code §§ 51-15-01, *et seq.*, with respect to purchases of various HIV cART drugs in North Dakota;

x. 73 Pa. Cons. Stat. §§ 201-1, *et seq.*, with respect to purchases of various HIV cART drugs in Pennsylvania;

y. S.C. Code Ann. §§ 39-5-10, *et seq.*, for purchases of various HIV cART drugs in South Carolina;

z. S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases of various HIV cART drugs in South Dakota;

aa. Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of various HIV cART drugs in Utah;

bb. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to purchases of various HIV cART drugs in Vermont;

cc. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of various HIV cART drugs in Virginia;

dd. W.Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of various HIV cART drugs in West Virginia;

ee. Wis. Stat. § 100.18; Wis. Stat. §§ 100.20, *et seq.*, with respect to purchases of various HIV cART drugs in Wisconsin; and

ff. Wyo. Stat. Ann. §§ 40-12-101, *et seq.*, with respect to purchases of various HIV cART drugs in Wyoming.

530. Defendants' unlawful acts had, and continue to have, a substantial and foreseeable effect on the commerce of each above state and territory by artificially raising and fixing prices for the drugs at issue paid for and/or dispensed in each state or territory.

531. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing into or out from each of the above states and territories, and had direct, substantial, and reasonably foreseeable effects upon trade and commerce in each respective state or territory.

532. During the relevant period, through Gilead, its co-conspirators, or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above states and territories every year.

533. As a direct and proximate result of Defendants' violation of each of the foregoing laws, Plaintiff has been harmed by paying artificially inflated, supracompetitive prices for the

drugs dispensed to its members throughout the U.S. and suffered damages in an amount to be proven at trial.

COUNT XVI:
Unjust Enrichment
(All Defendants)

534. Plaintiff incorporates by reference the allegations set forth in the preceding paragraphs.

535. Defendants have benefited from artificially high prices in the sale of HIV cART drugs resulting from the unlawful and inequitable acts alleged throughout this Complaint.

536. Defendants financial benefit resulting from their unlawful and inequitable acts are traceable to overpayments for HIV cART drugs made by Plaintiff.

537. Plaintiff has conferred upon Defendants an economic benefit, profits from unlawful overcharges, to the economic detriment of Plaintiff.

538. It would be futile for Plaintiff to seek a remedy from any party with whom it has privity of contract for its indirect purchases of HIV cART drugs.

539. It would be futile for Plaintiff to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it purchased HIV cART drugs, as any intermediary is not liable and would not compensate Plaintiff for the impact of Defendants' unlawful conduct.

540. The economic benefit of overcharges derived by Defendants through charging supracompetitive and artificially inflated prices for HIV cART drugs is a direct and proximate result of Defendants' unlawful conduct.

541. The economic benefits derived by Defendants rightfully belongs to Plaintiff, as it paid anticompetitive and monopolistic prices during the relevant period, benefiting Defendants.

542. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the U.S., except Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges for HIV cART drugs derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

543. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff.

544. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff all unlawful or inequitable proceeds they received.

545. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants that are traceable to Plaintiff.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff respectfully requests entry of judgment against Defendants and the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. Permanent injunctive relief enjoining Defendants from continuing their illegal conduct and requiring them to take affirmative steps to dissipate the continuing effects of their prior conduct;

C. An award of Plaintiff's actual, consequential, and compensatory damages, trebled, and/or other damages, in an amount to be proven at trial, including pre- and post-judgment interest at statutory rates;

D. Equitable relief in the nature of disgorgement, restitution, and/or the creation of a constructive trust to remedy Defendants' violations of various state unfair and deceptive trade practices, consumer protection, and unjust enrichment laws;

E. An award of Plaintiff's costs of suit, including reasonable attorneys' fees as provided by law; and

F. Such other and further relief as the Court deems just and proper.

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JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: December 14, 2021

Respectfully submitted,

CROWELL & MORING LLP

/s/ Daniel A. Sasse

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