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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

STALEY, *et. al.*,

Plaintiffs,

v.

GILEAD SCIENCES, INC., *et. al.*,

Defendants.

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

GILEAD'S NOTICE OF MOTION, MOTION TO DISMISS, AND MEMORANDUM IN SUPPORT THEREOF

Hrg: Jan. 16, 2020
Time: 9:00 a.m.
Ctrm: 5 – 17th Floor
Judge: Honorable Edward M. Chen

NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD: PLEASE TAKE NOTICE that on January 16, 2020 at 9:00 a.m., or as soon thereafter as this matter may be heard, in the United States District Court for the Northern District of California, located at 450 Golden Gate Avenue, San Francisco, CA 94102-3489, in Courtroom 5 on the 17th Floor, before the Honorable Edward M. Chen, Defendants Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC (collectively, "Gilead") will move the Court for an order dismissing, with prejudice, all claims against Gilead under Rule 12(b)(6) of the Federal Rules of Civil Procedure. The Motion is based on this Notice of Motion and Motion to Dismiss, the Memorandum of Points and Authorities, the Request for Consideration, the Declaration of Heather M. Burke ("Burke Decl."), all other pleadings and papers on file in this action, any other such matters upon which the Court may take judicial notice, the arguments of counsel, and any other matter the Court may properly consider.

RELIEF SOUGHT

Gilead seeks dismissal of all claims against it, with prejudice, under Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

STATE CASES

FEDERAL STATUTES

FEDERAL RULES

STATE STATUTES

MISCELLANEOUS

MEMORANDUM OF POINTS AND AUTHORITIES

The length, density, and rhetoric of the Corrected Consolidated Class Action Complaint (the "Complaint," ECF No. 118) cannot obscure its failure to make factual allegations sufficient to state a plausible claim for relief. When the Complaint is stripped of its pejorative characterizations and baseless conclusions, what remains is an account of lawful competition, including through joint ventures and other collaborations between Gilead and other pharmaceutical companies. Because the factual allegations of the Complaint fail to make out a plausible claim, the Complaint must be dismissed, in its entirety, under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (holding that putative antitrust class action must be dismissed because factual allegations in complaint were insufficient to state a plausible claim for relief).

INTRODUCTION

In this putative class action, twenty purchasers of HIV therapies assert claims against Gilead and other pharmaceutical companies under federal antitrust statutes as well as under certain state antitrust and consumer-protection statutes. The Complaint challenges essentially three aspects of alleged conduct by Gilead: (i) Gilead's joint ventures and other collaborations with other pharmaceutical companies, (ii) Gilead's internal decisions on the development and commercialization of a new product, and (iii) Gilead's settlement of certain patent-infringement litigation. In each instance, the factual allegations of the Complaint, even when fully accepted as true, establish that Gilead's conduct was well within the parameters of established law. Furthermore, beyond its failure to allege anticompetitive conduct, the Complaint suffers other fundamental flaws, such as a failure to allege a plausible relevant market and a failure to allege facts necessary to various state-law claims asserted.

A. Gilead's Joint Ventures and Other Collaborations to Develop and Commercialize New Fixed-Dose-Combination (FDC) Therapies

The centerpiece of the Complaint is its attack on joint ventures and other collaborations Gilead formed with other pharmaceutical companies to create new fixed-dose-combination therapies ("FDCs"). But the factual allegations of the Complaint (and the joint-venture/collaboration agreements themselves, which are incorporated by reference) provide no plausible basis for finding

those agreements anticompetitive or unlawful. Indeed, the factual allegations of the Complaint establish that Gilead's joint ventures and other collaborations were procompetitive and lawful.

The Complaint acknowledges that the joint ventures and other collaborations increased patient choice by permitting the creation of new FDCs that combined, into a single pill, Gilead's proprietary compounds and the proprietary compounds of its partners. The Complaint further acknowledges that such single-pill FDCs were valuable new products that could increase patients' compliance with life-saving drug regimens. The procompetitiveness of these FDC-creating arrangements is so apparent that the Complaint concedes: "Plaintiffs do not contend that creating or marketing FDCs, as such, is anticompetitive." Compl. ¶ 93.

Instead, the Complaint's attack on the joint-venture/collaboration agreements is limited to provisions purportedly restricting the ability of the partners to compete against the venture using an FDC having the same (or substantially the same) compounds. But this attack is legally foreclosed by the venerable "ancillary restraints" doctrine, which has long established that joint ventures and other collaborations may include reasonable restrictions preventing the partners from competing directly against the venture. *See, e.g.*, *Texaco Inc. v. Dagher*, 547 U.S. 1, 7 (2006) (stating that, under the ancillary restraint doctrine, a restriction that is "ancillary to the legitimate and competitive purposes" of a joint venture or other collaboration is "valid"); *Princo Corp. v. ITC*, 616 F.3d 1318, 1336 (Fed. Cir. 2010) (en banc) (holding that, under longstanding law, "agreements not to compete that might be suspect standing alone are regarded as reasonable when they are ancillary to [a joint venture or other collaborative effort]" (collecting cases)); *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1151 (9th Cir. 2003) (holding that a restraint is protected by the doctrine if "reasonably ancillary to the legitimate cooperative aspects of the venture"). As the case law has held since the recognition of the doctrine over a century ago, ancillary restraints are routine and warranted in joint ventures and other collaborations because such arrangements cannot be expected to succeed unless each partner may confidently invest in and promote the venture without fear that another partner will act unilaterally to undermine it for its own benefit.

Here, restraints on competition—where they exist at all—are narrowly drawn and reasonably ancillary to the legitimate and procompetitive purposes of the ventures. While each joint-

venture/collaboration agreement was negotiated and formed at a different time and with different terms, the agreements merely prevent the partners from, at most, competing directly against the venture with FDCs using the same (or substantially the same) compounds. Notably, the joint-venture/collaboration agreements left each partner free to compete against the venture's FDC in numerous other ways, including through different FDCs as well as through single-agent products not co-formulated into a single-pill FDC. The joint-venture/collaboration agreements also left each partner free to compete without restriction against the other partner outside the scope of the venture. And the Complaint acknowledges that the partners have, indeed, competed vigorously.

The Complaint bemoans the possibility that the narrow restraints on competition under the joint-venture/collaboration agreements could outlive patent protection or regulatory exclusivity covering components of the FDCs, such that the venture partners (all of whom are alleged to be brand pharmaceutical manufacturers) might not introduce a generic form of the FDC. Due to this possibility, the Complaint contrives to label the restraints as "No-Generics Restraints." Compl. ¶ 4. There is, of course, no provision by that name in any of the joint-venture/collaboration agreements; the Complaint invented that characterization. In fact, the restraints, where they exist, simply restrict each partner—and no one else—from competing against the ventures' FDCs with substantially similar FDCs, without regard to the existence or non-existence of patent protection or regulatory exclusivity. Such restraints fall comfortably within the ancillary restraints doctrine, which presupposes that the joint-venture partners are otherwise potential competitors.

Finally, the Complaint's overreaching extends to the point of absurdity in asserting the legal conclusion that the joint-venture/collaboration agreements' restraints—including routine exclusivity provisions in licenses—are per se illegal. Compl. ¶ 94. The law is settled that such restraints are analyzed under the rule of reason and that, if reasonably ancillary to the procompetitive purposes of the venture, are "valid" as a matter of law. *Dagher*, 547 U.S. at 5-8.

B. Gilead's Introduction of a New HIV-Fighting Compound

The Complaint also challenges the timing and manner in which Gilead chose to introduce a new and improved HIV-fighting compound, tenofovir alafenamide (TAF). Specifically, the Complaint alleges that Gilead, seeking to maximize profits and extend patent protections, delayed

introduction of TAF, and then engaged in a series of strategies to encourage the transition of patients to FDCs containing TAF. Compl. ¶¶ 9(a), 202. These factual allegations, even when assumed to be true, do not support a plausible claim for relief—as this Court has already held.

In *AIDS Healthcare* Foundation*, Inc. v. Gilead Sciences, Inc.*, No. 3:16-cv-00443, 2016 U.S. Dist. LEXIS 87578 (N.D. Cal. July 6, 2016) ("*AHF*"), *aff'd*, 890 F.3d 986 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 415 (2018), this Court (Alsup, J.) dismissed claims virtually identical to the Complaint's claims relating to Gilead's introduction of TAF. In that case, a large purchaser of HIV drugs sued Gilead, under federal and state antitrust statutes and state consumer-protection statutes, based on the timing and manner of Gilead's introduction of TAF. In dismissing those claims, this Court held emphatically, under controlling Ninth Circuit law, that Gilead, like any other company, was entitled to bring its improved products to market "whenever and however it chooses." *Id.* at *23 (quoting *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983)). Inexplicably, the Complaint recycles the dismissed *AHF* claims, even using the same contrived characterizations, such as faulting Gilead for keeping TAF "on the shelf" and for "gaming the system."

C. Gilead's Settlement of Patent-Infringement Litigation

Lastly, the Complaint takes issue with agreements between Gilead and certain generic pharmaceutical companies to settle litigation over whether Gilead's patents on certain products containing TAF's predecessor, tenofovir disoproxil fumarate ("TDF"), were infringed by generic versions. Under the patent-settlement agreements, Gilead and each generic company reached a compromise, permitting the generic company to introduce its generic product before the expiration of Gilead's patents. The Complaint challenges "acceleration" provisions in the agreements that permitted even earlier entry if another generic company obtained an earlier entry date. But the Complaint is devoid of factual allegations plausibly suggesting that these "acceleration" provisions were anticompetitive. On the contrary, the Complaint's factual allegations establish that the patent-settlement agreements, including the challenged "acceleration" provisions, were procompetitive and entirely lawful under the United States Supreme Court's controlling decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), and its progeny, including *In re Actos End Payor Antitrust Litig.*, No. 13-cv-

9244, 2015 U.S. Dist. LEXIS 127748, at *46-51 (S.D.N.Y. Sept. 22, 2015) (dismissing challenge to "acceleration" clause in patent settlement), *rev'd as to other claims*, 848 F.3d 89 (2d Cir. 2017).

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Even beyond being predicated entirely upon lawful and procompetitive alleged conduct by Gilead, the Complaint has other fundamental legal flaws. Although any monopolization or rule-of-reason claim must plausibly allege a relevant market, the Complaint fails to do so. Instead, the Complaint alleges, in the most conclusory way, a menu of alternative market definitions: a market for each branded product and any generic versions of it; another including "comparable versions" beyond actual generics; and yet another, all-encompassing "cART Market" of all products used in a "combination antiretroviral therapy" ("cART") regimen. Compl. ¶¶ 376, 379-380. Such contradictory and vacillating market definitions preclude any possible assessment of competitive effects and are legally deficient under controlling law. Finally, the Complaint fails to allege certain elements required under the state-law counts included in the Complaint.

All told, the factual allegations of the Complaint, individually and in aggregate, fail to state any plausible claim for relief. Instead, the factual allegations depict conduct that is entirely compliant with—and even encouraged by—established and controlling law. Beyond that, the factual allegations depict a success story in which Gilead and other pharmaceutical companies have been instrumental in combating the HIV pandemic and saving untold lives through investments and innovations, including the FDCs at the center of this action. Under these circumstances, the Complaint is not only meritless but threatens to deter procompetitive innovation. *See Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004) (dismissing putative class action for failure to state a claim and admonishing that overreaching antitrust enforcement may "chill the very conduct the antitrust laws are designed to protect") (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)). Dismissal is warranted.

STATEMENT OF ISSUE TO BE DECIDED

Whether the factual allegations of the Complaint state a plausible claim against Gilead under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and its progeny.

FACTS AS ALLEGED

In determining whether a complaint can survive a motion to dismiss under Rule 12(b)(6), *Twombly* and its progeny accord the assumption of truth solely to the complaint's "factual allegations." 550 U.S. at 555. An assumption of truth is not accorded to "labels and conclusions," "formulaic recitation[s]," "conclusory allegation[s]," "naked assertion[s]," "legal conclusions," "threadbare recitals," "bare assertions," or "bald allegations." *Twombly*, 550 U.S. at 555-57; *Ashcroft v. Iqbal*, 556 U.S. 662, 680-81 (2009).

The operative "factual allegations" are those found in the complaint "as well as other sources . . . , in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Documents may be considered incorporated into the complaint if "(1) the complaint refers to the document; (2) the document is central to the plaintiff's claim; and (3) no party questions the authenticity of the copy attached to the 12(b)(6) motion." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010). A court may take judicial notice of a fact that is "not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201; *Daniels-Hall*, 629 F.3d at 998-99 (taking judicial notice of information made publicly available by government entities). Factual allegations in a complaint need not be taken as true where contradicted by documents incorporated into the complaint or by judicially noticed facts. *Daniels-Hall*, 629 F.3d at 998.

Here, the relevant factual allegations are found in the Complaint and in various documents incorporated into the Complaint—including the joint-venture/collaboration agreements and settlement agreements central to the Complaint's claims—as well as in certain materials of which this Court may take judicial notice. The many unsupported assertions, characterizations, and legal conclusions in the Complaint are not entitled to the assumption of truth, nor are the Complaint's factual allegations that are contradicted by incorporated documents.

A. The Role of FDCs in the Fight Against HIV

Human Immunodeficiency Virus, or HIV, the infection responsible for one of the deadliest pandemics in history, was first reported in 1981. Compl. ¶ 50. In the decades since, effective

therapies have been developed to such an extent that the concentration of the virus in treated patients drops to undetectable levels. *Id.* ¶¶ 52-54. Patients with undetectable levels of the virus can live healthy lives with relatively manageable side effects and normal life expectancy. *Id.* ¶ 54.

Two innovations led to the introduction of effective HIV therapy. *Id.* ¶ 53. The first was the development of novel classes of powerful drugs that target the HIV virus. *Id.* The second was the discovery that an effective HIV treatment must include a combination or "cocktail" of drugs that inhibits the viral life cycle in multiple ways, an approach known as "combination antiretroviral therapy" or "cART." *Id.*

The compound tenofovir is a common component in a modern cART regimen, but tenofovir itself cannot be administered orally. *Id.* ¶¶ 56-59. Gilead, over time, developed two novel compounds called "prodrugs" that can be administered orally and that act to deliver tenofovir into the body, tenofovir disoproxil fumarate ("TDF") and, later, tenofovir alafenamide ("TAF"). *Id.* ¶ 59.

According to the Complaint, in a modern cART regimen, tenofovir is almost always used alongside either lamivudine ("3TC") or emtricitabine ("FTC"). *Id.* ¶ 60. When an HIV virus becomes resistant to either 3TC or FTC, the virus's susceptibility to tenofovir allegedly *increases*. *Id.* Thus, the combination of tenofovir with either 3TC or FTC allegedly makes it more difficult for the virus to develop resistance to a cART regimen. *Id.* 3TC and FTC are alleged to be remarkably similar, varying by a single atom, and can allegedly be used interchangeably. *Id.* ¶ 61.

If a patient stops taking a cART regimen, viral replication will soon restart, resulting in viral rebound and the resumed destruction of a patient's immune system. *Id.* ¶ 55.

The need to use multiple pills in cART regimens is a barrier to patient compliance. *Id.* ¶ 63. To reduce this burden, multiple antiretroviral compounds are often co-formulated together into a single pill. *Id.* These are known as "fixed-dose combinations" or "FDCs." *Id.* FDCs reduce the number of pills patients must take, thereby improving patients' compliance with their drug regimens. *Id.* ¶ 93.

Recognizing the importance of FDCs in cART regimens, beginning in 2004 the U.S. Department of Health and Human Services and the FDA began encouraging pharmaceutical companies to create new FDCs (and co-packaged products), including FDCs that required two or

more drug companies to partner in joint development. News Release, U.S. Dep't of Health & Human Servs., HHS Proposes Rapid Process for Review of Fixed Dose Combination and Co-Packaged Products (May 16, 2004), https://aidsinfo.nih.gov/news/705/hhs-proposes-rapid-process-for-review-of-fixed-dose-combination-and-co-packaged-products, Burke Decl. Ex. L (announcing an expedited review process for FDCs); Draft Guidance for Industry, FDA, Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV (May 2004), https://web.archive.org/web/20040707133707/http://www.fda.gov/OHRMS/DOCKETS/98fr/04D-0228-GDL0001-6283dft.pdf, Burke Decl. Ex. M (stating in Attachment A: "Scenario 1: Two or more innovator companies agree to jointly develop a new drug application (NDA) for a two- or three-drug FDC or co-packaged product"; listing in Attachment B examples of possible FDCs).

B. Gilead's New FDCs with Other Pharmaceutical Companies

Over the course of a decade beginning in late 2004, Gilead formed joint ventures or other collaborations with three other pharmaceutical companies—Bristol-Myers Squibb Company ("BMS"), Japan Tobacco, Inc. ("Japan Tobacco"), and Janssen R&D Ireland ("Janssen"). Each led to the introduction of new FDCs, thereby increasing patient choice, competition, and therapeutic options. Each arrangement was structured differently and had its own specific terms, but each permitted either party to compete against the resulting FDC (except, in some cases, with a substantially identical FDC), and each allowed robust competition between the parties outside the scope of their respective collaborations. The arrangements are not alleged to be dependent on one another in any way; to the contrary, each was an independent undertaking.

Any discussion of the FDCs requires consideration of a host of active pharmaceutical ingredients ("APIs"), API abbreviations, classes of therapies, and brand names. The charts at Paragraphs 66 and 67 of the Complaint summarize some of the APIs and products pertinent to this case. *See* Compl. ¶¶ 66-67.

1. Gilead's Collaborations with BMS

Gilead entered into two separate collaborations with BMS, ultimately resulting in the introduction of two new FDCs: Atripla® and Evotaz®.

a. The Atripla Agreement

On December 17, 2004, Gilead and BMS entered into a joint-venture agreement that led to the creation and introduction of the first complete FDC regimen in a single tablet, the triple-agent Atripla—a combination of Gilead's Truvada® (TDF/FTC) and BMS's Sustiva® (single-agent efavirenz or EFV). Compl. ¶¶ 118-119; Dec. 17, 2004 Collaboration Agreement, Burke Decl. Ex. A ("Atripla Agreement"). The Atripla Agreement contained extensive provisions setting forth the rights and obligations of the joint venture and the partners with respect to the development, manufacture, and commercialization of the new FDC. Atripla Agreement §§ 3-5. The parties were required to use "commercially reasonable efforts" in furtherance of the joint venture. *E.g.*, *id.* §§ 1.58, 3.5, 5.1(a), 5.2(c). Creating Atripla would not have been possible without the joint venture because at the time of the Agreement, TDF, FTC, and EFV all had more than a decade of patent protection remaining. Compl. ¶¶ 96, 127.

The U.S. Secretary of Health and Human Services, Tommy Thompson, applauded the collaboration:

> The availability of simplified treatment regimens for HIV/AIDS is important to our ability to make progress in the fight against the disease. . . . I am pleased to see the collaboration and efforts of Bristol-Myers Squibb and Gilead. This partnership to create a fixed-dose combination of three HIV medications represents an important advance in our collective effort to deliver simplified therapy for people living with HIV.

Gilead Press Release at 1 (Dec. 20, 2004), Annex L to Atripla Agreement. The FDA approved Atripla in 2006. Compl. ¶¶ 67, 119.

The Atripla Agreement made clear that each partner's license to the joint venture was not exclusive as to the licensor. Compl. ¶ 119; Atripla Agreement §§ 6.1, 6.2. For example, BMS's license of EFV to the joint venture provided that it was "not" exclusive as to BMS. Atripla Agreement § 6.1(b). Nor was there any restriction on BMS supplying EFV to others. Dec. 17, 2004 Manufacturing and Supply Agreement § 2, Burke Decl. Ex. B. The Complaint is thus simply incorrect in alleging that the Atripla Agreement "provided that BMS would supply its EFV exclusively to the Gilead/BMS joint venture for use in an FDC with Gilead's TDF and FTC." Compl. ¶ 123.

In fact, the Atripla Agreement expressly preserved BMS's rights to (1) continue to market and sell EFV; (2) develop, manufacture, and sell other FDCs containing EFV; and (3) conduct clinical

studies using EFV, or even with the FDC Atripla itself. *See* Atripla Agreement § 2.9(a). The Agreement similarly preserved Gilead's rights to do the same with respect to TDF/FTC. *Id.*

The Atripla Agreement thus permitted Gilead and BMS to compete against Atripla, and they did—as the Complaint acknowledges. First, Gilead continued to sell Truvada (as well as each of its components as the single-agent products Viread® and Emtriva®) and BMS continued to sell Sustiva. Compl. ¶¶ 118, 121, 256. Second, after Atripla, Gilead and BMS separately developed no fewer than nine new treatments for HIV. Compl. ¶¶ 67, 107. Indeed, the Complaint expressly admits that, over time, Gilead shifted its focus away from Atripla, to other products, in other joint ventures and otherwise, that competed against Atripla. Compl. ¶¶ 120, 139. Third, when a generic version of BMS's EFV was introduced, Gilead exercised its right under the Agreement to terminate BMS's participation in the joint venture, which continued to sell Atripla (Compl. ¶¶ 124-126, 141; Atripla Agreement §§ 14.5, 14.6), while BMS licensed EFV to Mylan to create an FDC with EFV, generic TDF, and generic 3TC (instead of Gilead's FTC), introducing even more competition. Compl. ¶ 140. In conclusion, under the Atripla Agreement both Gilead and BMS were free to compete against Atripla as well as against one another, and did so with vigor.

b. The Evotaz Agreement

Seven years later, Gilead and BMS entered into a separate agreement that resulted in the introduction of another new FDC, Evotaz, which combined BMS's Reyataz® (single-agent atazanavir or ATV) with Gilead's cobicistat COBI®—products that could not have been combined otherwise for at least seven years, upon generic entry of ATV. Compl. ¶¶ 133, 137; Oct. 25, 2011 Duo License Agreement, Burke Decl. Ex. C ("Evotaz Agreement"). COBI is a "booster," meaning that it inhibits the body from breaking down certain pharmaceutical products, such as ATV, thereby allowing them to be dosed less frequently. Compl. ¶¶ 64-65. Gilead licensed COBI to BMS, which thereby obtained the exclusive right to commercialize and sell a product combining COBI and ATV, with the obligation to use commercially reasonable efforts. Evotaz Agreement §§ 1.55, 6.1, 8.1. On January 29, 2015, the FDA approved Evotaz. Compl. ¶ 133.

The Complaint focuses on the Evotaz Agreement's restraint against Gilead combining COBI with generic ATV (a restraint inherent in the exclusive nature of the license). Compl. ¶ 134; *see*

Evotaz Agreement §§ 1.48, 1.135, 8.1(a), 14.2(a). While Gilead, in exchange for royalties on Evotaz sales (Evotaz Agreement § 9), is not permitted to introduce a substantially identical double-agent FDC, the Agreement allows extensive competition in other ways, including by allowing Gilead to sell COBI as a single-agent product, create a blister pack with COBI and generic ATV, or combine its other compounds with generic ATV. Compl. ¶ 134. And the Agreement allows BMS to sell ATV as a single-agent product and/or combine it with other companies' compounds. Moreover, contrary to the Complaint's contention (¶ 137(1)), the Evotaz Agreement does not (and indeed cannot) prevent other pharmaceutical companies from creating a product with generic ATV and generic ritonavir (RTV) (the latter of which the Complaint suggests could be used as a replacement for COBI). Compl. ¶ 113. And neither BMS nor Gilead is prevented from creating a competing product with another pharmaceutical product. In fact, Gilead did exactly this with Janssen by creating Prezcobix®, a combination of darunavir (DRV) and COBI. Compl. ¶¶ 67, 164. The Evotaz Agreement thus permitted both parties to compete against Evotaz, and—as with the Atripla Agreement—they did so.

2. Gilead's Collaboration with Japan Tobacco

Gilead's collaboration with Japan Tobacco enabled Gilead to develop and introduce into the United States two new FDCs, Stribild® and Genvoya®, and the single-agent product Vitekta®. Compl. ¶¶ 103, 107, 110.

a. The EVG License Agreement Covering Stribild and Genvoya

In March 2005, Japan Tobacco granted Gilead an exclusive license to develop and commercialize the compound elvitegravir (EVG, also known as JTK-303) in various countries, including the United States. Compl. ¶ 103; Mar. 22, 2005 License Agreement § 6.1, Burke Decl. Ex. D ("EVG License Agreement"). The license resulted in Stribild (TDF/FTC/EVG/COBI) in 2012 and Genvoya (TAF/FTC/EVG/COBI) in 2015. These two new quadruple-agent FDCs could not have been created without the EVG License Agreement, as at the time they were introduced their components had several years of patent protection remaining. Compl. ¶¶ 96, 108, 110. The license also allowed Gilead to introduce Vitekta (single-agent EVG) in the United States. Compl. ¶ 107.

The EVG License Agreement is exactly that: a license of EVG from Japan Tobacco to Gilead. It does not contain a "No Generics" provision, as misleadingly alleged in the Complaint. Compl. ¶¶

103, 106, 108-109. Under the Agreement, Gilead is required to devote "Diligent Efforts" to the development and commercialization of an EVG-containing product to be launched in the United States. Compl. ¶ 104; EVG License Agreement §§ 1.15, 3.1(a), 4.1, 5.1(a). At the same time, Gilead remains free to develop and commercialize any other product, even a product containing another "integrase inhibitor" other than EVG, as long as Gilead complies with its obligation to exercise "Diligent Efforts" to develop and commercialize the EVG-containing Product. EVG License Agreement § 6.7. As the Complaint confirms, since 2005, Gilead has commercialized no fewer than nine other new HIV treatments. Comp. ¶ 67.

Japan Tobacco, which is incorporated in Japan and has its principal place of business there, also acquired the exclusive rights to sell those new FDCs in Japan. Compl. ¶¶ 45, 103. Japan Tobacco obtained the right to require Gilead to supply it with the resulting FDC at cost plus a ten percent markup. EVG License Agreement §§ 7.1, 7.2. Japan Tobacco further remains free to develop and commercialize in the United States any other HIV treatment, so long as it does not contain EVG. *Id.* § 6.1.

b. Japan Tobacco Was Not a U.S. Competitor

The Complaint does not—and could not—allege any facts suggesting that Gilead and Japan Tobacco were competitors in the United States at the time of the EVG License Agreement, or that there was any reasonable possibility that Japan Tobacco would become a U.S. competitor (or even wanted to be). Although the Complaint makes various allegations about what a "competitor in Japan Tobacco's position" that was "untainted" by the EVG License Agreement would do (Compl. ¶¶ 112-115), the Complaint is devoid of factual allegations about Japan Tobacco's U.S. capabilities, history, or business plans. In short, the Complaint does not provide any factual basis supporting the notion that the License Agreement reduced competition in the United States.

3. Gilead's Collaborations with Janssen

Gilead also entered into four separate collaboration agreements with Janssen, resulting in four new FDCs: Complera®, Odefsey®, Prezcobix, and Symtuza®. Compl. ¶ 67.

a. The Complera, Odefsey, Prezcobix, and Symtuza Agreements

On July 16, 2009, Gilead partnered with Janssen to develop Complera, an FDC containing

Gilead's Truvada (TDF/FTC) and Janssen's rilpivirine (RPV). Compl. ¶ 142; July 16, 2009 License and Collaboration Agreement, Burke Decl. Ex. E ("Complera Agreement"). Under this Agreement, Gilead provided funding for the development of Janssen's single-agent RPV, then in clinical trials and eventually approved by the FDA as Edurant® on May 20, 2011. Complera Agreement §§ 3.1(c), 10.1; Compl. ¶¶ 67, 144. The Complaint estimates that Gilead paid approximately $100 million to Janssen to help fund this research and development. Compl ¶ 149; *see also* Complera Agreement § 10.1 (setting the figure at a maximum of €71.5 million). In return, Janssen granted Gilead a co-exclusive license with respect to RPV, meaning that both Gilead and Janssen could develop, manufacture, and commercialize Complera. Compl. ¶¶ 67, 146; Complera Agreement §§ 9.1(a), 10.1. On December 23, 2014, the Complera Agreement was amended to allow the development of another FDC, Odefsey, which uses TAF instead of TDF, while continuing to allow for the sale of Complera. Compl. ¶¶ 67, 169; Dec. 23, 2014 Amended & Restated Collaboration Agreement, Burke Decl. Ex. G ("Odefsey Agreement"). Without the license agreement and Gilead's funding, RPV may never have been approved by the FDA, preventing the development of Complera and Odefsey. Compl. ¶ 149; Complera Agreement § 10.1.

On June 27, 2011, Gilead and Janssen entered an agreement to pair Gilead's booster COBI with Janssen's darunavir (DRV) product, Prezista®, to create the FDC Prezcobix. Compl. ¶ 164; June 27, 2011 License Agreement, Burke Decl. Ex. F ("Prezcobix Agreement"). Under this Agreement, Gilead granted Janssen an exclusive license to COBI for the development, manufacture, and commercialization of Prezcobix, a product that combined specific dosages of COBI and DRV. Prezcobix Agreement § 8.1(a). Finally, on December 23, 2014, the parties entered into an agreement to create Symtuza, a product that combined Prezcobix with Gilead's TAF/FTC Descovy® product. Dec. 23, 2014 Amended & Restated Collaboration Agreement § 8.1.1, Burke Decl. Ex. H ("Symtuza Agreement").

For all four agreements, Gilead and Janssen were required to use commercially reasonable efforts to carry out their obligations. *E.g.*, Complera Agreement §§ 1.52, 3.1, 3.2; Odefsey Agreement §§ 1.57, 3.2.1; Prezcobix Agreement §§ 1.49, 3.2, 4.1, 6.1; Symtuza Agreement §§ 1.62, 3.2, 3.3, 4.1, 6.1. And at the time of all four agreements, the FDCs created would not have been possible for at

least five years due to patent protection of the included compounds. Compl. ¶¶ 96, 133, 150, 161, 166.

b. Gilead's Collaborations with Janssen Contemplated Competition

The Complera, Odefsey, Prezcobix, and Symtuza Agreements each limit the extent to which the parties to that agreement may market and sell either generic versions of the FDCs created under the joint ventures or generic versions of products that use therapeutically similar ingredients. Complera Agreement §§ 17.2(a), 17.3(a); Odefsey Agreement §§ 17.2.1; 17.3.1; Prezcobix Agreement §§ 14.2(a), 14.3(b); Symtuza Agreement §§ 14.2.1, 1.298, 1.299, 14.3.2. Thus, the parties are not permitted to develop and sell a product using either the exact same active ingredients (*id.*), or specified alternative active ingredients that are therapeutically substitutable or highly similar. *Id.*; *see, e.g.*, Compl. ¶ 59 (alleging TDF and TAF are two tenofovir "prodrugs"), ¶ 61 (alleging "3TC and FTC are remarkably similar, varying by the substitution of only a single hydrogen atom," and "can be used interchangeably"), ¶ 113 (alleging that "using RTV to boost EVG results in pharmacokinetic parameters similar to those observed with COBI boosting"), ¶ 200 (alleging COBI "has a close substitute in RTV").

Nothing in the Janssen-Gilead agreements prevents either party from using its own products alone or in combination with any other active pharmaceutical ingredients, other than as explicitly specified in the agreements. *See* Complera Agreement § 9.1(a)(ii), (b)(ii), 9.5, 17.2(a) ("retains rights to Exploit any combination products other than those described in clauses (A) and (B) of this Section 17.2(a)"); Odefsey Agreement §§ 9.1.1(a)-(c), 9.6; Prezcobix Agreement §§ 14.2(a), 14.3(b); Symtuza Agreement §§ 14.2.1, 14.3.2. Moreover, the Agreements specifically anticipated and allowed for both companies to conduct clinical trials of these new FDCs combined with other drugs. Complera Agreement § 3.2(b)(iii); Odefsey Agreement § 3.2.2.3; Prezcobix Agreement § 3(b)(v); Symtuza Agreement § 3.3.2.3.

The agreements allowed the parties to compete with other products against each FDC. Janssen, for example, could create products that combined generic versions of Gilead's drugs with a different so-called "third agent"; combine its single-agent product with generic versions of non-Gilead drugs; co-package its single-agent product with generic versions of Gilead's products, such as

in blister packs; and sell its single-agent product to a generic manufacturer to develop a different combination product. Indeed, Janssen used its RPV to create other FDCs, such as Juluca®, created in partnership with ViiV. *See* HHS, "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV" at F-51, K-30, O-1, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf, Burke Decl. Ex. K. Gilead likewise faced no such restrictions and, to the contrary, combined its COBI product with others to create other FDCs, such as Evotaz, Stribild, and Genvoya, as described above. *See* Compl. ¶ 67. The agreements thus did not prevent Janssen or Gilead from competing with Complera, Odefsey, Prezcobix, or Symtuza—and again, they did so.

C. Gilead's Development and Commercialization of the New Compound TAF

The Complaint's allegations relating to Gilead's development and commercialization of TAF are recycled from *AIDS* Healthcare *Foundation, Inc. v. Gilead Sciences, Inc.*, No. 3:16-cv-00443, 2016 U.S. Dist. LEXIS 87578, at *23-24 (N.D. Cal. July 6, 2016) ("*AHF*"), *aff'd*, 890 F.3d 986 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 415 (2018), where Judge Alsup dismissed the complaint for failure to state a claim. (Gilead recites the recycled allegations here and assumes their truth for purposes of this motion, but in fact disputes them categorically.)

The Complaint, like the *AHF* complaint, alleges that Gilead delayed the development and commercialization of its "new" and "safer" tenofovir-containing prodrug compound, TAF. Compl. ¶¶ 7-10, 202-312. Although initial clinical trials were promising (*id*. ¶¶ 205-210), on October 21, 2004, Gilead announced that it decided to "shelve" further development of TAF. *Id*. ¶ 211. According to the Complaint, Gilead decided to "shelve" the TAF project until "competition from generic TDF was imminent." *Id*. The Complaint further alleges that, in 2012, Gilead did not develop an FDC containing the compound dolutegravir (developed by Shionogi Inc. and later by ViiV Healthcare), even though such an FDC would have allegedly been superior to other FDCs that Gilead did develop. *Id*. ¶¶ 230-237.

When Gilead decided to introduce TAF-based FDCs, the Complaint alleges that Gilead took a number of steps to promote the transition to those new FDCs. *Id*. ¶¶ 238-312. First, Gilead allegedly "refused" to reduce the strength of TDF in its Stribild product—thereby "degrading" it—allegedly in

order to magnify the safety differences between Stribild and the new TAF-based product Genvoya. *Id.* ¶¶ 8, 238-239. Gilead also allegedly delayed seeking FDA approval to market standalone TAF (Vemlidy®, FDA-approved for Hepatitis B), altogether withholding it from the market from November 2015 to November 2016. *Id.* ¶¶ 240, 250, 253-261. Finally, Gilead "degraded" standalone TAF by seeking FDA approval to market it at what the Complaint alleges is too high a dosage (*id.* ¶¶ 9, 240, 250-251, 262-269), and marketed that standalone TAF with an indication only for Hepatitis B rather than for HIV (*id.* ¶¶ 240, 252, 270-275). Gilead's "gaming of the regulatory system" (*id.* ¶ 291) allegedly had the purpose and effect of impeding a generic alternative to a standalone TAF for HIV and shielding Gilead's TAF-based FDCs from competition of standalone products that include generic standalone TAF. *Id.* ¶¶ 288-312.

D. Gilead's Settlements with Teva and Other Generic Companies

In 2008 and 2009, Teva Pharmaceuticals sought FDA approval to sell generic versions of Gilead's Viread, Truvada, and Atripla, asserting that Gilead's patents covering those treatments were invalid, unenforceable, or not infringed by the proposed generic versions. Compl. ¶¶ 327, 328, 331. In response, Gilead brought two actions against Teva for patent infringement pursuant to the Hatch-Waxman Act, one as to Truvada and Atripla, and the other as to Viread. *Id.* ¶¶ 330, 332.

In the action as to Truvada and Atripla, by November 2010 Teva had surrendered all defenses based on inequitable conduct and several defenses based on patent invalidity. *See* Stipulation Regarding Disqualification and Non-Assertion of Defenses, *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 08-cv-10838 (S.D.N.Y. Nov. 15, 2010), ECF 59. During trial in January 2014, Teva agreed to drop all claims with respect to one of Gilead's patents. Stipulation of Dismissal, *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 08-cv-10838 (S.D.N.Y. Jan. 29, 2014), ECF 191. Less than two weeks later, and while the trial was still ongoing, the parties settled, with Teva agreeing to an entry date in September 2020—taking one year off the patent life of Gilead's last patent for the products, which expires in September 2021. Compl. ¶ 357; Settlement and License Agreement, *Gilead Scis., Inc. v. Teva Pharm. USA,* Inc., 08-cv-10838 (S.D.N.Y.), dated April 25, 2014, Burke Decl. Ex. J. Although four other patent challengers would later emerge, none was able to meaningfully challenge any aspect of Gilead's patents. Compl. ¶ 359.

Teva fared no better in the action relating to Gilead's patents covering Viread, the last of which expired on January 26, 2018. *See* Compl. ¶ 347. On April 26, 2012, the district court held for Gilead on outstanding claim-construction disputes. Order, *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 10-cv-1796 (S.D.N.Y. Apr. 26, 2012), ECF 68. Then, shortly before trial, Teva sought to replace its principal expert after the Federal Circuit determined that he was a "prevaricator"—a request the district court denied. Order, *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 10-cv-1796 (S.D.N.Y. Feb. 6, 2013), ECF 116. Two weeks later, the parties settled, with Teva agreeing to an entry date that took a mere six weeks off the remaining five years of patent life for the last-expiring Gilead patent covering Viread. Compl. ¶ 348; Settlement and License Agreement, *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 10-cv-01796 (S.D.N.Y.), dated April 22, 2013, Burke Decl. Ex. I. Thus, although the Complaint makes the conclusory allegation that "Gilead filed the patent infringement lawsuit against Teva without regard to the lawsuit's merits" (Compl. ¶ 332), by any reasonably objective measure the patents proved valid and enforceable. Two other patent challengers, Lupin and Cipla, continued litigating for over a year after Teva settled, but ultimately agreed to drop their claims, allegedly without receiving anything in return. Compl. ¶ 348.

The Gilead-Teva settlements contained "acceleration clauses" providing that if a subsequent generic challenger obtained an earlier entry date, Teva's entry date would move up accordingly—such that Teva would be permitted to enter six weeks prior to other generic challengers for the Viread patents and up to six months (i.e., the normal 180-day exclusivity period for a first filer under the Hatch-Waxman Act) prior to other challengers for the Atripla/Truvada patents. *See id.* ¶¶ 340-344, 357. The Complaint alleges that settlements with subsequent generic challengers likewise contained acceleration clauses, but no other generic challenger was able to obtain entry on any date earlier than patent expiration and the clauses were not triggered. *Id.* ¶ 359.

ARGUMENT

I. THE ALLEGED CONDUCT BY GILEAD FAILS TO STATE A PLAUSIBLE CLAIM AS A MATTER OF LAW

The factual allegations of the Complaint do not state a plausible claim. Instead, they describe conduct permitted—and even encouraged—by established law. As such, the Complaint must be

dismissed in its entirety for failure to state a claim. *Twombly*, 550 U.S. at 570.

The Complaint contains thirteen separate counts, each one naming Gilead. Each count is based on federal or state antitrust statutes, except Count Seven, which is based on state consumer-protection statutes. Each count takes its factual basis from the Complaint's allegations about (i) Gilead's joint-venture and collaboration agreements, (ii) Gilead's introduction of TAF, and/or (iii) Gilead's settlement of patent-infringement litigation. Each count is predicated on the legal conclusion that Gilead's conduct in these three respects was anticompetitive and unlawful.

As shown below, Gilead's conduct as alleged is lawful. Controlling case law establishes that Gilead's alleged conduct complied with federal antitrust law. Furthermore, because state antitrust statutes and state unfair competition statutes follow federal antitrust law, all counts must be dismissed. *See, e.g.*, *Dimidowich v. Bell & Howell*, 803 F.2d 1473, 1477 (9th Cir. 1986) (holding that California's Cartwright Act is similar to the Sherman Act); *Chavez v. Whirlpool Corp.*, 113 Cal. Rptr. 2d 175, 183-84 (Cal. Ct. App. 2001) (holding under California's Unfair Competition Law that conduct alleged to be "unfair" because it unreasonably restrains competition and harms consumers is not "unfair" if the conduct is condoned under antitrust laws); *AHF*, 2016 U.S. Dist. LEXIS 87578, at *25-28 (applying *Dimidowich* and *Chavez* to dismiss Cartwright Act and UCL claims where conduct comported with federal antitrust laws); *In re Graphics Processing Units Antitrust Litig.*, 527 F. Supp. 2d 1011, 1025 (N.D. Cal. 2007) ("*GPU*") ("Since plaintiffs' federal and state-law antitrust claims are predicated on the same allegations of conspiracy, they likewise are insufficient to state a claim for conspiracy."); *In re Aluminum Warehousing Antitrust Litig.*, No. 13-md-2481 (KBF), 2014 U.S. Dist. LEXIS 121435, at *128 (S.D.N.Y. Aug. 29, 2014) ("Plaintiffs' state law claims rely upon the same allegations of conspiracy, monopolization and unfair conduct as their antitrust claims. For the same reasons, none survive.").

A. Gilead's Collaborations Were Pro-Competitive and Any Restraints In Them Were Ancillary and Thus Valid

The Complaint is largely premised on its legal contention that Gilead's collaborations contain restraints that are "horizontal agreements constituting per se violations of the antitrust laws." Compl. ¶ 1. This is a profound misstatement of the law. To the contrary, restraints that are ancillary to

procompetitive joint ventures or other collaborations—far from per se illegal—have long been permitted and, indeed, encouraged. The instant collaborations are procompetitive—they created new, lifesaving products—and the challenged restraints are quintessential ancillary restraints.

In *Texaco Inc. v. Dagher*, 547 U.S. 1 (2006), the Supreme Court held that per se condemnation under Section 1 of the Sherman Act is not applicable to restraints between partners to a legitimate joint venture. *Id.* at 5-6. In *Dagher*, Texaco and Shell Oil had a joint venture to refine and market gasoline in the western United States, and they agreed that each would sell gasoline under their own brands at a unified price. *Id*. at 3. The Ninth Circuit held that the unified pricing was horizontal price-fixing subject to per se condemnation, but the Supreme Court reversed. *Id*. at 8. In doing so, the Supreme Court held that, while price-fixing by competitors is subject to per se condemnation, price-fixing by joint-venture partners is not. *Id*. at 5-6; *see also Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 203 (2010) (confirming that rule of reason generally applies to restraints in joint venture agreements: "per se rules of illegality are inapplicable").

In reaching its decision, the *Dagher* Court took the opportunity to address the "ancillary restraints doctrine," which it described as "govern[ing] the validity of restrictions imposed by a legitimate business collaboration, such as a business association or joint venture, on nonventure activities." 547 U.S. at 7. The Court stated: "Under the doctrine, courts must determine whether the nonventure restriction is a naked restraint on trade, and thus invalid, or one that is ancillary to the legitimate and competitive purposes of the business association, and thus valid." *Id.*; *see also Nat'l Collegiate Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 113-115 (1984) (acknowledging that joint venture restraint could make a new product possible); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 23 (1979) (excusing restraint in joint venture where restraint "is necessary to market the product at all").

The federal courts of appeals have also long applied the ancillary restraints doctrine, and that history was surveyed and applied by the United States Court of Appeals for the Federal Circuit, sitting en banc, in *Princo Corp. v. ITC*, 616 F.3d 1318 (Fed. Cir. 2010) (en banc). After reviewing the substantial authority establishing that collaborations—and especially collaborations creating new technologies or new products—can have profound procompetitive benefits, the Federal Circuit stated:

"The 'ancillary restraints' that are often important to collaborative ventures, such as agreements between the collaborators not to compete against their joint venture, are also assessed under the rule of reason." 616 F.3d at 1336 (citing, among other authorities, *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 214, 223-30 (D.C. Cir. 1986); *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 11 (1st Cir. 1979)). The Federal Circuit cited the seminal case on ancillary restraints, *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 280 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899), in which then-Judge, later Chief Justice, William Howard Taft wrote: "Restrictions in the articles of partnership upon the business activity of the members, with a view of securing their entire effort in the common enterprise were, of course, only ancillary to the main end of the union, and were to be encouraged." Based on all of this authority, the Federal Circuit upheld the restraint before it, concluding that "agreements not to compete that might be suspect standing alone are regarded as reasonable when they are ancillary to 'a larger endeavor whose success they promote.' *Polk Bros.*, 776 F.2d at 189." 616 F.3d at 1336.

In *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1151 (9th Cir. 2003), the Ninth Circuit held that a restraint in a joint venture or collaboration is protected by the ancillary restraint doctrine where the restraint is "reasonably ancillary to the legitimate cooperative aspects of the venture." This articulation of the ancillary restraint doctrine is consistent with the Supreme Court's subsequent explanation in *Dagher* that a restraint is "valid" as long as it is ancillary to the legitimate and competitive purposes of the joint venture. 547 U.S. at 7.

Here, the Complaint asserts that Gilead has formed joint ventures and other collaborations containing unlawful restraints on the competitive activity of the ventures' partners. Compl. ¶¶ 102-175. As shown above, one of the targeted ventures—Gilead's joint venture with BMS to form Atripla—does not in fact contain any restraint on either partner's competitive activity. The remaining collaborations contain restraints that are reasonably ancillary to the legitimate purposes of the collaborations and that, in the words of *Dagher*, are "thus valid." 547 U.S. at 7; *see* Thomas A. Piraino, Jr., *The Antitrust Analysis of Joint Ventures After the Supreme Court's* Dagher *Decision*, 57 Emory L.J. 735, 795 (2008) ("the *Dagher* Court stated that, when the ancillary restraints doctrine

does apply, it should be conclusive as to the legality of the restraint at issue").

Even if the ancillary restraints here somehow were not considered conclusively valid under *Dagher*, dismissal would nonetheless be required because the Complaint fails to plausibly allege an adverse effect on competition. *See Caudill v. Lancaster Bingo Co.*, No. 2:04-cv-695, 2005 U.S. Dist. LEXIS 24621, at *19 (S.D. Ohio Oct. 24, 2005) ("Because plaintiffs have failed to properly plead an essential element of a Sherman Act claim, namely, that the non-competition agreements have had an adverse effect on competitiveness in the market, defendants' motion for judgment on the pleadings shall be granted."); *see also Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2290 (2018) (affirming dismissal under rule of reason due to failure of plaintiffs to satisfy initial burden of establishing substantial anti-competitive effects in the relevant market).

The collaborations themselves are indisputably legitimate and procompetitive. They were formed, with the encouragement of the federal government during "one of the deadliest human pandemics in history" (Compl. ¶ 50), to create new FDCs—pioneering HIV medicines—that otherwise could not have existed. The Complaint extolls the therapeutic advantages of FDCs. Compl. ¶¶ 63, 93. The collaborations not only permit bringing together complementary components into new products, but, by imposing obligations upon the parties to exercise commercially reasonable efforts, they call for development, promotion, and commercialization of the new products. New products increase competition and consumer choice, and, in this industry, have profound impacts on patient health and welfare. These procompetitive benefits cannot reasonably be disputed, and the Complaint does not even attempt to do so. Compl. ¶ 93 ("Plaintiffs do not contend that creating or marketing FDCs, as such, is anticompetitive.").

To the extent that the agreements include restraints on competition, those restraints are modest, reasonable, and closely tied to the collaborations' procompetitive benefits. The restraints support the collaborations by ensuring that the partners are committed to the venture's product, and will have the incentive to invest in and promote that product; each partner knows that the other cannot introduce an identical (or nearly identical) FDC to compete with the venture's product, cynically "free riding" on the venture's regulatory and promotional activity. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476-77 (2013) (acknowledging that "[t]he process of submitting an NDA is both

onerous and lengthy," and that a "typical NDA spans thousands of pages and is based on clinical trials conducted over several years"). In this respect, the restraints serve to make the collaboration "more effective in accomplishing its purpose." *Rothery Storage*, 792 F.2d at 224. Still, as shown, the restraints are narrow and leave the partners free to compete in innumerable other ways with different products, including some that are close substitutes for the venture's product. *See supra* Facts as Alleged § B.

In the case of the COBI license to BMS to make and sell Evotaz, the only restraint on competition flowed from the exclusivity of the patent license; by granting BMS the exclusive right to combine COBI with ATV, Gilead surrendered the right to do that itself. (The Complaint misleadingly portrays this restraint as Gilead "return[ing] the favor" for BMS agreeing not to compete with Atripla (Compl. ¶ 5), without acknowledging that there was no initial "favor" by BMS.) Similarly, in the case of Gilead's collaborations with Janssen, the only restraints on competition were prohibitions on either partner selling substantially identical FDCs in competition with the collaborations' FDCs. With respect to all of these collaborations, the restraints were reasonably ancillary, as they prevented either partner from undermining the venture by pursuing individual sales of the identical (or nearly identical) FDC. *Polk Bros.*, 776 F.2d at 189 ("A restraint is ancillary when it may contribute to the success of a cooperative venture that promises greater productivity and output."). These collaborations left the partners free to compete beyond the narrow restraints, and the partners did so vigorously in multiple ways, generating multiple new therapies.

Gilead's collaboration with Japan Tobacco also took the form of an exclusive license; Japan Tobacco granted Gilead the right to make and sell Japan Tobacco's proprietary EVG compound in territories outside of Japan. This arrangement was plainly procompetitive because it facilitated EVG's availability in the United States as a single-agent product or an FDC component. The only "restraint" associated with the arrangement was that the license was exclusive, even as to Japan Tobacco in the United States. Compl. ¶ 103. Yet an exclusive license does not constitute an illegal restraint, but a transfer of an exclusive right. *See, e.g.*, *United States v. Westinghouse Electric Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) ("The right to license that patent, exclusively or otherwise, or to refuse to license at all, is 'the untrammeled right' of the patentee." (quoting *Cataphote Corp. v. Desoto*

Chem. Coatings, 450 F.2d 769 (9th Cir. 1971))); *Brownell v. Ketcham Wire & Mfg. Co.*, 211 F.2d 121, 128-29 (9th Cir. 1954) (holding that exclusive license of patent for U.S. territory is lawful under antitrust laws). Exclusive licenses are expressly authorized by the federal Patent Act. 35 U.S.C. § 261.

Furthermore, here the license was transferring exclusive rights in EVG from a company that could not exploit the compound in the United States to another that could. And that exclusivity incentivized Gilead to develop, commercialize, and promote EVG. *See, e.g.*, *Ralph C. Wilson Indus., Inc. v. Am. Broad. Cos.*, 598 F. Supp. 694, 706 (N.D. Cal. 1984) (observing that "exclusivity gives the licensee the incentive to promote and develop the licensed [asset]"). New products resulted. At the same time, Japan Tobacco was left free to compete in the United States (if it ever could), as long as it did not use EVG. This arrangement was decidedly procompetitive, and the "restraint" on Japan Tobacco was reasonably ancillary to the arrangement's procompetitive purposes. *See Princo*, 616 F.2d at 1336 (summarizing authorities on ancillary restraints).

In sum, the joint ventures, collaborations, and licensing agreements attacked in the Complaint are procompetitive and lawful based on the Complaint's own factual allegations. The challenged restraints all fit comfortably within the ancillary restraints doctrine and are "thus valid." *Dagher*, 547 U.S. at 7.

B. Gilead's Development and Introduction of TAF Cannot Be a Basis for Antitrust Liability

The Complaint also incorrectly contends that Gilead violated the law in how it developed TAF. Compl. ¶¶ 202-312. That alleged unlawful conduct includes delaying the development and commercialization of TAF; introducing it only in FDCs for HIV; and refraining from introducing TAF as a single-agent product for HIV. *Id.* None of this alleged conduct states a plausible claim, and this Court has held as much in *AIDS Healthcare Foundation, Inc. v. Gilead Sciences, Inc.*, No. 3:16-cv-00443, 2016 U.S. Dist. LEXIS 87578, at *23-24 (N.D. Cal. July 6, 2016) ("*AHF*"), *aff'd*, 890 F.3d 986 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 415 (2018).

In *AHF*, this Court dismissed virtually identical claims, concluding that antitrust liability cannot be based on how a company chooses to develop and commercialize a new and improved

product:

> "As a general rule, any firm, even a monopolist . . . may bring its products to market whenever and however it chooses." *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983). There is no legal basis for concluding that Gilead had any duty to release TAF as a standalone product. *See Allied Orthopedic* [*Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1002 (9th Cir. 2010)] ("[A] monopolist has no duty to help its competitors survive or expand when introducing an improved product design.").

2016 U.S. Dist. LEXIS 87578, at *23-24. This Court's decision in *AHF*, as reflected in its reliance on *Foremost Pro Color Inc.* and *Allied Orthopedic*, is consistent with longstanding law in the Ninth Circuit, where "[a] line of 'product innovation' cases has consistently rejected antitrust liability for a monopolist's decision about when or whether to market new products." *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 369 (9th Cir. 1988).

The *AHF* case cannot be distinguished, because it relied on essentially the same allegations as the Complaint here. *See* First Am. Compl., *AIDS Healthcare Found., Inc. v. Gilead Scis., Inc.*, 16-cv-0443 (N.D. Cal. Apr. 11, 2016), ECF 50, Burke Decl. Ex. N ("*AHF* Compl."). The *AHF* complaint alleged that the patent for TAF was "obvious at the time" (*AHF* Compl. ¶¶ 9, 99-100), and, because of that "weakness," Gilead engaged in anticompetitive practices to keep competitors off the market (*AHF* Compl. ¶¶ 11, 105). The *AHF* complaint was replete with allegations that Gilead "refuses to release a standalone version of TAF" (*AHF* Compl. ¶¶ 12, 31, 105, 108, 115), and that instead Gilead left TDF, which has greater "bone and kidney toxicity," on the market as a standalone (*AHF* Compl. ¶¶ 8, 11). The *AHF* complaint also contended that Gilead was "tying" and "bundling" TAF in FDCs to create a "patent thicket" to protect patent exclusivity (*AHF* Compl. ¶¶ 5, 14-18, 73, 105, 117, 142, 156-160). The *AHF* complaint also alleged that Gilead's collaborations with Japan Tobacco and Janssen were part of a conspiratorial strategy to insulate TAF from patent challenge. *AHF* Compl. ¶¶ 12-16.

The *AHF* plaintiffs similarly alleged that Gilead engaged in monopolization, including by electing "to release TAF as part of a combination drug [FDC] before seeking approval for TAF as a standalone." 2016 U.S. Dist. LEXIS 87578, at *23. Using characterizations recycled in the Complaint here, they contended that "defendants conspired to game the FDA system to insulate TAF

from patent challenges by combining it with additional patented ingredients." *Id*. at *26. They also alleged that Gilead "shelved its clinical trials" for TAF, in order to obtain a later "grant of [regulatory] exclusivity" to protect TAF against patent challenges. *Id*. at *27. And similar to the "degrading" allegations here, they also asserted that Gilead "left consumers to bear the higher bone and kidney toxicity of TDF longer than necessary." *Id*.; Compl. ¶¶ 242-247.

In *AHF*, this Court dismissed the antitrust claims challenging Gilead's product development decisions and FDA approval strategy: "True, Gilead elected not to seek approval for [standalone] TAF until several months after it released the first combination drug containing TAF, but it had no duty to pursue FDA approval of the standalone version." 2016 U.S. Dist. LEXIS 87578, at *21. The Court added: "To hold otherwise would require manufacturers to seek approval of each component of the drug before seeking approval of the combination drug. This could entirely undermine the FDA's policy of encouraging the development of combination drugs." *Id*. In this way, the court thus rejected the notion that courts should be de facto regulators in determining which potential products manufacturers should be compelled to produce, regardless of whether the development of those products was economically feasible or could expect success in the market. *See Trinko*, 540 U.S. at 407-08 ("Enforced sharing also requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are illsuited.").

Here, the Complaint alleges the benefits of TAF over TDF with respect to potential kidney toxicity and bone-density loss. *See, e.g.*, Compl. ¶¶ 205-206, 221. In light of these alleged benefits, there can be no dispute that Ninth Circuit precedent forecloses the Complaint's challenges to the timing and manner of Gilead's development of TAF: "A monopolist, no less than any other competitor, is permitted and indeed encouraged to compete aggressively on the merits, and any success it may achieve solely through 'the process of invention and innovation' is necessarily tolerated by the antitrust laws." *Foremost Pro Color, Inc.*, 703 F.2d at 544-45 (quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 281 (2d Cir. 1979)).

C. Gilead's Patent-Infringement Settlements, Including the Acceleration Clauses, Were Lawful

As its final contention of anticompetitive conduct by Gilead, the Complaint challenges

"acceleration clauses" found in settlement agreements under which Gilead and generic pharmaceutical companies resolved patent litigation. Compl. ¶¶ 313-360. These clauses permit a settling generic to enter even earlier than the date set by its settlement agreement if a later-settling generic enters earlier. Because these clauses merely set a date for generic entry before patent expiration, they are lawful under the Supreme Court's controlling decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). The only court to squarely address "acceleration clauses" held that they were permissible under *Actavis*, that they were procompetitive, and that a challenge to them fails to state a plausible claim. *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 U.S. Dist. LEXIS 127748, at *46-51 (S.D.N.Y. Sept. 22, 2015) (applying *Actavis*, 570 U.S. 136), *rev'd as to other claims*, 848 F.3d 89 (2d Cir. 2017)). That holding should be followed here.

1. The Complaint Fails to Plausibly Allege that Acceleration Clauses Are Anticompetitive

To settle Hatch-Waxman Act litigation, a patent holder may grant the generic challenger a license to enter on an agreed-upon date before expiration of the challenged patent. *See, e.g.*, *Actavis*, 570 U.S. at 158. However, when there are multiple generic challengers (as there were here, Compl. ¶ 313), a "first-filer" generic challenger that settles by agreeing on a specified entry date faces the risk that a later generic challenger (i.e., a "second filer") will, as the Complaint puts it, "use the leverage of [that later challenger's] patent challenge to negotiate a better licensed-entry date from [the patent holder]," thus leaving the first-filer "stuck on the sidelines while second-filers enter[] the market." Compl. ¶ 336. This result would eliminate most if not all of the benefits of settlement for first filers: after investing time and money to initiate a lawsuit under the Hatch-Waxman Act, they would be shut out of the very competition their patent challenge created. *Id.* ¶ 339 (explaining the important competitive advantages of entering the market first); *see also id.* ¶ 321 (later generic could potentially "enjoy a substantial period of de facto exclusivity in the generic sector of the market" at the expense of the first-settling generic).

To avoid this result, an "acceleration clause" accelerates the entry date for a settling generic if the patent is invalidated or another generic enters sooner. *See Actos*, 2015 U.S. Dist. LEXIS 127748, at *47. Because acceleration clauses facilitate settlement, while also potentially allowing

earlier entry, they have been recognized as "indisputably procompetitive." *See id.* ("the triggering of the acceleration clause in any of the Generic Defendants' settlement agreements with [the patent holder] would result in four or more generics entering the market, instead of three—an indisputably procompetitive effect"); *see also Actavis*, 570 U.S. at 154 (noting the "general legal policy favoring the settlement of disputes"); *id*. (finding that "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit"); *id*. at 158 (permitting settlements to be challenged only because the challenges do "not prevent litigating parties from settling their lawsuit"). And, as the Complaint alleges, such competition tends to rapidly benefit consumers. *See, e.g.*, Compl. ¶ 91 ("Once a generic equivalent enters the marketplace, the generic quickly captures sales of the branded drug, often garnering 80% or more of unit sales within the first six months. The [FTC] found that on average, within a year of generic entry, generics had captured 90% of brand unit sales and (with multiple generics in the marketplace) prices had dropped 85%.").

The Complaint characterizes "acceleration" clauses as a type of most-favored nation ("MFN") provision (Compl. ¶ 316), but MFN provisions in settlement agreements are common and widely accepted as lawful. *See, e.g.*, *JP Morgan Chase Bank, N.A. v. DataTreasury Corp*, 823 F.3d 1006, 1011-20 (5th Cir. 2016) (considering MFN in patent settlement; no suggestion that such provisions were anticompetitive). Antitrust plaintiffs (including some of these Plaintiffs' counsel) have long used MFNs in settlements to ensure that early-settling plaintiffs are not disadvantaged by better outcomes for later-settling plaintiffs. *See, e.g.*, *In re Mushroom Direct Purchaser Antitrust Litig.*, 2018 U.S. Dist. LEXIS 211488 at *24-25, *27, *36 (E.D. Pa. Dec. 17, 2018) (approving settlement including an MFN to protect later settlers, even over objections of non-settling defendants); *In re Vitamins Antitrust Litig.*, 398 F. Supp. 2d 209, 216 (D.D.C. 2005) (noting that approved settlement included MFN to protect early-settling class plaintiffs against better outcomes for opt-outs that might settle later). Parties in other contexts likewise insist on MFNs in settlements to protect early settlers. *See, e.g.*, *Newby v. Enron Corp.*, 2008 U.S. Dist. LEXIS 48516, at *36-37, *61-62 (S.D. Tex. June 24, 2008) (approving MFN in settlement agreement); *see also DeLoach v. Philip Morris Cos.*, 321 F. Supp. 2d 707, 716 (M.D.N.C. 2004) ("MFN clauses [in settlements] are generally enforceable"), *aff'd*

in part and rev'd in part sub nom. DeLoach v. Lorillard Tobacco Co., 391 F.3d 551, 563 (4th Cir. 2004); *In re Bernard L. Madoff Inv. Sec. LLC*, 2014 Bankr. LEXIS 4348, at *10-13, *28-29 (S.D.N.Y. Bankr. Oct. 10, 2014) (interpreting and applying MFN provision in settlement agreement). Indeed, such MFNs are so commonplace in settlement that they are discussed in the Manual for Complex Litigation: "Settlement agreements proposed early in the litigation often contain a 'most-favored nation' clause to encourage early settlement by protecting all parties against being prejudiced by later, more favorable settlements with others." Manual for Complex Litigation (Fourth) § 13.23 (2004).

Against this backdrop, the Complaint cannot survive a motion to dismiss merely by declaring that the settlement agreements at issue here contain MFNs. Rather, the Complaint must (at minimum) include factual allegations plausibly suggesting that the acceleration clauses here delayed competition and are unlawful. It does not. Instead, the Complaint theorizes that if a first-filing generic were to make the economically irrational decision to settle for an entry date without including an acceleration clause, subsequent patent challengers might then have a greater incentive to challenge the patent. Thus, the Complaint asserts, it must be anticompetitive not to encourage this further theoretical competition. Compl. ¶¶ 318-325. But, as *Actos* explained, "the mere possibility that the absence of an acceleration clause may result in more diverse generic competition" does not constitute a claim because the antitrust laws require "only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *Actos*, 2015 U.S. Dist. LEXIS 127748, at *50 (citing *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 409 (3d Cir. 2015) ("*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible.")).

Moreover, while subsequent generic challengers may have a theoretically greater "incentive" to challenge the patent if by doing so they could "leverage" their further patent challenge to obtain a period of exclusivity while the first-settling patent challenger was left on the "sidelines," this scenario assumes that there would be a first settler at all—a dubious assumption because no rational litigant would risk a subsequent challenger excluding them from the very competition their patent challenge brought about. *See* Compl. ¶ 321 (first filer expected to lose out on a "substantial period" during which another settling party obtained earlier entry), ¶ 336 (first filer would be "stuck on the sidelines"

without an acceleration clause). The Complaint's allegation thus requires generic pharmaceutical companies to be economically irrational by challenging patents, then subsequently entering settlements, and allowing later challengers to usurp the benefits of that challenge. *See* Compl. ¶ 321 (alleging that this *should* happen). This allegation fails the basic plausibility test of *Twombly*. 550 U.S. at 570.

Nor does the Complaint make any headway (¶¶ 320, 340-344) by asserting that some of the acceleration clauses here were "MFN-plus" agreements—i.e., they permitted the first patent challenger (Teva) to enter earlier than other generics to maintain a portion of the 180-day period of "first filer exclusivity" typically granted under the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(B)(iv); *In re Cipro Cases I & II*, 348 P.3d 845, 852 (Cal. 2015) ("To provide an incentive to assume the risks of exposure to such litigation, the first generic manufacturer to file an application and prevail is granted a potentially lucrative 180-day exclusivity window in which to market its drug without competition from any other generic manufacturer."). A first filer can spend years (five years in this case, Compl. ¶¶ 313, 348) and millions of dollars (*Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting)) litigating to try to invalidate a patent. And as the Complaint explains, without any exclusivity period much of the benefit of such effort can end up flowing to other patent challengers. *See* Compl. ¶¶ 336-339 (explaining how merely entering at the same time as other generic challengers would deprive Teva of the benefit of its patent challenge). The Complaint offers no plausible explanation for why it is anticompetitive for a first-filer patent challenger to demand—and receive—in settlement a period of exclusivity like the one accorded under the Hatch-Waxman Act.

2. The Acceleration Clauses Are Not "Reverse Payments"

To the extent that the Complaint suggests that the acceleration clauses constitute "reverse payments"—i.e., compensation to a patent challenger to drop its challenge—the suggestion is foreclosed by Actavis. Actavis made clear that setting an entry date on which a challenger would be permitted to enter—particularly an entry date prior to the expiration of the challenged patents—was not a "payment" but rather an opportunity for competition that benefits consumers. *Actavis*, 570 U.S. at 158 ("settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit"). An acceleration clause

does nothing more—it simply sets an entry date for the patent challenger, with the possibility that the patent challenger might be permitted to enter even earlier under certain circumstances.

Indeed, the settlement in *Actavis* itself contained an acceleration clause and neither the Supreme Court nor the FTC ever suggested that this clause should be viewed as a reverse payment. *See, e.g.*, Br. for Pet'r, *Actavis*, 2013 U.S. S. Ct. Briefs LEXIS 440, at *35 (U.S. Jan. 22, 2013) (FTC noting the existence of an acceleration clause in the challenged patent settlement, but treating it as a normal and routine part of settlement rather than any potential "reverse payment" or other antitrust problem); *see also Asahi Glass Co. v. Pentech* Pharm., *Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.) (holding "payment" in the form of competition not cognizable as a "reverse payment" under the antitrust laws). Not surprisingly, the court in *Actos*, applying *Actavis*, dismissed a claim that an acceleration clause constituted a "reverse payment." *Actos*, 2015 U.S. Dist. LEXIS 127748, at *46-51.

Even the FTC—which aggressively enforces reverse-payment claims in other contexts—has repeatedly declined to treat acceleration clauses as reverse payments. In *In the Matter of Impax Laboratories, Inc.*, 2019 FTC LEXIS 25, at *65 (F.T.C. Mar. 28, 2019), the FTC noted that "Hatch-Waxman Act patent litigation cannot be settled procompetitively without both an entry date and a license for the generic, so a payment consisting only of a license to operate in the relevant market—alone or with other clearly procompetitive terms—will not ordinarily trigger antitrust scrutiny, and so should not be considered part of a 'large and unjustified' payment." As an example of such "clearly procompetitive terms," the FTC then cited approvingly to *Actos* and its holding that a "reverse payment did not include (i) acceleration clauses that allowed the generic to enter the market upon the entry of any other generic, and (ii) a license to enter as an authorized generic on a date certain." *Id.* (citing *Actos*, 2015 U.S. Dist. LEXIS 127748, at *15-19).

3. The Complaint Fails to Offer Any Non-Conclusory Allegations of Patent Weakness to Support a Claim of Antitrust Injury

Finally, the Complaint's attack on the Gilead-Teva settlements depends on the proposition that without an acceleration clause, either Teva or some other generic challenger would have obtained an earlier entry date by successfully challenging the patent. *See, e.g.*, Compl. ¶¶ 351, 360. However,

the Complaint offers no factual allegations to suggest that any such challenge would actually succeed. Although the Complaint asserts that Gilead's patents were "weak" (Compl. ¶ 96), it contains no factual allegations to support that conclusion—which is refuted by the fact that although Teva spent years trying to find some way to invalidate Gilead's patents, it ultimately was forced to accept an entry date settlement only shortly before patent expiration. *See id.* ¶¶ 351, 360; Settlement and License Agreement (Apr. 22, 2013), *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 10-cv-01796 (S.D.N.Y.); Settlement and License Agreement (Apr. 25, 2014), *Gilead Scis., Inc. v. Teva Pharm. USA, Inc.*, 08-cv-10838 (S.D.N.Y.). Moreover, while other patent challengers continued litigating the challenged patents, none of these subsequent challengers was able to obtain any better result. *See id.* ¶¶ 343, 348-349, 359.

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Thus, notwithstanding the Complaint's challenges to Gilead's collaborations, development of TAF, and "acceleration clauses," the Complaint's factual allegations fail to make out a plausible case that Gilead engaged in anticompetitive conduct. This failure dooms every count of the Complaint, as anticompetitive conduct is a necessary element in any antitrust claim under Section 1 or Section 2 of the Sherman Act. *See Am. Needle*, 560 U.S. at 190 (holding that Section 1 claim must be predicated on "anticompetitive conduct"); *Trinko*, 540 U.S. at 407 (holding that Section 2 claim requires a showing of "anticompetitive conduct").

II. THE COMPLAINT FAILS TO ALLEGE A PLAUSIBLE RELEVANT MARKET

Even if the Complaint had alleged any cognizable anticompetitive conduct by Gilead, the Complaint would still have to be dismissed for its failure to plausibly allege a relevant market. *See Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1062-63 (9th Cir. 2001) (holding that any antitrust claim based on the rule of reason or monopolization must properly allege a relevant market within which to assess competitive effects); *Siegler v. Sorrento Therapeutics, Inc.*, No. 3:18-cv-01681-GPC-NLS, 2019 U.S. Dist. LEXIS 129755, at *36-38 (S.D. Cal. Aug. 2, 2019) (same). To state a claim, "Plaintiffs must identify the relevant geographic and product markets . . . and allege facts demonstrating that Defendants' conduct has an anticompetitive effect on those markets." *Big Bear Lodging Ass'n v. Snow Summit, Inc.*, 182 F.3d 1096, 1104-05 (9th Cir. 1999). "If a plaintiff alleges

a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss may be granted." *Hicks v. PGA Tour, Inc.*, 165 F. Supp. 3d 898, 908 (N.D. Cal 2016), *aff'd in part and remanded on other grounds*, 897 F.3d 1109, 1124 (9th Cir. 2018). To survive a motion to dismiss, a proposed product market must reflect the real world, and cannot be "artificial, contorted to meet [the plaintiff's] litigation needs." *Hicks*, 165 F. Supp. 3d at 910.

The Complaint here alleges contradictory markets "contorted to meet [Plaintiffs'] litigation needs." *Id.* On one hand, the Complaint alleges that every branded pharmaceutical product (with its AB-rated generic, if any) creates its own unique product market with no economic or therapeutic substitutes—but on the other hand, the Complaint also alleges that all cART therapies together are a market, with each cART therapy thus substitutable for every other cART therapy. Compl. ¶ 376. Remarkably, the Complaint then further alleges "markets comprising [each] branded drug and comparable versions of it," defined to include not only a branded product and its AB-rated generic but also other "comparable versions" that either exist in the real world or hypothetically could exist (with for example, 3TC substituted for FTC). *Id.* ¶ 379. In short, the Complaint alleges a relevant market that includes either one pharmaceutical product, multiple pharmaceutical products, or all cART pharmaceutical products, depending on the needs of the Complaint. Such vacillating product markets are legally deficient. *See Siegler v. Sorrento Therapeutics, Inc.*, 2019 U.S. Dist. LEXIS 129755, at *38-39 (dismissing antitrust claims where plaintiff alleged contradictory product markets).

The Complaint's contradictory product markets result from an inherent contradiction in the Complaint's theories. On one hand, the Complaint depends on the idea that components of FDCs can easily be swapped out, and that neither the FDA nor doctors would see any problem with, for example, replacing FTC in a product with 3TC or replacing COBI with RTV. *See, e.g.*, Compl. ¶ 97 (alleging that "a very closely related drug, lamuvidine (3TC), may be substituted for FTC, and vice-versa"), ¶ 200 (alleging that COBI is "merely a booster, and has a close substitute in RTV"). On the other hand, the Complaint needs each FDC to be its own relevant product market—or else it would have to admit that the robust interbrand competition among FDCs makes its antitrust allegations implausible. *See*

Compl. ¶ 378 (alleging that each FDC, and for that matter each single-agent product, is its own relevant market). Such contradictory pleading is not plausible; the pharmaceutical products at issue either are substitutable for one another, or they are not, and they cannot plausibly be both. *See* Hicks, 165 F. Supp. 3d at 908-10.

Beyond alleging contradictory product markets, the Complaint is far too conclusory and vague in alleging its product markets. The Complaint's allegations consist largely of bare assertions of "market power," such as the assertion that, in general, "brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including all of those at issue in this complaint." Compl. ¶ 369; *see also id.* ¶¶ 372-374 (alleging high profit margins). Other allegations simply paraphrase economic or legal tests relevant to defining markets, without meaningful factual content. *See, e.g.*, Compl. ¶¶ 361-363; *see Hicks*, 897 F.3d at 1122 (holding allegations insufficient where they "restate a test for market definition without any factual elaboration"). Other conclusory allegations simply disclaim that products other than AB-rated generics can constrain the pricing of a branded product. Compl. ¶¶ 370-373. The Complaint provides its most detail in addressing "treatment naïve" patients (*id.* ¶¶ 393-394), but the Complaint elsewhere acknowledges that this segment of patients is a small fraction of the overall patient population. *Id.* ¶ 50 (alleging estimated 1.1 million people in the U.S. with HIV in 2017, with only 40,000 newly diagnosed). And the Complaint is devoid of any allegations suggesting that these patients form a distinct submarket. *See Hicks*, 897 F.3d at 1121-23 (finding failure to plead any plausible market or submarket). In short, the Complaint's allegations on market definition are deficient.

In the *AHF* litigation challenging Gilead's introduction of TAF (as well as, in certain respects, Gilead's collaboration agreements with Japan Tobacco and Janssen), this Court concluded that the complaint failed to define a relevant product market. 2016 U.S. Dist. LEXIS 87578, at *23 ("Nowhere in the Complaint does AIDS Healthcare allege facts supporting a market definition limited to TAF-containing drugs. This failure to plead a market definition is fatal."). In *AHF*, the complaint contained similar allegations as the Complaint here, alleging a highly constrained relevant market based in part on the allegation that Gilead enjoyed high profit margins. *See AHF* Compl. ¶¶ 119-127. And even though in *AHF* there were not the contradictory market definitions the Complaint advances

here, still this Court found the market definition in *AHF* insufficient. 2016 U.S. Dist. LEXIS 87578, at *23. Accordingly, the Complaint's monopolization and rule of reason claims, all of which depend upon a properly defined market, must be dismissed on this independent basis.

III. THE COMPLAINT'S STATE-LAW CLAIMS FAIL FOR ADDITIONAL REASONS

The Complaint's state-law claims are the only claims under which damages may be sought. *Ill. Brick Co. v. Illinois*, 431 U.S. 720, 726, 736 (1977) (establishing the doctrine barring damages claims by indirect purchasers under federal antitrust statutes). While all the state-law claims fail to state a claim for the same reasons as the federal antitrust claims (*supra* at 18), many of the Complaint's state-law claims are deficient as a matter of law for independent reasons as well.

A. California Law May Not Be Applied to Nationwide Purchases

While the Complaint asserts claims under California law with respect to purchases made throughout the United States (Compl. ¶¶ 456(c), 457(b), 497(c), 508(c), 523(c), 538(f)), this Court has repeatedly rejected such an extraterritorial extension of California law, including because it would violate Due Process. *See In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d 1051, 1074 (N.D. Cal. 2015) (dismissing pursuant to Rule 12(b)(6) where Defendants challenged on Due Process grounds because "plaintiffs have not shown that California has a greater interest in applying its law than any other state," many of which are non-repealer states with conflicting laws (citing *Phillips Petrol. Co. v. Shutts*, 472 U.S. 797, 821-22 (1985))); *GPU*, 527 F. Supp. 2d at 1027 (same).

B. The Complaint Fails to Allege Plaintiffs Have Standing in Several States

1. Plaintiffs Lack Standing to Assert Claims Under the Laws of 25 Jurisdictions in Which They Fail to Allege Injury

Plaintiffs may bring state-law claims only under the laws of the state in which they made their purchases. *In re Capacitors Antitrust Litig.*, 154 F. Supp. 3d 918, 927 (N.D. Cal. 2015); *see also In re Carrier IQ, Inc., Consumer Privacy Litig.*, 78 F. Supp. 3d 1051, 1074-75 (N.D. Cal. 2015) (Chen, J.) (dismissing state-law consumer protection claims for lack of standing); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 251 (D. Conn. 2015) (dismissing state-law claims as to states where no purchase alleged). The Complaint alleges purchases by Plaintiffs (and therefore potential injury) in only 11 out of 36 states as to which it raises state-law claims: California, Connecticut, Florida,

Illinois, Maryland, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin. *See* Compl. ¶¶ 18-36. No purchase by any Plaintiff is alleged in the other 25 states as to which Plaintiffs raise state-law claims: Alabama, Arizona, Arkansas, the District of Columbia, Hawaii, Iowa, Idaho, Kansas, Maine, Massachusetts, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Utah, Vermont, or West Virginia. *See, e.g.*, Compl. Count Two ("Conspiracy"), ¶¶ 448-457; Count Seven ("Violation of State Consumer Protection Laws"), ¶¶ 493-498. Thus, as in *Carrier IQ*, here the number of consumers from the "other states in which state law claims are asserted is vast relative to the claims to which the named Plaintiffs have standing." 78 F. Supp. 3d at 1074. Just as in *Carrier IQ*, where this Court dismissed state consumer-protection claims from states where no injury was alleged (*id.* at 1075), other courts have dismissed state-law antitrust claims for standing/lack of injury where no purchase/injury had been alleged by a named plaintiff. *In re Capacitors*, 154 F. Supp. 3d at 928 (dismissing for lack of standing state law antitrust claims where none of named plaintiffs purchased product in that state); *In re Ditropan XL Antitrust Litig*, 529 F. Supp. 2d 1098, 1106-07 (N.D. Cal. 2007) (same); *In re Packaged Seafood Prods. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1095-96 (S.D. Cal. 2017) (same, citing *Capacitors*); *Aggrenox*, 94 F. Supp. 3d at 251 (same). The state-law claims for the 25 states where no purchases are alleged by any Plaintiff similarly should be dismissed here.

2. Plaintiffs Lack Standing as Indirect Purchasers to Assert Claims Under the Laws of Six States

Just as *Illinois Brick* bars indirect purchasers such as Plaintiffs from seeking damages under federal antitrust law, many states bar indirect purchasers from seeking damages under their state laws. The Complaint asserts claims under the laws of six such states that expressly bar indirect purchasers from asserting antitrust damages claims, such that those claims must be dismissed:

The Illinois Antitrust Act prohibits indirect purchasers from bringing antitrust-related class actions; only the state's Attorney General may do so. 740 Ill. Comp. Stat. § 10/7(2) ("[N]o person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General, who may maintain an action parens patriae . . . ."); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma*

USA, Inc., 74 F. Supp. 3d 1052, 1083-84 (N.D. Cal. 2014). Additionally, because the Complaint does not plead a claim under the Illinois antitrust statute, the Complaint's Illinois consumer-protection act claim should also fail. *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 395-96 (D.N.J. 2018).

Illinois Brick also applies to the Puerto Rican Anti-Monopoly Act because the legislature has not passed an *Illinois Brick*-repealer statute. *See, e.g.*, P.R. Laws tit. 10, §§ 251-276; *In re Opana Er Antitrust Litig.*, 162 F. Supp. 3d 704, 723 (N.D. Ill. 2016) (absent a Puerto Rico court decision or express *Illinois Brick*-repealer statute, indirect purchaser antitrust claims barred under Puerto Rican law); *see also In re Static Random Access Memory (SRAM) Antitrust Litig.*, 2010 U.S. Dist. LEXIS 131002, at *39-40 (N.D. Cal. Dec. 8, 2010).

The Rhode Island Antitrust Act bars antitrust suits by indirect purchasers for conduct occurring prior to the state's enactment of an *Illinois Brick*-repealer statute on July 15, 2013. 6 R.I. Gen. Laws § 6-36-7(d); *see United Food*, 74 F. Supp. 3d at 1087-88. That statute provided that it "shall take effect upon passage." 2013 R.I. Pub. Laws, ch. 365, § 2; *United Food*, 74 F. Supp. 3d at 1087-88 ("The conclusion that the statute does not apply retroactively is supported by the language of the law itself; that it shall take effect upon passage."). Thus, any Rhode Island Antitrust Act claim for damages based on conduct prior to July 15, 2013 must be dismissed.

The Utah Antitrust Act permits damages claims by indirect purchasers only if they are citizens or residents of the state. *See* Utah Code § 76-10-3109(1)(a); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 759-60 (E.D. Pa. 2014). No Plaintiffs are alleged to meet this description.

The Maryland Antitrust Act bars indirect purchasers from seeking damages. *See Davidson v. Microsoft Corp.*, 792 A.2d 336, 340-41 (Md. Ct. Spec. App. 2002).

The Massachusetts Consumer Protection Act does not permit indirect-purchaser claims unless they are brought by consumers. *See, e.g.*, *Ciardi v. F. Hoffman La Roche, Ltd.*, 762 N.E.2d 303, 309-12 (Mass. 2002); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, 2014 U.S. Dist. LEXIS 35387, at *64-66 (N.D. Cal. Mar. 13, 2014). Because five of the Plaintiffs here are union insurers, not consumers, their Massachusetts Consumer Protection Act claims must be dismissed.

C. The Complaint Fails to Allege Concerted Action in Three States Where Mere Unilateral Conduct Is Not Actionable

Counts Four and Six of the Complaint assert only unilateral conduct by Gilead. Compl. Counts Four, Six ("Against Gilead"), ¶¶ 467-475, 484-492. The antitrust laws of Kansas, New York, and Tennessee apply only to agreements between two or more parties; not to unilateral conduct. *See* Kan. Stat. § 50-101 (prohibiting trusts, which are defined as requiring "two or more persons"); N.Y. Gen. Bus. Law § 340(1) (declaring illegal only a "contract, agreement, arrangement or combination" in restraint of trade, which does not apply to unilateral conduct); Tenn. Code §§ 47-25-101 to -112 (barring only "arrangements, contracts, agreements, trusts, or combinations" in restraint of trade); *In re EpiPen Antitrust Litig.*, 336 F. Supp. 3d 1256, 1314 (D. Kan. 2018). Counts Four and Six under these three states' antitrust laws should be dismissed.

D. The Complaint Cannot Circumvent *Illinois Brick* by Asserting Antitrust Claims under Consumer-Protection Theories

The Complaint attempts to circumvent *Illinois Brick* by recasting antitrust claims as consumer-protection claims. Courts routinely reject such end-runs. *See, e.g.*, *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 231-32 (S.D.N.Y. 2012). Thus, the Complaint's consumer-protection claims under the laws of Arkansas, Connecticut, Illinois, Idaho, Missouri, Montana, Puerto Rico, Rhode Island, and Utah must fail.

E. The Complaint Fails to Adequately Plead Consumer-Protection Claims Under the Laws of 26 States

The consumer-protection claims under the laws of 26 states in Count Seven of the Complaint are entirely undifferentiated—providing no information on how the claims at issue satisfy the particular requirements of each state's individual consumer-protection statutes—and thus fail to meet Plaintiffs' pleading burden. *See Aggrenox*, 94 F. Supp. 3d at 255-56 (dismissing similarly-undifferentiated claims on this basis); *Actos*, 2015 U.S. Dist. LEXIS 127748, at *85-87 (same).

The consumer-protection claims must also be dismissed for these additional reasons:

First, to recover under the laws of 15 states at issue, a plaintiff must show that the conduct was *deceptive* or (in some states) at the very least that the conduct was directed toward and relied upon by consumers. Here, the Complaint alleges no such conduct. Dismissal is thus required under the consumer-protection laws of Arizona (Ariz. Rev. Stat. § 44-1522; California (Cal. Bus. & Prof.

Code § 17204; *Durell v. Sharp Healthcare*, 108 Cal. Rptr. 3d 682, 692-94 (Cal. Ct. App. 2010); *Medina v. Safe-Guard Prods.*, 78 Cal. Rptr. 3d 672, 679 (Cal. Ct. App. 2008)); District of Columbia (D.C. Code § 28-3904); *Alicke v. MCI Commc'ns Corp.*, 111 F.3d 909, 912 (D.C. Cir. 1997)); Idaho (Idaho Code § 48-603); Illinois (815 Ill. Comp. Stat. § 505/2); *Jensen v. Bayer AG*, 862 N.E.2d 1091, 1098 (Ill. App. Ct. 2007)); Kansas (Kan. Stat. § 50-626); Maine (Me. Rev. Stat. tit. 5, §§ 207, 213(1)); *Effexor*, 357 F. Supp. 3d at 396; Michigan (Mich. Comp. Laws § 445.903); New York (N.Y. Gen. Bus. Law § 349; *Harrison v. E. I. DuPont de Nemours & Co.*, 2016 U.S. Dist. LEXIS 77465, at *23-24 (N.D. Cal. June 13, 2016)); *In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, 172 F. Supp. 3d 724, 752-53 (D.N.J. 2016); *Leider v. Ralfe*, 387 F. Supp. 2d 283, 294-97 (S.D.N.Y. 2005)); Nevada (Nev. Rev. Stat. § 598.0915); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 417 (E.D. Pa. 2010)); *Picus v. Wal-Mart Stores, Inc.*, 256 F.R.D. 651, 657-59 (D. Nev. 2009)); New Mexico (N.M. Stat. § 57-12-2(D); *GPU*, 527 F. Supp. 2d at 1029-30); Rhode Island (6 R.I. Gen. Laws §§ 6-13.1-1(6); *In re Static Random Access Memory (SRAM) Antitrust Litig.* ("*SRAM I*"), 580 F. Supp. 2d 896, 909 (N.D. Cal. 2008) (citing *George v. George F. Berkander, Inc.*, 169 A.2d 370, 371 (R.I. 1961)); *ERI Max Entm't, Inc. v. Streisand*, 690 A.2d 1351, 1353-54 (R.I. 1997); *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1161-62 (N.D. Cal. 2009)); Tennessee (Tenn. Code § 47-18-104) (*In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 203 (D. Me. 2004)); Utah (Utah Code §§ 13-11-4, -5; *In re DRAM Antitrust Litig.*, 516 F. Supp. 2d 1072, 1117 (N.D. Cal. 2007)); and West Virginia (W. Va. Code §§ 46A-6-104, -102(7); *White v. Wyeth*, 705 S.E.2d 828, 837-38 (W. Va. 2010)).

Second, nine states allow a plaintiff to sue only in its capacity as a "consumer": District of Columbia (D.C. Code § 28-3901(a)(2)(B)(i) (only "consumers" can bring suit, defined as "[a] person [who] does or would purchase, lease (as lessee), or receive and normally use for personal, household, or family purposes"); *see also id.* § 28-3905(k)(1) (setting forth different types of consumers who may sue); Hawaii (Haw. Rev. Stat. § 480-2(d) ("unfair or deceptive acts or practices" claims may only be brought by "a consumer, the attorney general or the director of the office of consumer protection")); Kansas (Kan. Stat. §§ 50-623(b), 624(b)); *In re Solodyn Antitrust Litig.*, 2015 U.S. Dist. LEXIS 125999, at *67 (D. Mass. Sept. 16, 2015)); Maine (Me. Rev. Stat. tit. 5 § 213(1); Missouri

(Mo. Rev. Stat. § 407.025(1)); Montana (Mont. Code §§ 30-14-102(1), -133(1); *In re Auto. Parts Antitrust Litig.*, 2013 U.S. Dist. LEXIS 80338, at *105 (E.D. Mich. June 6, 2013)); North Carolina (*Food Lion, Inc. v. Capital Cities/ABC, Inc.*, 194 F.3d 505, 519-20 (4th Cir. 1999)); Rhode Island (6 R.I. Gen. Laws § 6-13.1-5.2(a); *Sheet Metal Workers*, 737 F. Supp. 2d at 445); Utah (Utah Code §§ 13-11-3(2)(a), 19); and Vermont (Vt. Stat. tit. 9, §§ 2461(b), 2451a(a); *In re Asacol Antitrust Litig.*, 2016 U.S. Dist. LEXIS 94605, at *50 (D. Mass. July 20, 2016)). Here, the five union insurers are not "consumers"; they are third-party payors, and their claims for these states must be dismissed. *See, e.g.*, *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1164-65 (N.D. Cal. 2015).

Third, the Complaint seeks class-action treatment under five state consumer-protection laws that prohibit class actions. In each state, the class-action prohibition survives *Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co.*, 559 U.S. 393 (2010). As Justice Stevens explained in his concurrence, when a state rule "is part of a State's framework of substantive rights or remedies," the state rule controls, and the bar on class actions remains effective. *Shady Grove*, 559 U.S. at 419 (Stevens, J., concurring). Justice Stevens's concurrence has been adopted by the majority of lower courts. *See, e.g.*, *Garman v. Campbell Cnty. Sch. Dist. No. 1*, 630 F.3d 977, 983-85 (10th Cir. 2010); *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 673-75 (E.D. Pa. 2010).

The Kansas Consumer Protection Act prohibits class actions as a substantive part of its approach to consumer protection. *See* Kan. Stat. § 50-634(b) ("A consumer who is aggrieved by a violation of this act may recover, *but not in a class action*, damages or a civil penalty . . . ." (emphasis added)); *In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 661 n.4 (E.D. Mich. 2011). Montana's Consumer Protection Act similarly provides that "[a] consumer who suffers any ascertainable loss . . . as a result of the use or employment by another person of a method, act, or practice declared unlawful by 30-14-103 may bring an individual but not a class action." Mont. Code § 30-14-133(1). And the Tennessee Consumer Protection Act is similarly limited to actions brought "individually," precluding class actions. Tenn. Code § 47-18-109(a)(1), (g); *see, e.g.*, *Tait v. BSH Home Appliances Corp.*, 2011 U.S. Dist. LEXIS 54456, at *21-25 (C.D. Cal. May 12, 2011).

The Utah Consumer Sales Practices Act expressly limits the circumstances under which consumers seeking damages may bring class actions. Utah Code § 13-11-19(2). A consumer may

bring a class action for damages caused by an act or practice only if that act or practice violates a rule adopted by the Utah consumer protection authorities (Utah Code § 13-11-19(4)); the Complaint does not allege that Defendants' behavior falls under any such rule.

Finally, while the Illinois Consumer Fraud & Deceptive Business Practices Act does not explicitly bar class actions, the statute may not be used to bring indirect purchaser class action antitrust claims that would have been prohibited under the Illinois Antitrust Act. 740 Ill. Comp. Stat. § 10/7; *Wellbutrin XL*, 756 F. Supp. 2d at 677.

F. The Complaint Does Not Allege Compliance with Seven States' Pre-Filing Requirements

The Complaint's claims under the antitrust laws of Arizona, Hawaii, Nevada, and Utah and consumer-protection laws of Alabama, Massachusetts, and West Virginia fail because the Complaint does not allege compliance with state-law notice requirements. *See* Ariz. Rev. Stat. § 44-1415; Haw. Rev. Stat. § 480-13.3(a)(1); Nev. Rev. Stat. § 598A.210(3); Utah Code § 76-10-3109(9); Ala. Code § 8-19-10(e); W. Va. Code § 46A-6-106(c); Mass. Gen. Laws. ch. 93A, § 9(3). Dismissal is appropriate when a plaintiff fails to comply with this threshold requirement. *See, e.g.*, *Effexor*, 357 F. Supp. 3d at 385-86; *Asacol*, 2016 U.S. Dist. LEXIS 94605, at *45-48.

CONCLUSION

In addition to the points and authorities in this memorandum, Gilead expressly incorporates the points and authorities in the memoranda of its co-Defendants. For all of the foregoing reasons, the Complaint should be dismissed in its entirety and with prejudice.

Dated: September 4, 2019

Respectfully submitted,
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