HOLLAND & KNIGHT LLP
Neal N. Beaton (*pro hac vice*)
Email: neal.beaton@hklaw.com
31 West 52nd Street
New York, NY 10019
Telephone (212) 513-3470
Facsimile (212) 385-9010

Additional Counsel Listed on Signature Page

Attorneys for Defendant
JAPAN TOBACCO INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

PETER STALEY; *et al*.

Plaintiffs,

v.

GILEAD SCIENCES, INC.; *et al*,

Defendants.

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

JAPAN TOBACCO INC.'S NOTICE OF MOTION AND MOTION TO DISMISS CORRECTED CONSOLIDATED CLASS ACTION COMPLAINT UNDER RULE 12(b)(6); MEMORANDUM OF POINTS AND AUTHORITIES

Hearing Date: January 16, 2020
Hearing Time: 1:30 p.m.
Courtroom: 5 – 17th Floor
Judge: Honorable Edward M. Chen

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT, on January 16, 2020 at 1:30 p.m., or as soon thereafter as counsel may be heard, defendant Japan Tobacco Inc. ("JT") will and hereby does move to dismiss the Corrected Consolidated Class Action Complaint ("Complaint") of Plaintiff Peter Staley, *et al.* ("Plaintiffs").

JT brings this motion pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. By this motion, JT asks this Court to dismiss the Complaint, and all purported causes of action therein against JT, for failure to state a claim upon which relief can be granted. Because it is evident that further amendment would be futile, JT seeks dismissal of the Complaint against it with prejudice.

This motion is and will be based on this Notice of Motion and Motion, the following Memorandum of Points and Authorities, the accompanying [Proposed] Order, the Declaration of Heather M. Burke, Dkt, 143-1, filed September 4, 2019 by Gilead, the Complaint and other pleadings on file in this matter, and such other matters and argument as the Court may properly consider.

Dated: September 4, 2019

By: /s/_____
Jerome W. Hoffman
HOLLAND & KNIGHT LLP
Attorneys for Defendant
JAPAN TOBACCO INC.

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

MEMORANDUM OF POINTS AND AUTHORITIES

TABLE OF CONTENTS

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

I. INTRODUCTION

This purported end user class action is based on allegations that Gilead,[1] and the other defendants, conspired to restrain competition with respect to an HIV treatment regimen known as "combination antiretroviral therapy" ("cART"). Compl. ¶¶ 1, 2. Plaintiffs raise five claims against Japan Tobacco Inc. ("JT"). The sole basis for those claims is a March 22, 2005 License Agreement (the "License") between Gilead and JT by which JT granted Gilead an exclusive license (except in Japan) to commercialize the compound elvitegravir ("EVG"), for which JT owns the patent. Compl. ¶ 98; Declaration Heather M. Burke ("Burke Decl."), Dkt. 143-1, filed Sept. 4, 2019 by Gilead, at Ex. D (License).

The Complaint should be dismissed against JT for a number of reasons, but first among them is that under the License, JT had no involvement in the sales or marketing of EVG or any HIV treatment sold by Gilead in the U.S. Plaintiffs do not allege a single fact supporting any claim that JT had any involvement in the alleged anti-competitive or "unfair, unconscionable, deceptive and fraudulent" conduct of Gilead or the other defendants. Second, Plaintiffs allege that Gilead entered into a "No-Generics Restraint" with JT and the other defendants. Compl. ¶ 4, *passim*. But the only agreement to which Plaintiffs refer involving JT is the License which contains no such restriction. The License granted Gilead a routine exclusive license (even as to JT) to commercialize EVG throughout the world, except in Japan. There is no language in the License that prohibits Gilead from combining EVG with any other compound to market a "generic" HIV medication. Calling the License a "No-Generics Restraint" is thus a total mischaracterization. Third, JT and Gilead were never horizontal competitors. Plaintiffs allege no facts to support a contention that JT ever had any marketing presence in the U.S. for pharmaceutical products. For that reason, JT and Gilead were not horizontal competitors and therefore legally incapable of conspiring as the License did not deprive the market of independent competitors. Fourth, Plaintiffs fail to allege a plausible relevant product market for the conspiracy to monopolize claim. Fifth, Plaintiffs fail to allege facts to show that JT had a specific intent to monopolize to support the alleged conspiracy to monopolize. Plaintiffs plead

[1] "Gilead" refers to, as the context may indicate, defendants Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC, collectively.

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

no facts to support the allegations that JT, through the License or otherwise, conspired with Gilead with the intent to stifle generic competition, much less that JT joined an "overarching conspiracy" with Gilead, BMS and Janssen with the specific intent to monopolize any HIV product market.[2] Plaintiffs' allegations that JT was a horizontal competitor of the other Defendants has no factual support. Because JT was not a horizontal competitor of any of Gilead or the other co-defendants, the License must be judged under the "rule of reason" which requires factual allegations of anticompetitive intent—which Plaintiffs fail to make. Any inference of intent to restrain trade or specific intent to monopolize based on Plaintiffs' "untainted competitor" theory is fundamentally implausible and inconsistent with the facts alleged. The "untainted competitor" conspiracy theory presumes that JT had a "crystal ball" in March 2005 and should have foreseen all of the developments in the market for HIV treatments over the next 10-12 years and reserved to itself for later use the right to combine EVG with TDF and other generic compounds to market in the U.S. a generic version of Stribild®. Equally improbable is Plaintiffs' contention that JT, as an "untainted competitor" should have developed a generic version of Stribild® in 2017 using generic TDF and other generic drugs along with EVG. Based on Plaintiffs' allegations, that generic version of Stribild® would have been a riskier, more toxic compound than the TAF-based Genvoya® that Gilead markets. *See* Compl. ¶ 205. That same theory also runs afoul of one of Plaintiffs' other contentions—that dolutegravir, when released in 2012, was superior to EVG as a third agent. Compl. ¶¶ 232-33. If true, that would have made a JT generic version of Stribild® using EVG less attractive to doctors and patients than other products using dolutegravir. Thus, Plaintiffs' own allegations, even if taken as true, undermine the plausibility of their "untainted competitor" theory. These flaws cannot be cured by amendment. Therefore, the Court should dismiss the Complaint as to JT with prejudice.

II. LEGAL STANDARD

A claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. Rule 8(a)(2). The purpose of Rule 8(a)(2) is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atlantic Corp v. Twombly*, 550 U.S. 544, 555 (2007). Failure to comply with "Rule 8(a) is grounds for dismissal."

[2] The terms "BMS" and "Janssen" have the same meanings here as in the Complaint.

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Gottschalk v. City & Cty. of San Francisco, 964 F. Supp. 2d 1147, 1154 (N.D. Cal. 2013) (citing *McHenry v. Renne*, 84 F.3d 1172, 1179 (9th Cir. 1996)). Dismissal under Rule 12(b)(6) is warranted where there is a "lack of a cognizable legal theory" or "absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't,* 901 F.2d 696, 699 (9th Cir. 1990).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). The court, however, need not accept as true the complaint's conclusory allegations, legal characterizations, unreasonable inferences or unwarranted deductions of fact. *Western Mining. Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981); *see also Iqbal*, 566 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). A claim has facial plausibility only when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 566 U.S. at 678. To show that a plaintiff is entitled to relief, the complaint must "permit the court to infer more than the mere possibility of misconduct." *Id.*

The Complaint here falls far short of meeting this pleading standard and should be dismissed with prejudice because the deficiencies in the Complaint are incurable by amendment.

III. ARGUMENT

A. PLAINTIFFS FAIL TO STATE FACTS TO SUPPORT A PLAUSIBLE CONSPIRACY THEORY AGAINST JT.

1. Plaintiffs' Allegations of a Conspiracy with any of the Other Defendants are Unsupported by the Facts.

In Count One, Plaintiffs allege a broad "overarching" conspiracy to monopolize among all of the Defendants under both Section 1 and Section 2 of the Sherman Act. In Count Two, Plaintiffs allege that the same "overarching" conduct as a restraint of trade under the antitrust laws of 31 different states and a conspiracy to monopolize under the laws of 29 states. The elements of a conspiracy to monopolize claim are "(1) the existence of a combination or conspiracy to monopolize; (2) an overt act in furtherance of the conspiracy; (3) the specific intent to monopolize; and (4) causal antitrust injury." *Paladin Assocs., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1158 (9th Cir. 2003) (citing *United States v. Yellow Cab Co.*, 332 U.S. 218, 224-25 (1947)).

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Counts One and Two incorporate allegations spanning at least 436 paragraphs. This "kitchen sink" approach to pleading would presumably allow Plaintiffs to provide ample detail as to the who, when, where and how of the formation of the conspiracy. Remarkably, Plaintiffs provide none of that basic information. Plaintiffs describe a variety of alleged conduct by Gilead, BMS and Janssen, but offer not one fact to explain the "who, when, where and how" JT made any agreement to authorize much less participate in such conduct. Nor are Plaintiffs' horizontal conspiracy allegations plausible. Not only was JT not responsible for any marketing in the U.S., Plaintiffs allege that the drugs Gilead sold were each in a separate market and that there were no reasonable substitutes other than AB generic equivalents of each of the branded drugs. Compl. ¶¶ 361-64, 370-71. Thus, JT was not a horizontal competitor capable of unlawfully conspiring with defendants Janssen and BMS whose products were not sold in the same product market as the EVG containing products Gilead sold using the License. Thus, the *per se* standard simply does not apply to these alleged facts.

Moreover, Plaintiffs' product market allegations are inconsistent with each other. Plaintiff's allegation that a separate "cART Market" existed [*e.g.* Compl. ¶¶ 376, 380] is undermined by the allegations that the products Gilead developed and sold containing EVG did not compete with the products Gilead developed and sold with Janssen and BMS. Compl. ¶¶ 362-80. If it is true that patients and physicians will not substitute one treatment regime for another that is proven to be effective [Compl. ¶¶ 363-64] and that each branded drug along with its AB generic equivalent is its own separate market [Compl. ¶¶ 361-65], then an alternative relevant product market consisting of all cART drugs cannot exist. Thus, Defendants cannot be horizontal competitors.

The cornerstone of Plaintiffs' "over-arching conspiracy" theory is that BMS, Janssen and JT each entered into agreements with Gilead that contained a "No-Generics Restraint" that prevented BMS, Janssen and JT from using their respective patented compounds together with other compounds whose patents had expired to create "generic" versions of the various branded Gilead products. Compl. ¶ 3. But Plaintiffs fail to allege facts to support the requisite "specific intent to monopolize" in Counts One and Two. Plaintiffs allege that, "[e]ach of Janssen, Japan Tobacco and BMS consciously committed to the overarching anticompetitive scheme." Compl. ¶ 442. But nowhere do Plaintiffs provide facts to detail the who, when, where and how as to BMS, Janssen and JT becoming

co-conspirators to each other's agreements with Gilead. Nor do Plaintiffs allege any plausible facts to support an inference of such an agreement or facts showing a specific intent to monopolize. *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1049 (9th Cir. 2008) ("Allegations of facts that could just as easily suggest rational, legal business behavior by the defendants as they could suggest an illegal conspiracy are insufficient to plead a violation of the antitrust laws."). In short, the Plaintiffs' "over-arching conspiracy" allegation fails to meet the *Twombly* standard and is contradicted by the License.

2. Plaintiffs' Allegations of a Conspiracy Between JT and Gilead are Unsupported by the Facts.

Nor are Counts Ten and Eleven, alleging a conspiracy between just JT and Gilead, supported by plausible facts. An alleged Section 1 conspiracy to restrain trade must plead evidentiary facts which would prove a contract or conspiracy among two or more persons or entities, with the intent to harm or restrain trade, and which actually injures competition. *Kendall*, 518 F.3d at 1047. The only actual agreement to which JT is alleged to have been a party is the License. But, tellingly, Plaintiffs did not append the License to the Complaint nor did they quote the precise terms of the License that constitute the "No-Generics Restraint" or even provide a citation to the paragraph number or page of the License where the "No-Generics Restraint" can be found. That is because the License contains no such restriction. Under the License (a redacted version of which is publicly available as part of Gilead's SEC filings) JT simply granted Gilead exclusive rights to EVG everywhere in the world except Japan. Burke Decl., Ex. D at Section 6.1. Gilead thereby acquired all of the rights that JT had as the patent owner. *Id.* Gilead agreed to pay JT an upfront payment, milestones and royalties on sales of HIV products containing EVG. But there is no requirement that such products sold by Gilead be "branded" or that they not be "generic." Under the License, Gilead was solely responsible for commercialization of EVG.[3] Thus, any decision to use EVG only in "branded" as opposed to "generic" products in the U.S. fell to Gilead, and not JT.

[3] Plaintiffs mischaracterize the License as a "joint development agreement." Compl. ¶ 4. Plaintiffs do not define what they mean by "joint development agreement" but under the License, Gilead, not JT, had the exclusive rights to commercialize EVG containing products in the U.S. *See* Burke Decl., Ex. D at Section 6.1. Gilead and JT did not jointly develop any HIV products in the U.S. JT has no rights to distribute any EVG-containing products in the U.S. Moreover, the License **affirmatively** states that there is **no** joint marketing activity in the U.S.: "Collaboration Guidelines. The relationship between JT and Gilead is that of independent contractors and neither Party shall have

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

And in this case, Gilead later combined EVG together with other compounds for which Gilead held patents or was a patent licensee, to create ground-breaking HIV treatments that were extremely effective and which saved or extended many thousands of lives. Compl. ¶¶ 391-92. But the success, acceptance and efficacy of Gilead's products were not assured at the outset. No one could predict what other breakthrough products might be developed by Gilead or by another company that would make Stribild® or Gilead's many other HIV products obsolete. In fact, it took until 2012—seven years after the License was signed—for Gilead to develop a FDA-approved product containing EVG (Stribild®). Compl. ¶¶ 248, 378.

Furthermore, Plaintiffs point to no specific sections of the License where any agreement to monopolize or restrain trade was reached between JT and Gilead (because there was none). Plaintiffs allege no facts to support the contention that Gilead and JT were horizontal competitors. The relationship defined by the License is purely vertical; JT as patent owner and Gilead as licensee. As explained in Section III.A.5, below, JT and Gilead were thus incapable of conspiring under such a relationship. But in any event, their vertical relationship should be judged under the Rule of Reason.[4]

3. Plaintiffs' "Untainted Competitor" Conspiracy Theory is Implausible.

Plaintiffs use 20/20 hindsight, not just to criticize JT for failing in 2005 to preserve its ability 12 years later to act as an "untainted competitor" and market a generic version of Stribild®, but also to infer that JT knowingly did so with the intent to restrain trade and to monopolize in violation of federal and state antitrust laws. This is a farfetched accusation and neither the License nor any other alleged facts support such an inference. Lacking any actual facts to show specific anticompetitive intent behind the License, Plaintiffs attempt to substitute an inference that JT agreed to license EVG exclusively to Gilead with the intent to restrain trade and/or to monopolize "the cART market, and narrower markets therein." Compl. ¶¶ 438, 447. Plaintiffs' inference is based on the theory that an "untainted" JT should have forgone entering into the License and instead waited until 2017 to

---

the power to bind or obligate the other Party in any manner, other than as is expressly set forth in this Agreement." Burke Decl., Ex. D at Section 2.4.

[4] *See* Antitrust Guidelines for the Licensing of Intellectual Property §§ 3.3, 3.4 and 5.4 (Jan. 12, 2017) (*available at*: https://www.justice.gov/atr/IPguidelines/download), noting that vertical exclusive licensing arrangements are evaluated under the Rule of Reason; *County Materials Corp. v. Allen Block Corp.*, 502 F.3d 730, 734-36 (7th Cir. 2007).

challenge Gilead's patents so that JT could market a generic version of Stribild®. Compl. ¶¶ 114, 438. This theory ignores the obvious pro-competitive benefits of the License, and borders on the absurd. Plaintiffs' theory would convert every exclusive license for a patent or copyright into a conspiracy to restrain trade by virtue of the licensor "agreeing" not to compete with the licensee in the sale of the licensed product. *See Futurevision Cable Systems of Wiggins, Inc. v. Multivision Cable TV Corp.*, 789 F. Supp. 760, 779 n.13 (S.D. Miss. 1992) ("Under Futurevision's theory, any supplier that grants an exclusive license to a licensee who allegedly uses the license as part of a scheme to monopolize its market is *per se* liable under the antitrust laws for conspiracy to monopolize. Such an application of the antitrust laws, however, would obviously result in suppliers foregoing the potential pro-competitive benefits from granting such licenses, and would therefore 'chill the very conduct the antitrust laws are designed to protect.'") (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)).

Plaintiffs also contend that had JT been "an untainted competitor" it would have entered the market in March 2018 with a generic FDC using EVG, along with generic versions of TDF, 3TC and RTV. Compl. ¶ 112. But this generic FDC would have faced competition from Gilead's branded EVG- containing FDCs, Stribild® (TDF-based) and Genvoya® (TAF-based), and also the branded dolutegravir-containing FDC Triumeq® sold by ViiV. Compl. ¶¶ 113, 236. According to Plaintiffs, by 2012 EVG had become an inferior product in the wake of the development of dolutegravir. Compl. ¶¶ 230-37. Furthermore, according to Plaintiffs, TAF was less toxic and far safer than TDF.[5] Compl. ¶¶ 202-29. In fact, Plaintiffs assert that forcing patients to take TDF-based, rather than TAF-based, products could cost 16,000 lives and 150,000 injuries. Compl. ¶¶ 225-26. So under Plaintiffs' theory, in 2005 JT should have had the foresight to deny Gilead an exclusive license for EVG and instead waited 12 years to bring a generic FDC drug to market using what Plaintiffs say are inferior (EVG), more toxic (TDF) and/or less safe (TDF) ingredients than what was then available in 2017; causing more deaths and injuries. This conspiracy theory is not just implausible, it is preposterous.

[5] According to Plaintiffs, by 2015, Gilead had begun to switch patients from TDF-based formulations to TAF-based formulas which would have made it even harder for JT to get patients to switch back to a TDF-based drug that was not as safe. Compl. ¶¶ 181, 182, 221, 238.

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Alternatively, Plaintiffs contend that in 2005 JT should have forgone granting Gilead an exclusive license, waited until 2012 until Gilead introduced Stribild®, then filed an NDA, waited another 30 months and then, as early as February 2015, introduced a generic version of Stribild® using EVG, and generic TDF, FTC and COBI. Compl. ¶ 115. But elsewhere Plaintiffs say that generic TDF was not available until December 2017. Compl. ¶¶ 62, 98, 112. Plaintiffs also concede that Gilead's patent on COBI has yet to expire. Compl. ¶ 65. If so, then where would JT secure generic versions of these drugs in 2015? Plaintiffs' conspiracy theory once again flunks the *Twombly* test.

4. JT had No Duty to Develop a Generic HIV Drug with EVG.

While Plaintiffs do not make a claim against JT under Sherman Section 2 for a unilateral refusal to deal, an underlying assumption of Plaintiffs' "untainted competitor" theory is that JT, as a patent owner, had some unidentified duty in March 2005 to reserve the right to later develop a generic drug using EVG. JT had no such duty. As explained in *In re Adderall XR Antitrust Litigation*:

> In the absence of any purpose to create or maintain a monopoly, the [Sherman Act] does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal...." *United States v. Colgate & Co.,* 250 U.S. 300, 307, (1919). Today, "the sole exception to the broad right of a firm to refuse to deal with its competitors" comes into play only "when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Elevator Antitrust Litig.,* 502 F.3d 47, 52, 53 (2d Cir. 2007) (per curiam).

754 F.3d 128, 134 (2d Cir. 2014). In that case, the Second Circuit ruled that in the absence of a pre-existing and presumably profitable course of dealing, a branded drug supplier had no duty to deal with a generic drug manufacturer. Shire, the owner of the Adderall patent, allegedly breached a supply agreement with the plaintiffs that was part of a patent infringement settlement. When Shire refused to supply the plaintiffs with unbranded Adderall, they filed an antitrust lawsuit which the district court dismissed on the grounds that Shire had no duty to deal with the plaintiffs and that Shire's refusal to supply the unbranded ingredients was simply a breach of the settlement, not an antitrust violation.

Here, Plaintiffs do not allege that in March 2005 JT had a pre-existing course of dealing with any manufacturer of generic HIV drugs to supply EVG, nor could they because there was none. JT itself is not alleged to have marketed any HIV drugs in the U.S. Thus, under the longstanding dictates

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

of the *Colgate* doctrine, JT had no duty to license EVG to any generic manufacturers. To the contrary, as a patent owner, JT had every right to commercialize its EVG patent as it determined to be best. *Image Tech. Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1215 (9th Cir. 1997) ("The right to license [a] patent, exclusively or otherwise, or to refuse to license at all, is 'the untrammeled right' of the patentee.").[6] Based on these principles, JT did not violate the antitrust laws when it entered into the License with Gilead; it did exactly what it was entitled to do under the patent laws. Plaintiffs' attempt to convert every exclusive license into a refusal to deal and to impose a duty on JT to license EVG only on a non-exclusive basis is at odds with well-established rights of a patent owner to freedom of contract. *Huawei Technologies, Co, Ltd v. Samsung Electronics Co, Ltd.*, 340 F. Supp. 3d 934, 953 (N.D. Cal. 2018). The Court should accordingly dismiss the antitrust claims in Counts One, Two, Ten and Eleven with prejudice. And to the extent that the claims in Count Seven are based on the same conduct, that Count should be dismissed with prejudice as well.

5. As a Patent Owner, JT is Incapable of Conspiring With Its Exclusive Licensee, Gilead.

Finally, Plaintiffs' allegations of a conspiracy between JT and Gilead are impossible as a matter of law. Conspiracy requires the concerted action of more than a single entity. *Filco v. Amana Refrigeration, Inc.*, 709 F.2d 1257, 1261 (9th Cir. 1983). The Supreme Court has held that a corporation and its wholly-owned subsidiaries cannot conspire with each other as a matter of law. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984) (explaining that parent corporation and subsidiary have a "complete unity of interest" rather than a "sudden joining of two independent sources of economic power previously pursuing separate interests."). The court reasoned that the coordinated activity of parties lacking independent sources of economic power and separate interests does not warrant judicial scrutiny. *Id.* at 770-71. "[T]he broader principle [is] that substance, not form, should determine whether a separately incorporated entity is capable of conspiring under [Section 1 of the Sherman Act]." *Id.* at 773 n.21.

[6] *See also* 35 U.S.C. § 271(d)(4) (no patent owner shall be deemed guilty of misuse or illegal extension of the patent right by refusing to license or use any rights to the patent).

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Lower courts have applied the reasoning of *Copperweld* to a variety of economic relationships. *See, e.g., Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1147-48 (9th Cir. 2003) (collecting Ninth Circuit cases).[7] The common thread in these cases is economic unity. *Id.* at 1148. "Where there is substantial common ownership, a fiduciary obligation to act for another entity's economic benefit or an agreement to divide profits and losses, individual firms function as an economic unit and are generally treated as a single entity." *Id.* Importantly here, the *Copperweld* doctrine has also been held by a court in this district to apply in the context of a patent owner and an exclusive licensee. *See Levi Case Co., Inc. v. ATS Prods., Inc.*, 788 F. Supp. 428 (N.D. Cal. 1992). Considering that relationship, the court in *Levi Case* (Walker, J.) observed that the patent owner's only rights relating to the patent after it granted the exclusive license were receipt of royalties and approval of sublicenses. *Id.* at 431-32. The patent owner, by virtue of granting the exclusive license, could not compete in the market covered by the patent and neither could anyone else because a patent is a legally-sanctioned restraint on trade. *Id.* The court thus concluded that the patent owner and exclusive licensee "were not independent sources of economic power" and that no agreement between the two "involving the exploitation of the patent in which they both held an interest can be considered to deprive the marketplace of 'independent sources of economic power previously pursuing separate interests.'" *Id.* at 432 (quoting *Wahl v. Rexnord, Inc.*, 481 F. Supp. 573, 588 (D.N.J. 1979), *rev'd on other grounds*, 624 F.2d 1169 (3d Cir. 1980)).

The court in *Levi Case* acknowledged that the relationship between a patent owner and licensee can be a conspiracy in violation of the antitrust laws if the license "deprives the marketplace of independent actors." *Levi Case*, 788 F. Supp. at 431. That occurs where the patentee/licensee relationship is ancillary to the anticompetitive conduct at the heart of the alleged conspiracy. *See, e.g., In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, MDL No. 2445, 2017

[7] In the Ninth Circuit, *Copperweld's* single-entity rule applies to, *inter alia*, subsidiaries controlled by a common parent, *Thomsen v. W. Elec. Co.*, 680 F.2d 1263, 1265-66 (9th Cir. 1982), firms owned by the same person, *Las Vegas Sun, Inc. v. Summa Corp.*, 610 F.2d 614, 616, 618 (9th Cir. 1979), principal-agent relationships, *Calculators Haw., Inc. v. Brandt, Inc.*, 724 F.2d 1332, 1336 (9th Cir. 1983), agreements between franchiser and franchisee, *Williams v. I.B. Fischer Nevada*, 999 F.2d 445, 447-48 (9th Cir. 1993), and to "partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share the risks of loss as well as the opportunities for profit." *Arizona v. Maricopa County. Med. Soc'y*, 457 U.S. 345, 356 (1982).

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

WL 4910673, at *8-9 (E.D. Pa. Oct. 30, 2017) (declined to find that defendants could not conspire as a matter of law where the complaint alleged conspiracy to remove product from market). That is not the case here. The conspiratorial conduct alleged by Plaintiffs here is premised solely on the exclusive license granted by JT, the patent owner, to Gilead to commercialize EVG throughout the world (except in Japan). Compl. ¶ 103. But an exclusive license, by itself, "does not constitute an illegal restraint of trade or violation of the antitrust laws." *Rail-Trailer Co. v. ACF Indus., Inc.*, 358 F.2d 15, 16-17 (7th Cir. 1966). And Plaintiffs make no plausible allegation that the License here somehow "deprived the marketplace of independent actors." Rather, like the patent owner in *Levi Case*, JT's only right relating to the EVG patent after entering the License was to receive upfront and milestone payments followed by royalties on the sale of HIV products containing EVG. *See* Burke Decl., Ex. D at Section 6.1. JT, by virtue of the License, could not compete with Gilead using EVG and neither could anyone else.[8] Under such circumstances, the Court here should similarly conclude that JT and Gilead "were not independent sources of economic power" and that no agreement between the two "involving the exploitation of the patent in which they both held an interest can be considered to deprive the marketplace of independent sources of economic power previously pursuing separate interests." *Levi Case*, 788 F. Supp. at 432 (internal quotations and citations omitted); *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499, at *5 (D. Del. May 26, 2011) (finding plaintiff did "not state a claim for conspiracy or combination in restraint of trade because of the relationship between [the defendants], an exclusive licensee and patent holder."); *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. CIV.A. 99-6299, 2000 WL 987865, at *6 (E.D. Pa. July 18, 2000) (holding that where patentee sells its product exclusively to licensee at lower price, and where plaintiff must obtain product from licensee at higher price, no antitrust violation exists given "fundamental legitimacy of the exclusive distributorship arrangement for the patented product.").

[8] Plaintiffs do not allege any facts to support the bare legal conclusion that JT was one of "Gilead's most likely competitors" or that JT ever was a "horizontal" competitor of Gilead, Janssen and BMS. Compl. ¶¶ 3, 4, 513, 520. For example, Plaintiffs do not allege that JT had any sales or marketing structure in the U.S. in 2005 such that JT was an "independent actor" who previously competed with Gilead such that the License deprived the marketplace of "independent sources of economic power previously pursuing separate interests" as stated in *Levi Case*. In fact, Plaintiffs' allegations confirm that JT was not an actual or potential competitor in any relevant HIV product market in the U.S. Compl. ¶ 67 (listing all of the 17 products included in the Complaint, for none of which is JT the NDA holder in the U.S.).

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

B. PLAINTIFFS LACK STANDING TO SUE UNDER THE STATE AND FEDERAL ANTITRUST LAWS.

1. Plaintiffs Lack Standing to Sue for Damages Under Federal Law.

As indirect purchasers, Plaintiffs lack standing to sue JT for money damages under the Sherman Act (Counts One and Ten). *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). In *Illinois Brick*, the Supreme Court ruled that persons who do not purchase directly from one of the members of an alleged conspiracy, but instead purchase from independent wholesalers or distributors, may not sue for damages under Section 4 of the Clayton Act. *Id*. at 737-38. Here, Plaintiffs do not allege that they purchased directly from any of the Defendants or alleged co-conspirators. To the contrary, Plaintiffs admit that they did not purchase the subject drugs directly from Defendants. Compl. ¶ 414 (defining class as indirect purchasers). Therefore, Plaintiffs lack standing to sue for damages based on the *Illinois Brick* doctrine and the Court should dismiss Plaintiffs' claims for damages in Counts One and Ten with prejudice.

2. Plaintiffs Lack Standing to Sue and/or Fail to State Claims Under Certain State Laws.

JT adopts and incorporates by reference the arguments made by Defendant Gilead as to all of the state law claims raised against JT in Counts Two, Seven and Eleven.

C. PLAINTIFFS' STATE LAW CONSUMER PROTECTION CLAIMS MUST BE DISMISSED AGAINST JT.

Plaintiffs' claims in Count Seven are based on the allegation of "a gross disparity between the price that Plaintiffs and the Class members paid for the brand and generic products and the value received, given that a less expensive substitute generic or comparable product should have been available." Compl. ¶ 494. The Court should dismiss Count Seven against JT for three reasons. First, as explained above, Count Seven fails to allege any facts against JT to show that it engaged in any conduct that was "unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices." Second, under the express terms of the License, Gilead had sole and complete control over the commercialization of EVG, and thus Plaintiffs do not state a plausible claim against JT for violation of any of the state consumer protection laws. *See* Burke Decl., Ex. D at Section 5. Third, while Gilead's conduct is not attributable to JT, Gilead had no duty to market its branded drugs in

any particular way so as to limit the life of any of its patents or to assist others in the development of generic versions of its products. "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) (internal quotation omitted); *AIDS Healthcare Found., Inc. v. Gilead Sciences, Inc.*, No. 3:16-cv-00443-WHA, 2016 WL 3648623, at *7 (N.D. Cal. July 6, 2016) ("There is no legal basis for concluding that Gilead had a *duty* to release TAF as a standalone product."). Gilead did not withdraw its TDF-based products from the marketplace when it introduced its TAF-based products. Therefore, its conduct was not "unfair, unconscionable, deceptive or fraudulent," but instead was lawful pro-competitive behavior of a patent owner who continued to innovate and bring to market new and improved HIV treatments. *See Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010) ("If a monopolist's design change is an improvement, it is 'necessarily tolerated by the antitrust laws…'" (quoting *Foremost*, 703 F.2d at 545)). In any event, because the conduct to which Plaintiffs point was Gilead's not JT's, there is simply no basis to assert claims against JT for violating any state consumer protection laws and the Court should dismiss Count Seven with prejudice as to JT.

IV. CONCLUSION

The Court should dismiss Plaintiffs' claims against all Defendants for the reasons stated in Defendants' motions. But Plaintiffs' claims against JT are particularly weak. The allegations as to JT are not just implausible, but border on being preposterous; they are confusing, internally inconsistent and pre-suppose that JT had a crystal ball to foresee developments in the market many years in advance.[9] Plaintiffs' alleged facts actually show that JT, in order to commercialize its patent on EVG, entered into a lawful vertical exclusive license with Gilead to take advantage of Gilead's marketing capabilities in areas outside of Japan, where JT had no marketing presence. As a matter of law under the *Copperweld* doctrine, a vertical exclusive licensing agreement like the License is not a conspiracy in restraint of trade. Unlike the agreements between Gilead and BMS and Gilead and Janssen, JT

[9] As one court commented on a plaintiff's monopolization theory that relied on similar logic, "[t]hat type of analysis—or lack of analysis—borders on the absurd. No one has an unclouded crystal ball as to future events, nor does anyone have a vested right in the expectation that the future will remain the same as the present." *United Asset Coverage, Inc. v. Avaya Inc.*, 409 F. Supp. 2d 1008, 1046 (N.D. Ill. 2006).

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

granted Gilead complete authority over all marketing decisions relating to EVG outside Japan. Therefore, the marketing conduct about which Plaintiffs complain did not involve JT. And last, no facts are alleged to show that JT conspired with Gilead, Janssen and BMS in any "over-arching conspiracy" to monopolize any market for HIV treatments. Indeed, according to Plaintiffs, none of Gilead's products containing EVG competed with the products Gilead marketed with Janssen and BMS. The facts Plaintiffs allege fail to state that JT did anything wrong. JT does not belong in this lawsuit and no further pleading will change that conclusion. Plaintiffs' claims against JT should be dismissed with prejudice.

Notice of Intent to Seek Attorneys' Fees and Costs

JT hereby gives notice of its intent to seek attorneys' fees and costs in connection with its defense of these claims pursuant to state laws that provide for such recovery of attorneys' fees and expenses, including, but not limited to, Section 501.2105(1), Florida Statutes.

Dated: September 4, 2019

HOLLAND & KNIGHT LLP

By: /s/
Jerome W. Hoffman (*pro hac vice*)
Attorneys for Defendant
JAPAN TOBACCO INC.

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450

Additional Counsel for Defendant Japan Tobacco Inc.:

Jerome W. Hoffman (*pro hac vice*)
Email: jerome.hoffman@hklaw.com
50 N. Laura Street, Suite 3900
Jacksonville, FL 32202
Telephone (904) 353-2000
Facsimile (904) 358-1872

Thomas J. Yoo (SBN 175118)
Email: thomas.yoo@hklaw.com
400 S. Hope St., 8th Floor
Los Angeles, CA 90071
Telephone (213) 896-2400
Facsimile (415) 896-2450

John Kern (SBN 206001)
Email: john.kern@hklaw.com
Ashley L. Shively (SBN 264912)
Email: ashley.shively@hklaw.com
50 California Street, Suite 2800
San Francisco, CA 94111
Telephone (415) 742-6970
Facsimile (415) 743-6910

SIGNATURE ATTESTATION

The undersigned attests that, pursuant to Local Rule 5-1(i)(3), concurrence in the filing of this document has been obtained from counsel for all other signatories listed, and on whose behalf the filing is submitted, and counsel concur in the filing's content and have authorized the filing.

By: /s/ Ashley L. Shively
Ashley L. Shively
HOLLAND & KNIGHT LLP

Holland & Knight LLP
400 South Hope Street, 8th Floor
Los Angeles, CA 90071
Tel: 213.896.2400
Fax: 213.896.2450