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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PETER STALEY, *et al.*,

Plaintiff,

v.

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

Defendant.

Case No. 3:19-CV-2573-EMC

CLASS ACTION

DEFENDANTS JOHNSON & JOHNSON AND JANSSEN R&D IRELAND'S NOTICE OF MOTION AND MOTION TO DISMISS, AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: January 16, 2020
Time: 1:30 p.m.
Courtroom: 5 - 17th Floor
Judge: Honorable Edward M. Chen
Trial Date: Not Set

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on January 16, 2020 at 1:30 p.m., or as soon thereafter as the matter may be heard, in the courtroom of the Honorable Edward M. Chen, United States District Judge, Northern District of California, located at 450 Golden Gate Avenue, San Francisco, CA 94102-3489, in Courtroom 5 on the 17th Floor, the undersigned Janssen R&D Ireland ("Janssen") and Johnson & Johnson ("J&J") will, and hereby do, move the Court for an order dismissing Plaintiffs' Corrected Consolidated Class Action Complaint (the "Complaint" or "CC"), ECF No. 118, against Janssen and J&J with prejudice.

This Motion is made pursuant to Federal Rule of Civil Procedure 12(b)(6). This Motion is based on this Notice of Motion and Motion; the accompanying Memorandum of Points and Authorities; the Declaration of Heather M. Burke in Support of the Motion to Dismiss filed by Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC (collectively, "Gilead"), ECF No. 143-1; Gilead's Request to Consider Materials in Support of Its Motion to Dismiss, ECF No. 145; the pleadings and evidence on file in this matter; oral argument of counsel; and such other materials and argument as properly may be presented in connection with the hearing of the Motion.

Janssen and J&J also join the Motion to Dismiss filed by Gilead, ECF No. 143, and adopt the reasons and arguments set forth therein as further grounds for dismissal of the Complaint. In addition, Janssen and J&J join in Sections III(A)(3) and III(B) of Japan Tobacco Inc.'s Motion to Dismiss, ECF No. 158, addressing, respectively, the implausibility of Plaintiffs' "untainted competitor" theory and their lack of standing to sue for damages under federal law.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES, RULES & REGULATIONS

OTHER AUTHORITIES

MEMORANDUM OF POINTS AND AUTHORITIES

STATEMENT OF ISSUES TO BE DECIDED

The issues presented are: (1) Whether Plaintiffs have failed to allege, in Counts One, Two and Seven of their Complaint, a plausible "overarching conspiracy" claim against Janssen and J&J; (2) Whether Plaintiffs have failed to allege, in Counts Eight and Nine, a plausible claim that Janssen's collaboration agreements with Gilead violated the Rule of Reason; and (3) Whether Plaintiffs' Complaint against J&J fails for the additional reason that the only allegation against J&J is that it is the indirect corporate parent of Janssen.

INTRODUCTION

Even accepting all of the allegations in their Complaint as true, Plaintiffs have failed to state a plausible claim that Janssen violated the antitrust laws by collaborating with Gilead to develop four fixed-dosed combination drugs ("FDCs") to treat human immunodeficiency virus ("HIV"): Complera®; Prezcobix®; Odefsey®; and Symtuza®.

Absent the collaborations between Janssen and Gilead, none of these innovative medications would be available today. The new FDCs were possible only because Janssen combined one of its patented "third agent" HIV medications—Rilpivirine ("RPV") or Darunavir ("DRV")—with Gilead's Nucleoside Reverse Transcriptase Inhibitors ("NRTIs") and/or Gilead's "booster," Cobicistat ("COBI"). The two companies shared the investments and risks necessary for product development and regulatory approval. The Janssen/Gilead collaborations are, therefore, lawful, procompetitive joint ventures.

The protections in the agreements against free riding on the collaborations by either Janssen or Gilead, which Plaintiffs misleadingly characterize as "No-Generics Restraints," are reasonably ancillary to the joint ventures. Gilead and Janssen each expressly retained the right to develop new stand-alone HIV treatments and new FDCs in competition with one another—and, as the Complaint acknowledges, the two companies did so. For example, Gilead used COBI, which is in Prezcobix and in Symtuza, in three other FDCs—Evotaz®, Stribild®, and Genvoya®. Thus, by their terms, the Janssen and Gilead collaboration agreements enhanced inter-brand competition for HIV treatments.

None of the agreements prevented third parties from seeking approval for generic equivalent

FDCs once the Janssen and Gilead patents expired. Furthermore, because each of the four FDCs at issue is currently protected by one or more Janssen and Gilead patents, Plaintiff have not suffered any plausible antitrust injury. Any competitive harm tethered to the expiration of any one of the patents is entirely speculative, particularly since Janssen's patents on its RPV and DRV medications do not expire until, respectively, 2025 and 2026.

Separately, Plaintiffs attempt to cast Janssen, without any supporting allegations, as participating with Gilead, Bristol-Myers Squibb Company ("BMS") and Japan Tobacco, Inc. ("JT") in an "overarching conspiracy" involving a wide range of HIV treatments. Plaintiffs have neither pled the elements of such a far-reaching and far-fetched conspiracy under established Ninth Circuit precedent—the who, with whom, what, where and when—nor have they alleged a reasonable basis to infer one. As such, Plaintiffs' overarching conspiracy claims fail to allege a plausible claim for relief under *Twombly*.

Finally, the Court should dismiss the Complaint against J&J for the additional reason that it was not even a party to the collaboration agreements with Gilead. Plaintiffs' only allegation against J&J is that it is the indirect corporate parent of Janssen. That is not a legally sufficient basis to pursue a claim against J&J.

For these reasons, Counts One, Two, and Seven of the Complaint should be dismissed for failing to state a plausible claim that Janssen and J&J participated in an "overarching conspiracy" in violation of Sections 1 and 2 of the Sherman Act. Counts Eight and Nine should be dismissed for failing to state a claim that Janssen's collaboration agreements with Gilead violated the antitrust laws under the Rule of Reason analysis. Moreover, as no amendment could cure these deficiencies in these five counts, Janssen and J&J respectfully request dismissal of the Complaint against them with prejudice.

FACTUAL ALLEGATIONS AND BACKGROUND

Beginning in 2009, Janssen and Gilead entered into separate agreements to collaborate on the development and manufacture of four innovative FDCs for HIV: Complera, Odefsey, Prezcobix and Symtuza. FDCs are a type of combination antiretroviral therapy ("cART"), which is considered an "innovation" in the treatment of HIV. CC ¶ 53. FDCs have become the

recommended first-line treatment for patients diagnosed with HIV. *Id.* ¶ 56. They improve the likelihood of a patient's compliance with taking a prescribed HIV treatment because an FDC reduces the "pill burden" associated with taking multiple individual drugs to treat HIV. *See id.* ¶ 63. An FDC for the treatment of HIV typically comprises two drugs from the NRTI class, the combination of which is referred to as a "backbone drug," and one drug from another class—such as an integrase inhibitor or a protease inhibitor—which is often referred to as a "third agent." *Id.*

Janssen supplied the third agents for each of the four FDCs it jointly developed with Gilead. *See id.* ¶ 95. One of the two third agents supplied by Janssen at issue here is RPV, a drug in the non-nucleoside reverse transcriptase inhibitor class. *Id.* ¶¶ 66–67. The FDA approved RPV in May 2011. *Id.* ¶ 144. Patents protect RPV from generic competition in the U.S. at least until 2025. *Id.* ¶ 150. The other Janssen third agent at issue is DRV, a drug in the protease inhibitor class. *Id.* ¶¶ 66–67. The FDA approved DRV in June 2006. *Id.* Patents protect DRV from generic competition in the U.S. until at least December 26, 2026. *Id.* ¶ 173.

Complera: This FDC combines Janssen's third agent RPV with Gilead's patent protected backbone drug emtricitabine ("FTC") and tenofovir disoproxil fumarate ("TDF"), which is the less potent predecessor to tenofovir alafenamide fumarate ("TAF"). CC ¶¶ 207, 218; Burke Decl., ECF No. 143-1, Ex. E, License and Collaboration Agreement (the "Complera Agreement"), dated July 16, 2009. When Janssen and Gilead executed the Complera Agreement in 2009, the FDA had not yet approved RPV. CC ¶ 144. For the commercialization of Complera, Janssen granted Gilead a co-exclusive license to RPV, Complera Agreement § 9.1, and Gilead agreed to reimburse Janssen up to approximately $100 million for costs associated with the development of RPV. *Id.* § 10.1; CC ¶ 149. The FDA approved Complera in 2011. CC ¶ 143.

The Complera Agreement precludes Janssen and Gilead from making and selling a generic equivalent of Complera, but it does not prevent either joint venture partner from making other FDCs. Burke Decl. at Ex. E, Complera Agreement § 17.2(a). For example, Gilead was free to combine FTC and TDF with BMS's own third agent efavirenz ("EFV"), to make a competing FDC marketed as Atripla. CC ¶ 67. Complera also competes with Stribild and other FDCs made by Gilead. *Id.* ¶¶ 67, 139.

Prezcobix: This FDC combines Janssen's third agent DRV with Gilead's booster COBI. Burke Decl., at Ex. F, License and Collaboration Agreement (the "Prezcobix Agreement"), dated June 27, 2011. COBI is patent protected until 2029. CC ¶ 164. Gilead granted Janssen an exclusive license to use COBI for the development and manufacture of Prezcobix, Prezcobix Agreement § 8.1; Janssen is responsible for commercializing the FDC and for setting its price, CC ¶ 170. Janssen is also responsible for the registration, manufacture, and distribution of Prezcobix on a worldwide basis. Burke Decl. at Ex. F, Prezcobix Agreement §§ 4.1, 6.1. The FDA approved Prezcobix in 2015. CC ¶ 164. The Prezcobix Agreement precludes Janssen and Gilead from making and selling a generic equivalent of Prezcobix, but it does not prevent either joint venture partner from making other FDCs. Prezcobix Agreement § 14.2.

Odefsey: This FDC combines Janssen's third agent RPV with Gilead's backbone drugs FTC and TAF. Burke Decl., at Ex. G, Amended & Restated License and Collaboration Agreement (the "Odefsey Agreement"), dated December 23, 2014. The Odefsey Agreement expanded the Janssen/Gilead collaboration involving Complera to include Gilead's TAF. CC ¶ 152. The FDA approved Odefsey in 2016. *Id.* ¶ 152. TAF is patent protected until 2032. *Id.* ¶ 110. Under the Odefsey Agreement, Gilead is responsible for manufacturing, registering, distributing, and commercializing Odefsey in the U.S., among several other regions. *Id.* ¶ 154. The Odefsey Agreement, during its term, precludes Janssen and Gilead from making and selling a generic version or near generic version of Odefsey, but it does not prevent either joint venture partner from making other FDCs. Burke Decl. at Ex. G, Odefsey Agreement § 17.2.

Symtuza: This FDC combines Janssen's third agent DRV with Gilead's backbone drugs FTC and TAF, as well as Gilead's booster COBI. Burke Decl. at Ex. H, Amended & Restated License and Collaboration Agreement (the "Symtuza Agreement"), dated December 23, 2014. Under the Symtuza Agreement, Gilead granted Janssen an exclusive license to Symtuza worldwide, and Janssen is responsible for manufacturing, registering, distributing, and commercializing Symtuza. CC ¶ 170. The FDA approved Symtuza for sale in the U.S. in 2018. *Id.* ¶ 165. The Symtuza Agreement precludes Janssen and Gilead from making and selling a generic version or near generic version of Symtuza, but both joint venture partners retain the right to make other FDCs.

Burke Decl. at Ex. H, Symtuza Agreement § 14.2. Gilead combined its COBI "booster" to make other FDCs such as Evotaz, Stribild and Genvoya. CC ¶ 67.

ARGUMENT

I. PLAINTIFFS HAVE NOT PLED SUFFICIENT FACTS OF ANY CLAIMED OVERARCHING CONSPIRACY, LET ALONE ONE INVOLVING JANSSEN

A. The Complaint Does Not Allege the Requisite Facts Connecting Janssen to Any Claimed Overarching Conspiracy with Gilead, BMS and JT.

Plaintiffs claim that Janssen participated in an overarching conspiracy involving all of the Defendants, but, as to Janssen, the Complaint alleges only separate bilateral agreements with Gilead. To plead an overarching conspiracy, Plaintiffs must do more: they must plead facts connecting Janssen to such a broad plan to harm competition. *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1047 (9th Cir. 2008). *Kendall* requires Plaintiffs to plead evidentiary facts to "answer the basic questions" about their conspiracy claims: "who, did what, to whom (or with whom), where, and when?" *Id.* at 1048. Although the Complaint need not contain "detailed 'defendant by defendant' allegations," it "'must allege that each individual defendant joined the conspiracy and played some role in it because, at the heart of an antitrust conspiracy is an agreement and a conscious decision by each defendant to join it.'" *In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d 1051, 1066 (N.D. Cal. 2015) (quoting *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 586 F. Supp. 2d 1109, 1117 (N.D. Cal. 2008)).

Here, there are no allegations that Janssen had "knowledge of" the terms of Gilead's collaboration agreements with BMS or JT. *In re High-Tech Emp. Antitrust Litig.*, 856 F. Supp. 2d 1103, 1112 (N.D. Cal. 2012) (finding plaintiffs included sufficient allegations that defendants had knowledge of each other's participation in alleged conspiracy). Nor does the Complaint include any allegations that each of Janssen's, BMS's, or JT's agreements with Gilead were in any way "interconnected." *Id.* at 1115–16. Every Defendant must be specifically connected to the alleged conspiracy. *See, e.g., Brennan v. Concord EFS, Inc.*, 369 F. Supp. 2d 1127, 1136–37 (N.D. Cal. 2005) (granting defendants' motion to dismiss where the complaint contained no allegations "specifically connecting" them to the alleged conspiracy).

The allegations identifying Janssen pertain only to bilateral agreements with Gilead, and

are legally insufficient to state a claim of an overarching conspiracy involving all Defendants. *See, e.g.*, *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 327 (3d Cir. 2010) ("Contrary to plaintiffs' arguments, one cannot plausibly infer a horizontal agreement among a broker's insurer-partners from the mere fact that each insurer entered into a similar contingent commission agreement with the broker."); *see also Buetow v. A.L.S. Enters., Inc.*, 564 F. Supp. 2d 1038, 1042 (D. Minn. 2008) (rejecting argument that licensing agreements among certain defendants constituted "direct evidence" of an overarching conspiracy). Further, the Complaint alleges no facts to support an inference that the Janssen/Gilead agreements were interdependent, such that the success of those agreements was dependent on the success of Gilead's agreements with BMS or JT. *See Richards v. Neilsen Freight Lines*, 810 F.2d 898, 904 (9th Cir. 1987) (requiring evidence of interdependence to infer an overarching conspiracy from a series of bilateral agreements). Indeed, the allegations in the Complaint of interbrand competition establish that any such theory is implausible.

Although the Complaint suggests that the alleged overarching conspiracy is of a hub-and-spoke type, Plaintiffs do not satisfy the pleading requirements for such a claim because there are no allegations connecting each of Janssen's, BMS's, or JT's respective collaborations with Gilead together. *See Rheumatology Diagnostics Lab., Inc. v. Aetna, Inc.*, No. 12-cv-05847-WHO, 2013 WL 5694452, at *9–10, (N.D. Cal. Oct. 18, 2013) (dismissing hub-and-spoke conspiracy claim because set of agreements with a common entity is not "an actionable horizontal conspiracy" unless "there is some set of facts showing a connecting agreement among the horizontal competitors that form the spokes." (quoting 1 ANTITRUST LAW DEVELOPMENTS 20 (Am. Bar Ass'n Section of Antitrust Law, 7th ed. 2012))).

B. There Is No Basis to Infer Janssen's Participation in Any Claimed Overarching Conspiracy.

Plaintiffs' allegations about an overarching conspiracy are simply conclusory statements, such as "[e]ach of Janssen, [JT], and BMS consciously committed to the overarching anticompetitive scheme," CC ¶ 444; and "Defendants willfully and unlawfully engaged in schemes for the anticompetitive purpose of delaying and impairing competition and thereby maintaining supracompetitive prices for their products," *id.* ¶ 400. Those types of vague and bare allegations

do not suffice. *Rheumatology Diagnostics Lab.*, 2013 WL 5694452, at *11 ("[R]epeating the same conclusion over and over without giving any *facts* to support it is insufficient to state a claim—Rule 8 cannot be worn down by brute force. As the Ninth Circuit instructs, a plaintiff must 'plead the necessary evidentiary facts to support those conclusions.'" (quoting *Kendall*, 518 F.3d at 1047–48)).

Beyond Plaintiffs' conclusory allegations, there are no allegations to support a plausible inference of an overarching conspiracy. For example, Plaintiffs do not allege ***any*** communications—direct or indirect—among Defendants that would even infer an overarching conspiracy. Nor are there any allegations that Defendants joined together to achieve a common unlawful goal. Without allegations of a "unity of purpose" among Defendants, Plaintiffs cannot establish a Section 1 conspiracy claim. *In re High-Tech Employee Antitrust Litig.*, 856 F. Supp. 2d at 1118 (citing *Am. Tobacco Co. v. United States*, 328 U.S. 781, 810 (1946)).

The Complaint also lacks any allegations that Janssen acted against its economic self-interest. In particular, Plaintiffs do not allege that, absent an overarching conspiracy that included BMS and JT, Janssen lacked an incentive to collaborate with Gilead on the development and manufacture of four new FDCs. *See, e.g.*, *William O. Gilley Enters., Inc. v. Atl. Richfield Co.*, 588 F.3d 659, 669 (9th Cir. 2009) (per curiam) (affirming dismissal of antitrust conspiracy claim where evidentiary facts were consistent with unilateral and independent business decisions). Indeed, as the Court observed in *Buetow*, which involved another deficient overarching conspiracy claim, "the exact opposite is true: the licensing agreements actually *negate* any suggestion of a conspiracy because they provide a plausible alternative explanation for the Defendants' parallel conduct." 564 F. Supp. 2d at 1042 (citing *Bell Atlantic Co. v. Twombly*, 550 U.S. 544, 567–68 (2007) for the proposition complaint did not suggest conspiracy when "an obvious alternative explanation" existed for the defendants' conduct).

C. Plaintiffs Fail to Allege Facts Supporting the Specific Intent Element Required for a Conspiracy to Monopolize Under Section 2.

Plaintiffs allege that their claim of an overarching conspiracy violates both Sections 1 and 2 of the Sherman Act. These are "legally distinct" offenses, each requiring different proof; a

Section 2 conspiracy to monopolize claim requires a specific intent to monopolize. *Stanislaus Food Prods. Co. v. USS-POSCO Indus.*, No. CV F 09-560 LJO SMS, 2011 WL 2678879, at *13, *14, n.8 (E.D. Cal. July 7, 2011) (citations omitted). In addition to failing to allege an agreement among all Defendants, Plaintiffs fail to allege that Janssen had the "specific intent to monopolize and anticompetitive acts designed to effect that intent." *Hunt–Wesson Foods, Inc. v. Ragu Foods, Inc.*, 627 F.2d 919, 926 (9th Cir. 1980), *cert. denied*, 450 U.S. 921 (1981); *see also Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1154 (9th Cir. 2003) (specific intent is a required element for a Section 2 claim of conspiracy to monopolize). Plaintiffs only allege that "Gilead's conscious objective was to further its dominance in the cART Market by and through the overarching anticompetitive scheme." CC ¶ 443. That is insufficient. *See Stanislaus Food Prods. Co. v. USS-POSCO Indus.*, No. CV F 09-560 LJO SMS, 2010 WL 3521979, at *28 (E.D. Cal. Sept. 3, 2010) (dismissing Section 2 claims because allegations of specific intent were "conclusory and superficial").

Moreover, Plaintiffs' conspiracy to monopolize claim against Janssen is inherently implausible. Plaintiffs' Section 1 claims allege that Gilead, Janssen, BMS, and JT are competitors. But nowhere does the Complaint allege any facts to infer a plausible reason why Janssen would conspire with BMS and JT to create a monopoly for Gilead's benefit.

II. PLAINTIFFS' CLAIMS REGARDING THE JANSSEN/GILEAD AGREEMENTS SHOULD BE DISMISSED UNDER THE RULE OF REASON

A. The Collaboration Agreements Are Subject to the Rule of Reason.

Each of the collaboration agreements between Janssen and Gilead constitutes a joint venture for antitrust purposes. As described above, the two companies combined their standalone HIV medications and shared in the risks of product development and regulatory approval. The result was four new FDCs, which Plaintiffs themselves acknowledge have substantial benefits for HIV patients. *See, e.g.*, CC ¶ 194 ("FDCs reduced this pill burden significantly, often allowing a patient to take just a single pill once a day to effectively treat HIV.") Under these admitted facts, each of the collaboration agreements is subject to analysis under the Rule of Reason. *See, e.g., Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 8–9 (1979); *In re ATM Fee Antitrust Litig.*,

554 F. Supp. 2d 1003, 1015 (N.D. Cal. 2008) (when defendants are members of a joint venture that depends on "a certain degree of cooperation" if the venture is to be preserved, *any* horizontal restraint is subject to rule of reason analysis) (citing *Nat'l Collegiate Athletic Ass'n. v. Bd. of Regents*, 468 U.S. 85, 117 (1984)).

For the several reasons discussed below, Plaintiffs have failed to allege the essential elements of a Rule of Reason case against Janssen.

1. The Contractual Provisions Challenged by Plaintiffs Are Reasonable Ancillary Restraints.

Plaintiffs have not identified in their Complaint any unreasonable ancillary restraints in the collaboration agreements between Janssen and Gilead. What Plaintiffs misleadingly allege to be "No-Generics Restraints" on their face do not foreclose competition between the two companies or generic entry by third parties. As described above, Janssen and Gilead retained the right to compete against each other—and did so—with either standalone HIV medications or other FDCs. They only agreed not to sell generic versions or near-similar versions of the four FDCs developed by the joint ventures. As such, the provisions are reasonable ancillary restraints to lawful joint ventures, not horizontal non-compete agreements. *See, e.g., Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) ("A restraint is ancillary when it may contribute to the success of a cooperative venture that promises greater productivity and output."); *Ixchel Pharma, LLC v. Biogen Inc.*, No. 2:17-00715 WBS EFB, 2018 WL 558781, *3 (E.D. Cal. Jan. 25, 2018) ("Rather than defining § 2.13 as some sort of illegal non-compete agreement, the court views it instead as an ancillary restraint, one that is subordinate to the larger lawful, agreement between Forward and defendant.").

Absent the ancillary restraints in the collaboration agreements, Janssen was vulnerable to free riding by Gilead on their joint venture activities. "[T]he Supreme Court made it clear that elimination of the free ride is an efficiency justification available to horizontal restraints that are ancillary to a contract integration." *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 228 (D.C. Cir. 1986). "The free ride can become a serious problem for a partnership or joint venture." *Id.* at 212–13; *see also Polk Bros.*, 776 F.2d at 188–89 (rule of reason applied to ancillary

restraint intended to prevent free riding); *Major League Baseball Props., Inc. v. Salvino*, 542 F.3d 290, 340 (2d Cir. 2008) ("exclusivity and profit-sharing provisions" of joint venture agreement "reasonably necessary" because they eliminate the "free riding problem"). It is implausible to expect Janssen to collaborate on the development of four new FDCs without some reasonable protection against free riding by the other party on the joint ventures' shared investments and risk.

2. Plaintiffs Have Not Defined a Plausible Relevant Market.

Plaintiffs fail to adequately plead a relevant product market, which is a required element of their claims that the Janssen/Gilead collaboration agreements are unlawful. "Under the rule of reason, a plaintiff must plead that the challenged agreement, by virtue of the defendants' market power, was unreasonably restrictive of competition in a relevant market and that the plaintiff suffered antitrust injury." *Cascades Comput. Innovation LLC v. RPX Corp.*, No. 12-CV-01143 YGR, 2013 WL 316023, at *9 (N.D. Cal. Jan. 24, 2019). Conclusory allegations are not afforded the assumption of truth. *See, e.g.*, *Am. Sales Co., Inc. v. AstraZeneca AB*, No. 10 Civ. 6062 (PKC), 2011 WL 1465786, at *2–3 (S.D.N.Y. Apr. 14, 2011).

The Complaint attempts to define two relevant product markets in which to assess the competitive effects of the allegedly unlawful conduct. One market purportedly comprises each brand HIV drug of Defendants and its generic equivalent; the other market purportedly comprises cART regimens. *See* CC ¶¶ 57, 376, 378. Neither market is plausible.

As to the first alleged market, Plaintiffs' assert that "[d]ue to, among other reasons, its use and varying ability to treat the conditions for which it is prescribed, and its side effect profile, each of the brand drugs is differentiated from all drug products other than AB-rated generic versions." *Id.* ¶ 363. A relevant product market is not defined by differentiation; it is "determined by the reasonable interchangeability of use or the cross elasticity of demand between the product itself and substitutes for it." *Am. Sales*, 2011 WL 1465786, at *2 (citation omitted); *see also Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001) ("The product market includes the pool of goods or services that enjoy reasonable interchangeability of use and cross-elasticity of demand." (citations omitted)). The Complaint says nothing about reasonable interchangeability or cross elasticity of demand in attempting to plead such a narrow relevant product market.

On the contrary, to the extent the Complaint does make specific allegations of interchangeable substitute products, those allegations contradict any claim that the relevant product market is limited to each brand drug and its generic equivalents. *See, e.g.*, CC ¶ 113 (an FDC comprising EVG and generic RTV could have competed with "both Stribild and Genvoya because patients could have taken it together with Truvada (TFG/FTC) or Descovy (TAF/FTC)"); *id.* ¶ 139 (Complera and Stribild compete against Atripla. TAF-based FDCs replace TDF-based FDCs); *id.* ¶ 153 (Janssen could have marketed a "comparable product" to Odefsey by using "TAF (or TDF), 3TC (rather than FTC), and RPV"); *id.* ¶¶ 184, 186 (as-effective FDCs could be made with "generic or comparable versions of TDF and/or FTC"); *id.* ¶ 388 ("3TC is a competitor to FTC"). When a proposed product market "'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 must be granted.'" *Chapman v. N.Y. State Div. for Youth*, 546 F.3d 230, 238 (2d Cir. 2008) (quoting *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997)).

The so-called "cART Market" alleged in the Complaint also does not satisfy the requirement of pleading a product market in which to assess the effects of the Janssen/Gilead collaboration agreements, because it is defined in terms of *any HIV treatment*—in the broad category of cART—*that includes at least one Gilead component*. CC ¶ 1. Plaintiffs do not allege that any of the four FDCs that Janssen jointly developed with Gilead—Complera, Prezcobix, Odefsey and Symtuza—had market power in this alleged cART Market.

3. Plaintiffs Fail to Plead Antitrust Injury.

To survive a motion to dismiss on a Sherman Act Section 1 claim, another element Plaintiffs must adequately plead is antitrust injury. *See Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1197 (9th Cir. 2012) (requiring plaintiffs to plead "that they were harmed by the defendant's anti-competitive contract, combination, or conspiracy, and that this harm flowed from an 'anti-competitive aspect of the practice under scrutiny'") (citation omitted). In conclusory fashion, Plaintiffs claim that "[b]ut for Gilead and Janssen's unlawful conduct, competitors would have begun marketing generic or comparable versions of the brand products much sooner than they did

and/or would have been able to market such versions more successfully." CC ¶ 502. This theory of antitrust injury is fundamentally flawed.

First, each of the FDCs co-developed by Janssen and Gilead is lawfully protected from generic competition by patents or regulatory exclusivity. *See id.* ¶ 130 (Gilead's FTC patent protected until 2021); *id.* ¶ 110 (Gilead's TAF patent protected until 2032); *id.* ¶ 150 (Janssen's RPV patents extend to 2025); *id.* ¶ 164 (Gilead's COBI patent protected until 2029); *id.* ¶ 173 (Janssen's DRV patents extend to 2026 "assuming no pediatric exclusivity is awarded"). Plaintiffs acknowledge this restraint on generic competition in the Complaint, for example, where it states: "the markets require government approvals to enter and/or may be covered by patents or other forms of intellectual property." *Id.* ¶ 398. Thus, until the Gilead and Janssen intellectual property protections expire, it is those protections—not the agreements between Janssen and Gilead—that block third-party manufacturers from marketing generic versions of the Janssen/Gilead FDCs. Accordingly, any alleged harm to competition is purely speculative at this point, particularly since the patent protection on Janssen's RPV (the third agent in Complera and Odefsey) does not expire until 2025, and the patent protection on Janssen's DRV (the third agent in Prezcobix and Symtuza) does not expire until 2026.

Further, once the blocking patents expire, nothing in the collaboration agreements between Janssen and Gilead precludes third-party manufacturers from seeking FDA approval, without any need for assistance from the joint venture partners, to market generic versions of Complera, Odefsey, Prezcobix, or Symtuza. Indeed, the Complaint acknowledges that generic manufacturers have already filed ANDAs for some of the compounds that make up the FDCs at issue. *See, e.g.*, *id.* ¶ 163 (in October 2010, Janssen received notice from Mylan that it had submitted an ANDA for Prezista); *id.* ¶ 62 (the FDA approved generic TDF in December 2017).

III. THE COMPLAINT AGAINST J&J SHOULD BE DISMISSED ALSO BECAUSE THERE ARE NO SPECIFIC ALLEGATIONS AGAINST IT

To avoid dismissal, Plaintiffs must allege that each individual Defendant joined in the conspiracy and played some role in it. *See, e.g.*, *In re Capacitors Antitrust Litig.*, 106 F. Supp. 3d at 1066; *see also In re TFT-LCD (Flat Panel) Antitrust Litig.*, 586 F. Supp. 2d at 1117. J&J, the

indirect corporate parent of Janssen, is not alleged to have participated in a conspiracy with the other Defendants, nor was it even a party to any of the collaboration agreements at issue. In fact, Plaintiffs make no specific allegations as to J&J individually. *See* CC ¶ 48 ("Janssen R&D Ireland and [J&J] are collectively referred to herein as 'Janssen.'").

Plaintiffs are, presumably, relying on J&J's status as an indirect corporate parent as a basis to keep them in the case. However, a corporate parent cannot be held liable merely because a Sherman Act claim has been asserted against its subsidiary. *In re Pressure Sensitive Labelstock Antitrust Litig.*, 566 F. Supp. 2d 363, 376 (M.D. Pa. 2008); *see also Calvert v. Huckins*, 875 F. Supp. 674, 678–79 (E.D. Cal. 1995) (finding that plaintiff failed to show that grandparent and parent companies did anything other than "exercise the broad oversight typically indicated by common ownership and common directorship" and holding that "consolidating the activities of a subsidiary into the parent's annual reports is a common business practice"). For this additional reason, J&J should be dismissed.

CONCLUSION

For the foregoing reasons, Janssen and J&J respectfully request the Complaint be dismissed against them with prejudice.

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