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BRISTOL-MYERS SQUIBB COMPANY &
E. R. SQUIBB & SONS, L.L.C.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

PETER STALEY; STEVE FULLER; GREGG S. GONSALVES, PhD; BRENDA EMILY GOODROW; ANDREW R. SPIELDENNER, PhD; ROBERT J. VAZQUEZ; JASON WALKER; MICHAEL WARNER; JACOB ZYDONIS; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND; and SERVICE EMPLOYEES INTERNATIONAL UNION, LOCAL NO. 1 HEALTH FUND, on behalf of themselves and all others similarly situated.

Plaintiffs,

v.

GILEAD SCIENCES, INC.; GILEAD HOLDINGS, LLC; GILEAD SCIENCES, LLC; GILEAD SCIENCES IRELAND UC; BRISTOL-MYERS SQUIBB COMPANY; E. R. SQUIBB & SONS, L.L.C.; JAPAN TOBACCO, INC.; JAPAN TOBACCO INTERNATIONAL U.S.A., INC.; AKROS PHARMA INC.; JANSSEN R&D IRELAND; and JOHNSON & JOHNSON, INC.,

Defendants.

Case No. 3:19-cv-2573

BRISTOL-MYERS SQUIBB COMPANY AND E.R. SQUIBB & SONS LLC'S MOTION UNDER RULE 12 TO DISMISS FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

Date: January 16, 2020
Time: 1:30 p.m.
Dept: Courtroom 5 - 17th Floor

Honorable Edward M. Chen

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 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 Bristol-Myers Squibb Company and E.R. Squibb & Sons, L.L.C. (together, "BMS") will and hereby do move the Court for an order dismissing, with prejudice, all claims against BMS under Rule 12(b)(6) of the Federal Rules of Civil Procedure. This Motion is based on this Notice of Motion and Motion, the Memorandum of Points and Authorities, Gilead's Request for Judicial Notice and exhibits thereto (ECF No. 145), and the Declaration of Heather Burke in Support of Gilead's Motion to Dismiss and exhibits thereto (ECF Nos,. 143-1 to 143-16), the 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.

STATEMENT OF ISSUE TO BE DECIDED

Whether the factual allegations of Plaintiffs' Corrected Consolidated Complaint state a plausible antitrust claim against BMS under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

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INTRODUCTION

Bristol-Myers Squibb Company and E.R. Squibb & Sons, L.L.C. (together, "BMS") obtained the rights under Gilead's patents to develop two novel and important medications to treat HIV: Atripla® and Evotaz®, fixed dose combination ("FDC") drugs combining multiple patented drugs in a single pill. Atripla®, the result of a collaboration with Gilead to combine Gilead's Truvada® and BMS' Sustiva®, was the first drug to combine all of the agents of HIV therapy in one pill. The Secretary of Health and Human Services celebrated Atripla® as "an important advance in our collective effort to deliver simplified therapy for people living with HIV." Dec. 17, 2004 Collaboration Agreement ("JV Agreement"), Annex L, Burke Decl. Ex. A, ECF No. 143-2.

Plaintiffs acknowledge that reducing pill burden is an important goal in HIV treatment, and profess not to challenge the procompetitive benefits of FDC drugs. They also recognize that each of the component drugs was protected by patents that prevented either party to the agreements from combining them on its own. Nevertheless, they contend that the agreements that made such drugs possible contained so-called "no-generic restraints" that foreclosed defendants and others from developing hypothetical mix-and-match combinations of various standalone therapies. There is nothing in the Complaint but conjecture as to what would have happened but for the challenged agreements, and this alone warrants dismissal. But the Complaint suffers from an even more obvious flaw: the contention that the Atripla® and Evotaz® agreements precluded either party from creating competing drugs using generic components is belied by the agreements themselves.

The Atripla® joint venture agreement does not contain any restraint on the development of FDCs formulated with generic components. To the contrary, its terms left each company free to use its patented components with generic versions of any other drug, including generic versions of the other's components. It also allowed each party to license their patented components to third parties for use in any other combination. And, not only did it not prevent the parties from creating or marketing a competing FDC using generic components, it expressly contemplated that either party could and would do just that once the other's patented version was no longer needed. The plain language of the agreement makes this clear, refuting Plaintiffs' unsupported "no-generics" allegation.

The Evotaz® agreement also lacks any so-called "no generics" provision. By giving BMS an

exclusive license to use its patented Tybost® (COBI) in combination with BMS' Reyataz® (ATV), Gilead surrendered the right to make and market the same combination itself. But any exclusive license does this; by granting another the sole right to use its patent for a particular purpose, the licensor surrenders the right to do so itself. Plaintiffs' theory would make all exclusive licenses unlawful, when they are expressly allowed by the patent statute itself. 35 U.S.C. § 261. Nor did the Evotaz® agreement prevent Gilead from licensing COBI to other companies for use in other FDCs, even those that would compete with Evotaz®. In fact, as Plaintiffs acknowledge, Gilead did just that.

Plaintiffs' claim that BMS participated in an "overarching conspiracy" with other companies to assist Gilead in maintaining a monopoly on its own products is equally implausible. The Complaint contains not a single allegation to connect BMS to Gilead's agreements with other parties and does not (and cannot) allege that BMS shared a common goal with Gilead to help Gilead perpetuate a monopoly. Moreover, the theory makes no sense: what reason would BMS have to commit to a scheme that was intended to help Janssen and Japan Tobacco create FDCs with Gilead that were intended to and would compete directly with BMS's own products?

Finally, Plaintiffs' theory of anticompetitive harm with respect to both agreements is implausible. Plaintiffs maintain that but for the agreements between Gilead and BMS, someone might have created various mix-and-match FDCs combining patented and generic components as soon as some components were no longer protected by patents. Alternatively, they posit that BMS itself would have challenged patents on Gilead's drugs to introduce all-generic versions on its own. Putting aside the improbability that a brand pharmaceutical company would file an Abbreviated New Drug Application, challenging another company's patents, and seek approval to market a generic drug, these hypotheses fail to articulate a cognizable antitrust injury. As Plaintiffs themselves admit, each of the individual component drugs of Atripla® and Evotaz® remained available to patients, prescribers, and payors at all times. As a result, any patient could purchase standalone Truvada® (containing patented TDF and FTC) to use with standalone generic EFV to capture savings on the latter drug, and any payor could decline to reimburse purchases of a more expensive all-brand-component FDC on that basis. The same is true of Evotaz® and its components. The FDCs were more convenient for doctors and patients, to be sure, and reducing pill burden is important, as the

Complaint points out. But the contention that the agreements "prevent[] purchasers from obtaining [the] competitive benefits" of generic components (CCC ¶ 129) is refuted by the factual allegations in the Complaint.

BACKGROUND

BMS is a global innovator biopharmaceutical company that discovers, develops, and delivers medicines, including medicines to treat HIV infection.[1] CCC ¶ 118. BMS held patents on two standalone HIV "third agents": efavirenz ("EFV"), which it marketed as Sustiva®; and atazanavir sulfate ("ATV"), which it marketed as Reyataz®. In 2004 and 2011, BMS and Gilead entered into two separate agreements, each for the purpose of co-formulating one of BMS' third agents with a Gilead product to create a new single tablet FDC.

The Atripla® Joint Venture: In 2004, BMS and Gilead agreed to collaborate on an FDC that would pair BMS' EFV with Gilead's NRTI "backbone," consisting of TDF and FTC. CCC ¶ 118. Gilead and BMS formed a joint venture, Bristol-Myers Squibb & Gilead Sciences, LLC, (the "JV") to develop and commercialize Atripla®, the first single tablet regimen to treat HIV. CCC ¶¶ 67, 118. Atripla® reduced the "pill burden" on patients, improving adherence and efficacy. CCC ¶ 194.

Under the agreement, Gilead and BMS each granted the JV licenses to its patented components to develop Atripla®. CCC ¶ 119. While the licenses were "exclusive" as to the JV, they were *not* exclusive as to the parties. *See* JV Agreement, § 6.1.[2] This meant that the JV itself was only authorized to use the licensed component drugs for the purpose of creating a specific FDC combining TDF, FTC, and EFV. But because the licenses were non-exclusive as to the licensors, each party retained full rights to combine its own drugs with any other drugs, including generic versions of the other party's drugs. So, for example, the license grant would not have prevented BMS from combining EFV with generic TDF/FTC, if those became available. Likewise, Gilead retained rights to combine its patented components TDF/FTC with generic EFV, should that become available. In addition, nothing in the agreement prevented BMS from licensing its EFV to third parties for use

[1] The evolution of HIV combination therapies, as well as the many benefits of FDCs, is described in Gilead's Memorandum in Support of its Motion to Dismiss ("Gilead Br."), pp. 6-8, ECF No. 143.
[2] As noted in Gilead's brief, the Court may consider the at-issue BMS/Gilead agreements attached as Exhibits A and B to the Declaration of Heather Burke ("Burke Decl.") because they have been "incorporated by reference" in the Complaint. *See* Gilead Br. at p. 6.

in combination with other compounds; likewise, Gilead could do the same. *Cf.* CCC ¶ 140.

Moreover, the agreement contemplated that generic versions of the component drugs might become available, and explicitly provided a way for the JV itself to use them in Atripla® when that occurred. CCC ¶¶ 124-25; JV Agreement, § 14.5. The agreement allowed the party whose component remained under patent to terminate the other's involvement in the JV, once generic versions of that party's product(s) became available. CCC ¶ 124. And, as the Complaint acknowledges, that is exactly what happened. On the eve of the expiration of BMS' patent, Gilead exercised its right to terminate BMS from the JV pursuant to that provision in December 2017. CCC ¶ 127, 141. Gilead continues to market Atripla®. CCC ¶ 378.

The COBI License: On October 25, 2011, seven years after formation of the Atripla® JV, BMS and Gilead executed a separate licensing agreement that allowed BMS to develop and commercialize another FDC. This FDC combined BMS' patented ATV, a protease inhibitor third agent, with Gilead's COBI, a booster drug then in development. CCC ¶¶ 131, 133. Under this agreement, Gilead granted BMS an exclusive license to make, use, and sell COBI co-formulated with ATV. Oct. 25, 2011 Licensing Agreement, § 8.1, Burke Decl., Ex. B. In January 2015, BMS received FDA approval for the FDC, which it markets as Evotaz®. CCC ¶ 133. The license grant was limited to co-formulation with ATV; Gilead retained the right to license (or itself use) its COBI for any other use. Gilead exercised this right in 2014, when it licensed COBI to Janssen for the development of a competing FDC, Prezcobix®, which combines COBI with Janssen's third agent DRV. CCC ¶¶ 168-69.[3] Throughout the course of the agreement, both components of Evotaz® were sold independently.

Causes of Action Asserted Against BMS: The Complaint asserts five causes of action that name BMS: three claims premised on a purported overarching conspiracy (Counts I, II and VII) and two counts premised on the specific agreements between BMS and Gilead (Counts XII and XIII).

ARGUMENT

To survive a motion to dismiss, a complaint alleging violation of the antitrust laws must plead

[3] Notably, as Plaintiffs acknowledge, neither Evotaz® nor Prezcobix® contains tenofovir or any other Gilead NRTI, making it unclear how these drugs relate to Plaintiffs' theory of an overarching conspiracy to promote Gilead's purported monopoly in tenofovir products. *See* CCC ¶ 67, 133, 164,. The Complaint's allegations that *each* agreement prohibited creation of an FDC containing generic versions of Gilead's NRTIs (CCC ¶95) is accordingly incorrect.

"enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *accord Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). It is not enough to assert in conclusory fashion that a defendant participated in a conspiracy; conspiracy is a legal conclusion. *See Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1047 (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." *Id.* at 1049. Rather, an antitrust plaintiff must plead facts that if proved would establish "each defendant's agreement to participate in what it knows to be a common goal." *R.E. Davis Chem. Corp. v. Nalco Chem. Co.*, 757 F. Supp. 1499, 1515 (N.D. Ill. 1990). Plaintiffs fail to meet this standard.

I. THE COMPLAINT FAILS TO ALLEGE ANY VIOLATION OF THE ANTITRUST LAWS ARISING FROM THE ATRIPLA® AGREEMENT

A. The Atripla® Collaboration Was a Procompetitive Joint Venture.

Plaintiffs readily concede that the challenged Atripla® agreement was a procompetitive joint venture that created a new and groundbreaking product combining Gilead's Truvada® with BMS' Sustiva®, therapeutically distinct products that were often prescribed together. As Plaintiffs allege, the JV priced the Atripla® FDC slightly below the combined cost of Sustiva® and Truvada® if purchased separately, reflecting the competition it faced from the parties' standalone components (CCC ¶ 121); payors would be unlikely to reimburse for the combination product if its individual components could be purchased at lower cost.

B. The Atripla® Agreement does Not Contain a "No-Generics Restraint."

Plaintiffs do not dispute the life-saving benefits of FDCs, and they profess not to "contend that any statutory or regulatory exclusivity that FDCs may enjoy is anticompetitive." CCC ¶ 93. The crux of Plaintiffs' allegations concerning the Atripla® agreement is that it contained a "No-Generics Restraint" by which BMS and Gilead purportedly "agreed not to create or market a competing FDC made with generic or comparable versions of Gilead's NRTIs even after the patents on them expired." CCC ¶ 95. Any such restriction in a joint venture is lawful—after all, it is reasonable for each party to a proposed joint venture to expect the other not to directly compete with it. *See Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 190 (7th Cir. 1985) (upholding territorial restraint between

JV and parents as necessary to prevent free riding) (citing *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752 (1984)); *Major League Baseball Props., Inc. v. Salvino*, 542 F.3d 290, 340 (2d Cir. 2008) (upholding joint venture among baseball clubs prohibiting sale of trademark licenses); *compare Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 38 (D.C. Cir. 2005) (condeming agreement between joint venture parties not to compete on sales of products that were not part of the joint undertaking). But the Court need not reach that issue here because the plain language of the JV Agreement reflects that nothing in it restrained either party from marketing a competing FDC using generic components.

Section 6.1(b) of the JV Agreement provides: "BMS hereby grants to the JV a sole, royalty-free license (which license shall be exclusive as to Gilead, its Affiliates and all Third Parties **but not as to BMS and its Affiliates**) . . . only to Exploit the Combination Product . . ." (emphasis added). The Agreement defines "Combination Product" as: "the fixed-dose co-formulated product developed pursuant to this Agreement containing, as its only active pharmaceutical ingredients per single daily dose, 300 mg TDF, 200 mg FTC and 600 mg EFV." JV Agreement, § 1.50.Gilead granted a similar license, which was not exclusive as to Gilead. JV Agreement, § 6.1(a). Taken together, these provisions authorized the JV's use of BMS' and Gilead's drugs for the purpose of making the combination product, Atripla®. But by granting to the JV non-exclusive licenses, both patentees—BMS and Gilead—reserved rights to use their drugs for any purpose—including in combination with generic TDF, FTC, and EFV should they become available.[4]

The limited licenses also allowed both BMS and Gilead to combine their molecules with "comparable" drugs. Indeed, Plaintiffs allege that during the term of the Atripla® agreement, Gilead launched Complera® and Stribild®, two FDCs containing Truvada® and Janssen's third agents that "compete against Atripla®." CCC ¶¶ 107, 139, 143. They also concede that, in contrast to the other at-issue agreements, the Atripla® agreement "did *not* prohibit BMS from making a *comparable* FDC." CCC ¶ 140. As the Complaint points out, BMS exercised its right to do so by licensing Sustiva® to Mylan to make a comparable, competing FDC comprising TDF, 3TC, and EFV. *Id.*

[4] Furthermore, while the JV might not have been explicitly *authorized* by the licenses to create combination products containing generic components, neither was it (or each party individually) *contractually prohibited* from doing so. In general, if a licensee exceeds the scope of a license the licensee may subject itself to a patent infringement lawsuit but it is not in breach of the license. *See Macom Tech. Sols. Holdings, Inc. v. Infineon Techs., AG*, 881 F.3d 1323, 1329 (Fed. Cir. 2018).

Moreover, the parties recognized that generic versions of the component drugs would become available, and the agreement expressly took that eventuality into account. As Plaintiffs acknowledge, the agreement provided a roadmap for either party to develop an FDC with generic components *even through the JV itself*. CCC ¶¶ 124-25. Section 14.5 provides:

> Either Member Party (the "Continuing Member Party") may terminate this Agreement . . . in the event that there is the Launch in the Territory of at least one (1) Generic Version of all of the Single Agent Products (or the Double Agent Product) of the Terminated Member Party (a "Generic Version Launch") and the Continuing Member Party delivers notice of termination within thirty (30) days after the Generic Version Launch . . . .

Either party accordingly had the option to terminate the other from the JV upon the generic launch of the other party's contributions. When that happened, the JV would not be dissolved, but instead could continue to manufacture Atripla® using generic inputs. *See* JV Agreement § 14.6(b).

As the Complaint concedes, as soon as EFV became available in December 2017, Gilead *immediately* terminated BMS from the JV. CCC ¶ 141. Gilead continued to operate the JV and to market Atripla®. These events refute the Complaint's suggestion that a so-called "penalty" provision (CCC ¶¶ 124-25) would deter the non-terminated party from substituting a generic version of the other's. Gilead *in fact* terminated the agreement and did so immediately, so-called penalty or not.

In sum, the Atripla® agreement: (1) left each company free to use its drug components individually or in combination with generic components; (2) allowed them to license EFV or TDF/FTC to third parties for use in any other combination; and (3) expressly provided a process for the substitution of generic versions of the component compounds upon the generic launch of either BMS or Gilead's patented drugs. Plaintiffs' allegations are refuted by the agreement, and on a motion to dismiss, the court is "not required to accept as true conclusory allegations which are contradicted by documents referred to in the complaint." *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1295-96 (9th Cir. 1998); *see also Tritz v. U.S. Postal Serv.*, 721 F.3d 1133, 1140 (9th Cir. 2013) (dismissing a complaint for failure to state a claim where attached documents directly contradicted the complaint's allegations). The agreement in no way restricted the use of generic drugs, and Counts XII and XIII should be dismissed to the extent they relate to the Atripla® agreement.

II. THE COMPLAINT FAILS TO ALLEGE ANY VIOLATION OF THE ANTITRUST LAWS ARISING FROM THE EVOTAZ® AGREEMENT

A. The Evotaz® Agreement is a Lawful Exclusive Patent License.

Despite alleging that the COBI license is exclusive and disclaiming any challenge to lawfully granted patents, Plaintiffs assert that the license was an unlawful horizontal market allocation because it "prohibit[ed] Gilead from commercializing its own FDC that contains a generic version of ATV." CCC ¶ 134. An "exclusive license, by itself, does not constitute an illegal restraint under the antitrust laws." *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428, 432 (N.D. Cal. 1992). Exclusive patent licenses like this one are commonplace, lawful, and procompetitive.

As the owner of the COBI patent, Gilead was free to practice its patent or give to another the exclusive right to do so. The patent statute itself makes clear that a patent holder can "grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. § 261; *see also Cataphote Corp. v. DeSoto Chem. Coatings, Inc.*, 450 F.2d 769, 774 (9th Cir. 1971) ("A patentee has the untrammeled right to suppress his patent or to grant an exclusive or nonexclusive license.") (citing *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 94 (1902)).

A patentee like Gilead may limit its license to a specified territory, a group of customers, or a particular class or "field" of use. *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 126 (1938) ("[T]he owner of [a] patent may legally restrict a licensee to a particular field and exclude him from others."); *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006) ("Field of use licensing restrictions, i.e., permitting the use of inventions in one field and excluding it in others, are also within the scope of the patent grant."). Courts recognize that such field of use patent licenses are often procompetitive and output expanding, especially when, as here, they facilitate the invention of a new product that neither party could have made on its own. In *United States v. Birdsboro Steel Foundry & Mach. Co.*, 139 F. Supp. 244 (W.D. Pa. 1956), for example, the court upheld exclusive cross-licenses allowing two steel machinery manufacturers to create an innovative product combining their respective technologies. The court reasoned that neither company could "independently of the other, make cooling beds containing the advantageous features desired by the trade without trespassing on patent rights owned by the other." *Id.* at 250. Here, the COBI license agreement allowed BMS to create a new FDC that could not have existed without a license from Gilead. *See*

also Abbott Labs. v. Baxter Int'l Inc., No. 01-cv-4809, 2002 WL 467147, at *10 (N.D. Ill. Mar. 27, 2002) (recognizing procompetitive benefits of exclusive license that "created a new competitor" to patentee's product), *aff'd*, 315 F.3d 829 (7th Cir. 2003).

The license grant was within the scope of Gilead's patent, and development of any competing product was foreclosed by the patent, not the license. Plaintiffs' theory ignores the existence of the patent altogether. In *United States v. CIBA GEIGY Corp.*, 508 F. Supp. 1118 (D.N.J. 1976), the court rejected a similar challenge to a license agreement between CIBA Geigy and Abbott, which restricted Abbott's ability to sell the licensed drug in bulk form to generic manufacturers. The court rejected the government's contention that the agreement foreclosed generic competition because it "fails to account for the existence of the patent monopoly." *Id.* at 1150. The court explained:

> Any limitation contained in a patent license, by definition, results in a restraint of trade. The restraint inheres in the grant of the patent itself which by its terms conveys the power to exclude. Therefore, it seems fruitless to attempt to judge the legality of a particular limitation contained in a license in terms of the competition it prevents from coming into existence. Rather, the legality of a limitation or series of limitations can only be judged with references to the scope of the monopoly created by the letters patent.

Id. at 1149. Finding that the restriction did not expand CIBA's monopoly beyond that implicit in the patent grant itself, the court upheld the use restriction. *Id.* The COBI license is no different. Plaintiffs complain only that the license prohibited Gilead from doing what it gave BMS the exclusive right to do. But every exclusive patent license does this. The patent confers on the patentee the right to decide whether the most profit-maximizing course is to practice its patent itself, in whole or in part, whether to license another to do so, or to do neither.

Furthermore, even under Plaintiffs' theory, the agreement did not restrain competition. Gilead reserved for itself and its potential licensees the right to combine COBI with other third agents to make FDCs that were comparable to Evotaz®. This is exactly what Gilead did when it licensed COBI to Janssen to make other FDCs, Prezcobix® and Symtuza®. CCC ¶¶ 164-65.

B. Plaintiffs Allege No Facts to Support the Assertion that the COBI License was a Quid Pro Quo for the Atripla® Agreement

Plaintiffs assert that the COBI license was somehow a "quid pro quo" for Atripla®. CCC ¶¶ 4-5, 131. While there is nothing nefarious about one wholly lawful agreement being consideration

for another, the allegation is unsupported and implausible in light of the Complaint's other allegations.

Plaintiffs offer no facts to support this "quid pro quo" theory, and Plaintiffs' own timeline undercuts it. BMS and Gilead entered into the COBI license in October 2011—nearly seven years after the Atripla® JV agreement was signed. Plaintiffs offer no explanation for how some future license to a booster compound that was not yet in development was intended to return the "favor" BMS did by entering into the Atripla® JV. Failing to allege any other facts suggesting a relationship between Evotaz® and Atripla®, Plaintiffs' quid pro quo theory does not satisfy *Twombly*.

Moreover, the swap theory alleged in the Complaint is that the Atripla® agreement somehow served to extend the patents on Gilead's tenofovir components, while the COBI license agreement somehow served to extend exclusivity for BMS' component. CCC ¶¶ 4-5, 131. But in both cases, BMS' patents expired before Gilead's. Atripla® is a combination of Gilead's TDF, the patent for which expired in January 2018 (CCC ¶ 96); BMS' EFV, whose patent would also expire in January 2018 (CCC ¶ 127); and Gilead's FTC, with a patent expiration date of 2021. CCC ¶ 96. Evotaz® is a combination of Gilead's COBI, at least one patent for which will not expire until 2029, (CCC ¶ 133) and BMS' ATV, which faced generic competition in December 2017 (CCC ¶ 137). In both instances, Gilead had the longer-running patents. Plaintiffs' purported quid pro quo consists of two quids. Plaintiffs' challenge to the exclusive nature of the COBI license should be rejected as a matter of law. Counts XII and XIII should be dismissed to the extent they relate to that agreement.

III. PLAINTIFFS HAVE NOT PLAUSIBLY ALLEGED HARM ARISING FROM THE ATRIPLA® OR EVOTAZ® AGREEMENTS.

A further defect in all of Plaintiffs' claims against BMS is the insufficiency of their allegations of antitrust injury. The Complaint suggests two distinct theories of injury. The first is that but for BMS' agreements with Gilead, an "untainted competitor" would have successfully challenged Gilead's and/or BMS' patents and entered the market with a less expensive FDC before the expiration of the last of the patents covering the FDC's components. The second is that the FDC agreements deprived patients and payors access to cheaper, generic alternatives to the patented drugs. The first theory is unduly speculative; the second is refuted by allegations in the Complaint itself.

With respect to Atripla®, Plaintiffs assert that BMS, had it not been "tainted" by its

participation in the JV, would have challenged Gilead's TDF and FTC patents. CCC ¶¶ 129–130. This theory relies on a series of unreasonable assumptions: (1) that an innovator pharmaceutical company like BMS with no generics business unit would file an Abbreviated New Drug Application to challenge Gilead's patents; (2) that Gilead would then sue BMS for patent infringement and lose; and (3) that BMS would then formulate, seek approval for, and market an FDC containing all generic components. Had BMS failed in any of those steps, there would have been no FDC combination of TDF, FTC, and EFV until the last relevant patent on all three drugs expired in 2021. CCC ¶¶ 127-30. The collaboration between the parties therefore brought the new FDC drug to market 15 years sooner than it would have been available in the absence of collaboration.

With respect to the COBI license agreement, Plaintiffs' "untainted competitor" theory is that but for the agreement, Gilead would have launched an FDC containing COBI and generic ATV by December 2017, when generic ATV became available. CCC ¶¶ 137-38. But Plaintiffs fail to explain why a patentee in Gilead's position would choose to wait until generic ATV became available to develop an innovative COBI/ATV FDC, instead of pursuing a collaboration with BMS, as it did. Indeed, the Complaint alleges facts suggesting that Gilead had an independent business justification for licensing its COBI to BMS when both COBI and ATV were patent protected. *See Univ. Grading Serv. v. eBay, Inc.*, 563 F. App'x 571, 572 (9th Cir. 2014) (dismissing antitrust claims where "the claimed conspiracy would have made no economic sense" and defendant "presented a valid business justification" for the challenged policy). The licensing agreement allowed Gilead to reap the fruits of its lawful patents on COBI immediately, and permitted BMS to introduce a new FDC drug six years earlier than it otherwise could have. The Complaint's theory as to what a hypothetical "untainted" competitor would have done instead of pursuing licensing arrangements—plainly a more efficient way to get to market—is too speculative to support a cognizable theory of antitrust injury.

More fundamentally, Plaintiffs' theories of competitive harm entirely ignore that in all cases the relevant components of the FDCs remained available for purchase as stand-alone products. *See* CCC ¶¶ 67, 280-81.[5] Thus, as soon as any one drug became available in generic form, a purchaser

[5] Cases alleging impermissible "tying," or a seller's refusal to sell one product unless the buyer also purchases another, are instructive. There, courts recognize "[w]here the buyer is free to take either *(cont'd)*

could buy the generic version of that standalone component while continuing to buy or reimburse for the patent-protected brand versions of the other ingredient(s). This alternative would allow the purchaser to enjoy any benefit of a lower price on the generic component. The Complaint nowhere alleges that this alternative was unavailable to purchasers of the BMS FDCs. As a result, the harm at issue here is not an *economic* harm but instead the *non-economic* harm to a patient unable to procure the desired products—whether directly or because of payor's policies—in a more convenient single tablet form. The benefits of a single pill are undeniable in this therapeutic area. But having to take two pills a day instead of one is not the type of interest protected by the antitrust laws, which concern quantifiable *economic* injury. *See, e.g.*, *Ashley Meadows Farm, Inc. v. Am. Horse Shows Ass'n*, 617 F. Supp. 1058, 1064 (S.D.N.Y. 1985) (where challenged rule "caused [plaintiff] some inconvenience, these allegations simply do not indicate that [plaintiff] has suffered any injury redressable under the antitrust laws."). For this reason as well, Counts XII and XIII should be dismissed.

IV. THE ALLEGATIONS DO NOT SUPPORT THE EXISTENCE OF ANY OVERARCHING CONSPIRACY

In an effort to subject the defendants to joint and several liability for all of the agreements, Plaintiffs claim that all defendants entered into an overarching conspiracy. But this allegation also fails to satisfy *Twombly*. First, Plaintiffs do not allege any facts to support an inference that all defendants were aware of and committed to a "common scheme" to help Gilead protect its tenofovir drugs from competition. Not a single factual allegation supports the theory that all defendants knowingly and willfully joined together for any such purpose; the Complaint makes no reference to any meeting or communications among the defendants at all. Plaintiffs here allege only that Gilead, over the course of a decade, entered into separate, bilateral agreements with BMS, Janssen, and Japan

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product by itself there is no tying problem even though the seller may also offer the two items as a unit at a single price." *Robert's Waikiki U-Drive, Inc. v. Budget Rent-a-Car Sys., Inc.*, 732 F.2d 1403, 1407 (9th Cir. 1984). This is because stand-alone products sold separately are substitutes for the products sold in the same package. *See Pac. Bell Directory v. William Muhr, LLC*, No. 04-cv-9657, 2006 WL 8434072, at *9 (C.D. Cal. Aug. 16, 2006) ("If two products are offered as a bundle but the tying product can be purchased separately, then there is no antitrust violation . . ."). Similarly, the introduction of innovative improvements on existing products is only anticompetitive "when it coerces consumers and impedes competition." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015). These principles apply here. Patients and payors had a choice to purchase standalone drugs individually.

Tobacco, each of which took different forms and combined different drugs to create new HIV therapies. *See* CCC ¶¶ 94-95.

Further, there are no facts in the Complaint to support an inference that the agreements were interdependent—i.e., that the success of one venture was dependent on the success of the others. *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 Complaint itself suggests that any such theory is implausible. It is not credible that BMS would have joined in a scheme wherein Gilead would disparage TDF-based FDCs like Atripla® because, as Plaintiffs note, the Atripla® agreement was never amended to develop a successor product using TAF. CCC ¶ 139. It is equally implausible that BMS would have joined in a conspiracy that would enhance sales of competing FDCs to the detriment of its own. As Plaintiffs allege, Gilead began to market other FDCs developed with Janssen and Japan Tobacco (Complera® and Stribild®, respectively) "that compete against Atripla." CCC ¶ 139. Indeed, Gilead "thereafter concentrated its marketing efforts in promoting those products rather than Atripla®." CCC ¶ 139. The success of Atripla® was not dependent on the success of the Janssen or Japan Tobacco collaborations; to the contrary, the Complera® and Stribild® agreements undermined the JV. Likewise, the success of the COBI license was not dependent on the success of any of Gilead's other collaborations; Gilead subsequently entered into an agreement with Janssen to combine COBI with its protease inhibitor.

The theory that BMS participated in an overarching conspiracy for the benefit of Gilead and its other partners does not satisfy *Twombly*'s demand for plausibility. Thus, even if the Court finds that some claims regarding some agreements not involving BMS may go forward, Counts I, II and VII must be dismissed as to BMS.[6]

CONCLUSION

For the above reasons, BMS respectfully requests the Court dismiss all claims against BMS.

[6] BMS joins in Defendant Gilead's additional grounds for dismissal. First, the Atripla® JV and the COBI license were pro-competitive collaborations, and any restraints were reasonably ancillary to the procompetitive purpose. *See* Gilead Br. pp. 18-23. Second, Plaintiffs' claims must be dismissed for failure to allege a relevant market. *See id.* at 31-34. Third, Plaintiffs' state law claims must be dismissed for lack of standing, failure to allege concerted action, and failure to allege consumer protection theories. *See id.* at 34-40.

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Respectfully submitted,

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