# UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA

HUMANA INC., Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), Defendant. CV 19-6926 DSF (MRWx)

Order GRANTING in Part and DENYING in Part Defendant's Motion to Dismiss (Dkt. 65)

Defendant Mallinckrodt ARD LLC moves to dismiss (a) Counts I, II & III (federal and state antitrust laws) in their entirety, or at least to the extent based on any state's antitrust law except Maine, Vermont, or Wisconsin law; (b) Counts IV & V (RICO), Count VI (unfair competition law), Count VII (state consumer fraud and deceptive trade practices acts), and Count VIII (state insurance fraud statutes) to the extent based on allegations regarding co-pay assistance programs; (c) Count IX (tortious interference with contract) in its entirety; and (d) Count VII (state insurance fraud statutes) to the extent asserted under Kentucky or New Jersey law as alleged in Plaintiff Humana Inc.'s Second Amended Complaint (SAC). Dkt. 65-1 (Mot.). Plaintiff opposes. Dkt. 71 (Opp'n). The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15. For the reasons stated below, the motion is GRANTED in part and DENIED in part.

#### I. FACTUAL AND PROCEDURAL BACKGROUND

Defendant produces H.P. Acthar Gel (Acthar), a drug that has been available in the United States since it was approved by the FDA in 1952. Dkt. 60 (SAC) ¶¶ 2, 44. Plaintiff operates or administers Medicare Part D plans on behalf of federal and state governments and provides coverage for prescription drugs, including Acthar, through other plans. Id. ¶ 39. Acthar is an adrenocorticotropic hormone (ACTH) used as an anti-inflammatory. Id. ¶ 41. Acthar is approved to treat exacerbations of multiple sclerosis (MS) as well as other diseases and disorders. <u>Id.</u> ¶ 45. However, for many of these conditions, Acthar is not the "first-line treatment." Id. ¶ 46. Cheaper, non-ACTH drugs are used to treat the same indications. <u>Id.</u> ¶¶ 49-50, 60. Infantile spasms is the only condition for which Acthar is the "first-line treatment." Id. ¶ 51 n.4. There is only one other FDA-approved drug for infantile spasms. Id. ¶ 49 n.3. Acthar is the only long-acting ACTH drug approved for sale in the United States. Id. ¶ 61. Another ACTH drug, Synacthen, is approved for sale outside of the United States. <u>Id.</u> ¶ 70. Acthar is not marketed outside of the United States. Id.

Until 2001, when Defendant's predecessor, Questcor, acquired worldwide rights to sell and manufacture Acthar for \$100,000, plus royalties, Acthar was priced more competitively with other anti-inflammatory drugs. Id. ¶ 47. At that time, because Acthar was expensive to produce and not the first-line treatment for most conditions, the prior manufacturer considered discontinuing production. Id. However, as soon as Questcor acquired the rights to sell Acthar, it increased the price from approximately \$40 per vial to nearly \$750 per vial. Id. ¶ 54. On August 27, 2007, Questcor further increased the price from \$1,650 to \$23,269 per vial. Id. ¶ 55. By 2018, the price had increased to \$38,892. Id. ¶ 56. Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from \$50 million to \$500 million. Id. ¶¶ 57-58. Humana itself paid for almost \$800 million worth of Acthar since 2001. See id. ¶ 86.

In 2010, Questcor established an MS Acute Exacerbation Fund (MS Fund) with Chronic Disease Fund, Inc. (CDF), a Texas-based charity. Id. ¶¶ 29, 97-98, 108. The MS Fund helped patients with government insurance, such as Medicare, with co-pays for Acthar. Id. ¶ 98. Although the donation agreement stated that the donated funds were generally for the treatment of patients with acute exacerbations of MS, in reality it did not provide co-pay assistance to purchase any other drugs. Id. In 2011, Questcor established a Lupus Exacerbation Fund (Lupus Fund) that was purportedly to provide co-pay assistance for "any medically appropriate therapy," but in fact was used only to provide assistance for Acthar. Id. ¶ 100. In 2012, Questcor created a similar fund for rheumatoid arthritis (RA Fund). Id. ¶ 101. Between the time Questcor established the MS Fund in 2010 and 2013, Acthar sales for MS treatment nearly quadrupled. Id. ¶ 108.

In late 2012 and early 2013, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Id. ¶¶ 73-76. Questcor and three other companies (who were not disclosed) submitted serious bids. Id. The three other companies intended to develop Synacthen to compete with Acthar; Questcor had "inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer." Id. ¶ 76. However, Questcor's bid was the highest, at a minimum of \$135 million. Id. ¶¶ 77-78. Neither Questcor nor Defendant "made more than superficial efforts to pursue commercialization of Synacthen . . . to protect Acthar monopoly pricing." Id. ¶ 81. In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen to treat infantile spasms and nephrotic syndrome in the United States. Id. ¶ 82.

On March 9, 2020, the Court granted Defendant's motion to dismiss the antitrust claims and the tortious interference with contractual relations claim in the First Amended Complaint with leave to amend and denied the motion as to the remaining claims. Dkt. 57 (March Order). Defendant again seeks dismissal of the antitrust claims and tortious interference claims in their entirety, as well as

dismissal of the RICO claims, unfair competition claim, state consumer fraud and deceptive practices claims, and insurance fraud claims to the extent they are based on co-pay assistance programs. Defendant additionally seeks dismissal of the insurance fraud claims to the extent they are based on Kentucky or New Jersey law and 22 of the 25 state-law antitrust claims as barred by the statute of limitations.

## II. LEGAL STANDARD

Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. "[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam). However, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." Ashcroft v. Igbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement." Id. (quoting Twombly, 550 U.S. at 557) (alteration in original) (citation omitted). A complaint must "state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. This means that the complaint must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Igbal, 556 U.S. at 678. There must be "sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively . . . and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011).

Ruling on a motion to dismiss is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – that the pleader is

entitled to relief." <u>Iqbal</u>, 556 U.S. at 679 (alteration in original) (citation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

As a general rule, leave to amend a complaint that has been dismissed should be freely granted. Fed. R. Civ. P. 15(a). However, leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." <u>Schreiber Distrib. Co. v. Serv-Well</u> Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986).

## III. DISCUSSION

## A. Antitrust Claims (Counts I through III)

Plaintiff alleges that Defendant has monopoly power in the market for "long-acting ACTH drugs in the United States" and that Questcor's acquisition of the rights to develop and market Synacthen in the United States "restrained trade" in the relevant market and "eliminated [a] potential competitive threat" in order to "maintain its monopoly" so it can "stabilize or raise the price of Acthar to a higher level" and "suppress[] the output of long-acting ACTH drugs below the level of output" that would exist in a competitive market. SAC ¶¶ 140-42, 146-48. This conduct purportedly violates Sections 1 and 2 of the Sherman Antitrust Act and corresponding state antitrust laws.

"In order to state a Section 1 claim . . . plaintiffs must plead facts which, if true, will prove '(1) a contract, combination or conspiracy among two or more persons or distinct business entities; (2) by which the persons or entities intended to harm or restrain trade or commerce among the several States, or with foreign nations; (3) which actually injures competition," and "(4) 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." Brantley v. NBC Universal, Inc., 675 F.3d 1192, 1197 (9th Cir. 2012) (first quoting Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1046 (9th Cir. 2008); then quoting Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990)). Section 2 "targets 'the willful acquisition or maintenance of [monopoly] power as distinguished from

growth or development as a consequence of a superior product, business acumen, or historic accident." Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc., 555 U.S. 438, 448 (2009) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570 (1966)). "Simply possessing monopoly power and charging monopoly prices does not violate § 2." Id. at 447-48.

## 1. Market Power

Both Section 1 and Section 2 claims depend on whether Plaintiff has sufficiently alleged Defendant has market power in a relevant antitrust market. Newcal Indus., Inc. v. Ikon Office Sol., 513 F.3d 1038, 1044 n.3 (9th Cir. 2008) ("The 'relevant market' and 'market power' requirements apply identically under the two different sections of the Act, meaning that the requirements apply identically to" both Section 1 and Section 2 claims and plaintiff's "market allegations are either sufficient or insufficient for all [antitrust] claims."). "An antitrust complaint therefore survives a Rule 12(b)(6) motion unless it is apparent from the face of the complaint that the alleged market suffers a fatal legal defect." Id. at 1045. One such fatal defect is the failure of the alleged market to "encompass . . . all economic substitutes for the product." Id. The Court previously dismissed Plaintiff's antitrust claims, in part, for failing to allege a facially sustainable product market definition. March Order at 13.

Plaintiff now alleges that the relevant market is the market for "the sale of long-acting ACTH drugs in the United States." SAC ¶¶ 140 (Section 2), 147 (Section 1). Plaintiff further alleges that Defendant's product, Acthar, "represents 100% of th[at] sub-market."  $\underline{\text{Id.}}$  ¶ 60. Defendant contends that "the SAC . . . proposes yet another even narrower ACTH-only market that continues to exclude economic substitutes for Acthar described in Humana's own complaint." Mot. at  $2.^1$  This is true in some sense if each allegation is considered in a

<sup>1</sup> Although Defendant emphasizes that the proposed market definition is "even narrower" with the exclusion of short-acting ACTH, Defendant does not

appear to dispute that short-acting ACTH drugs are reasonably excluded from the relevant market. <u>See</u> Mot. at 6 (addressing why Plaintiff must

vacuum. In addition to the many paragraphs identified in the March Order that remain materially unchanged, March Order at 6-7 (citing FAC ¶¶ 6, 13, 43, 46, 49, 57, 84, 147, 151), Plaintiff's amended complaint adds allegations that appear to contradict its proposed market, see, e.g., SAC ¶¶ 49-50 ("prednisone is approved by the FDA to treat all of the same diseases and disorders as Acthar" and "Acthar has similar pharmacodynamic effects as corticosteroids"); id. ¶ 49 ("Acthar has been compared to intravenous methylprednisolone for treatment of MS relapses and to prednisone for treatment of sarcoidosis"). However, Plaintiff has also added allegations in support of its claim that there is a "long-acting ACTH drug[] . . . submarket within a broader market for adrenal hormone drugs." Id. ¶ 89. And within these allegations, the Court concludes that Plaintiff has adequately alleged a long-acting ACTH submarket.

"To plead an antitrust claim based on a submarket, 'the plaintiff must be able to show (but need not necessarily establish in the complaint) that the alleged submarket is economically distinct from the general product market." <u>Hicks v. PGA Tour, Inc.</u>, 897 F.3d 1109, 1121 (9th Cir. 2018) (quoting <u>Newcal Indus., Inc. v. Ikon Office Sol.</u>, 513 F.3d 1038, 1045 (9th Cir. 2008). A plaintiff can do so by alleging "industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." <u>Id.</u> (quoting <u>Brown Shoe Co. v.</u> United States, 370 U.S. 294, 325 (1962)).

allege indication-based markets and acknowledging Plaintiff's allegation that "short-acting ACTH drugs are not included in the relevant market 'because there is no overlap in the medical conditions that the drugs are approved to treat or diagnose" (citing SAC ¶ 52 n.6)); <u>id.</u> at 11-12 ("Only for those indications for which Synacthen proves effective and safe could it even be considered a possible potential new entrant, as Humana admits when excluding from its proposed market definition 'short-acting ACTH drugs."").

# a. <u>Industry or public recognition of the submarket as a</u> separate economic entity

Plaintiff alleges that "[l]ong-acting ACTH drugs are recognized by Mallinckrodt, medical providers, and the public as differentiated from other adrenal hormone drugs." SAC ¶ 89.a.; see also id. ¶ 50 ("Acthar . . . appears to be viewed by certain providers or patients as distinct from corticosteroids."). For example, "the widely-used First Data Bank (FDB) drug database" classifies corticosteroids like prednisone in a separate Therapeutic Class from Acthar and other ACTH drugs. Id. ¶ 52. Additionally, Defendant has acknowledged in its public filings that Acthar "has limited direct competition due to the unique nature of the product." Id. ¶ 61.

On the other hand, Plaintiff alleges that Defendant has "aggressively marketed" "studies . . . that claim to show clinical evidence supporting the superiority of Acthar compared with corticosteroid drugs." SAC ¶ 51. However, this seems to support, rather than refute, the idea that Acthar and corticosteroids are in the same market. See Hicks, 897 F.3d at 1122 ("claims of increased effectiveness" of products in the proposed submarket does not "place" those products "in a distinct market"). And Plaintiff also alleges that the FTC "recognized 'ACTH drugs' as a relevant antitrust market when evaluating [Defendant's] acquisition of Synacthen." SAC ¶ 89.a.ii. As the Court noted in the March Order, however, the fact that the FTC required Defendant to grant a license only for the treatment of two specific indications "highlights the flaws in a market definition untethered to drugs that are reasonably interchangeable for a given condition." March Order at 9 n.3.

Plaintiff's allegations as to this factor cut both ways.

# b. <u>Product's peculiar characteristics and uses</u>

Plaintiff contends ACTH drugs have a "biological mechanism of action [that] is distinct from other drugs in that they stimulate the adrenal gland to produce cortisol" while "Glucocorticoid drugs . . . do not work through the adrenal gland." SAC  $\P$  89.b.i.; see also id.  $\P$  51

("Acthar's mechanism of action is slightly different from that of corticosteroids"). Similarly, the only other drug approved to treat infantile spasms, Sabril, "is not a steroid, but is instead in a class of anticonvulsant drugs" that "works by inhibiting the breakdown of a particular neural transmitter." Id. ¶ 49 n.3. Defendant contends "the new allegations regarding the nature of corticotropin and its mechanism of action do not negate the fact that for some indications, noncorticotropin treatments remain available." Mot. at 8. And as the Court previously held, biological differences alone do not render ACTH drugs a distinct market. March Order at 7 n.2. However, the product's "peculiar characteristics," is one of many factors the Court is instructed to consider in determining whether the complaint has alleged a plausible submarket.

Importantly, Plaintiff also alleges ACTH drugs have uses different from other drugs used to treat the same conditions. For example, "Acthar is supposed to be a last-line treatment alternative that may be tried after corticosteroids have failed in the hope that Acthar, through its slightly different mechanism of action, may be effective where similar drugs have not been." SAC ¶ 51; see also id. ¶ 89.d.i. (Acthar is supposed to be prescribed only where "those drugs have either failed to treat their conditions or those drugs are contraindicated for that patient."); id. ¶ 89.d.iii ("Humana limits approved use of Acthar (other than for infantile spasms) under its policies to patients who have 'contraindications or intolerance to corticosteroids that are not expected to also occur with Acthar"). And for infantile spasms, "Sabril may be used in combination with longacting ACTH drugs, or it may be suitable where long-acting ACTH drugs have been ineffective at controlling infantile spasms or were not well tolerated by the patient." Id. ¶ 49 n.3.2 Defendant does not

<sup>&</sup>lt;sup>2</sup> Defendant contends that "the fact that 'Sabril may be used in combination with long-acting ACTH drugs' (SAC  $\P$  49 n.3) creates no fact issue as to whether it is not an alternative but a complementary product, like software is to hardware." Dkt. 78 (Reply) at 2 n.1 (citing Phillip E. Areeda & Herbert Hovenkamp, <u>Antitrust Law</u> § 565a (4th ed. 2020)). Defendant does not

address these allegations, focusing solely on the fact that long-acting ACTH drugs are FDA approved to treat the same conditions as other drugs.<sup>3</sup> But, Plaintiff has adequately alleged that, although ACTH drugs and other drugs can be used the treat the same conditions, they are not interchangeable in that doctors or patients are not choosing between long-acting ACTH drugs and other drugs at any given time. Rather, doctors and patients are only turning to long-acting ACTH drugs when other drugs are not an option. This supports a long-acting ACTH submarket.

## c. Unique production facilities

Plaintiff alleges that "Acthar is produced at only one facility in Prince Edward Island, Canada . . . using a complex, biologic process that is difficult to replicate" while "Glucocorticoid drugs are synthesized by manufacturers of chemicals for pharmaceuticals in a variety of facilities throughout the world" that "are not equipped to produce Acthar, nor could they be easily modified in order to do so."  $\underline{\text{Id.}}$  ¶ 89.c. This supports a long-acting ACTH submarket.

## d. Distinct customers

As discussed above, Plaintiff alleges that "[u]sers of Acthar are distinct from users of other adrenal hormone drugs because" Acthar is only supposed to be prescribed where "those drugs have either failed to treat their conditions or those drugs are contraindicated for that patient." Id. ¶ 89.d.i.; see also id. ¶ 89.d.iii ("Humana limits approved use of Acthar (other than for infantile spasms) under its policies to patients who have 'contraindications or intolerance to corticosteroids that are not expected to also occur with' Acthar"). Plaintiff further

explain why this is so. Further, at this stage, Plaintiff need not create a fact issue. All factual allegations are accepted as true.

<sup>&</sup>lt;sup>3</sup> That Defendant glossed over the import of these new allegations is evident by Defendant's incorrect claim that Plaintiff "attempts to justify the[] exclusion [of other drugs] based *solely* on its allegation that 'the drugs exhibit a very low degree of cross-price elasticity." Reply at 1.

alleges that "Acthar is inappropriately prescribed as a result of bribes paid to doctors . . . for patients for whom corticosteroids are an appropriate medical and economic substitute" and "[a]bsent the illegal bribe, Acthar would not be prescribed for these patients." Id. ¶ 89.d.ii. Defendant contends this allegation "confuses the issue more" because Plaintiffs describe Acthar and corticosteroids as "appropriate medical and economic substitute[s]." Mot. at 7. However, the Court understands Plaintiff's allegation to acknowledge that Acthar is considered for the same type of consumers (or the same uses) only where doctors are choosing to prescribe Acthar improperly and illegally. Because the parties do not address it, the Court assumes, without deciding, that where a Defendant's alleged illegal conduct causes products to be treated as substitutes when they otherwise would not be, the products are not treated as substitutes for market definition purposes. Therefore, this supports a long-acting ACTH submarket.

## e. <u>Distinct prices and sensitivity to price changes</u>

Plaintiff alleges that "Acthar's price to Humana in 2019 averaged more than \$65,000 per prescription, more than 650,000% of the average prescription price for a glucocorticoid drug (\$9.79)," id. ¶ 89.e.i., and "[t]he price of Acthar has increased repeatedly and substantially while the price of other Glucocorticoid drugs has decreased," id. ¶ 89.f.i.; see also id. ¶ 62 (from 2011 to 2019 the price of Acthar increased while the price of Glucocorticoid drugs decreased, but the quantity of Acthar reimbursed by Plaintiff substantially increased, while the quantity of reimbursed Glucocorticoid drugs decreased). If the two drugs were economic substitutes, the increasing price disparity between Acthar and Glucocorticoid drugs would have caused consumers to switch from Acthar to Glucocorticoid drugs, but that was not the case. This was confirmed through Plaintiff's economic analysis of the cross-price elasticity of demand provided in the SAC. Id. ¶¶ 63-64.

Defendant challenges Plaintiff's analysis on a number of grounds. However, these criticisms appear better directed to a challenge at the summary judgment stage based on the parties' expert opinions. For example, Defendant contends the cross-elasticity number is unhelpful because it aggregates indications and excludes nonglucocorticoid alternatives "making it impossible from the allegations to discern whether a positive cross-elasticity of demand exists between ACTH and non-ACTH drugs when used to treat some conditions while a negative cross-elasticity of demand exists when used to treat others." Mot. at 9. Defendant contends the SAC itself "suggest[s] Acthar faces different levels of competition between indications – from glucocorticoids for some indications and from non-glucocorticoid alternatives for others." Id. However, beyond infantile spasms, for which glucocorticoids are not FDA approved, the SAC gives no reason to assume that cross-elasticity of demand would be positive for some indications and negative for others. And Plaintiff does not allege that non-glucocorticoid alternatives exist for indications other than infantile spasms. See Opp'n at 7 ("Humana believes that no such [nonglucocorticoid alternatives] exist, so it cannot be expected to have identified them itself").

As to infantile spasms, Plaintiff did not perform a cross-elasticity analysis with Sabril. Defendant contends Plaintiff's "argument that Sabril is irrelevant because the [infantile spasm] market is small, and not because of any low cross elasticity of demand (Opp. 8, n.11), is telling." Reply at 2 n.1. However, Defendant points to no requirement that at the motion to dismiss stage, a Plaintiff must perform a statistical econometric analysis of the cross-elasticity of every potential substitute. Plaintiff has alleged that Sabril's characteristics and uses are materially different; that is sufficient at this stage.

<sup>&</sup>lt;sup>4</sup> Defendant contends the March Order rejected the factual premise that Defendant was able to raise its price without losing sales. Reply at 1 (citing March Order at 11). But all the Court held was that none of the allegations in the FAC supported that claim. Plaintiff has now added such allegations.

Defendant also contends that because the analysis begins in 2011, it does not exclude any "continuing loss of sales to corticosteroids resulting from the 2007 price adjustment for Acthar and related formulary restrictions" and it also "ignor[es] myriad factors affecting supply and demand for conditions for which Acthar is not commonly used." Reply at 2. Plaintiff need not exclude all potentially relevant or confounding factors in the rough cross-elasticity analysis set forth in its complaint. Plaintiff's proposed submarket need only be plausible; it need not be proven.

Finally, Defendant contends Plaintiff's analysis is flawed because it relies only on its own data. Mot. at 9 n.3. However, Plaintiff covers millions of patients and therefore – particularly at the motion to dismiss stage – its own data can serve as a proxy for the "aggregate demand of consumers." Id.

Therefore, this factor supports a long-acting ACTH submarket.

# f. Specialized vendors

Plaintiff alleges "Acthar is distributed only through a limited network of specialty pharmacies . . . , while other adrenal hormone drugs are widely available through tens of thousands of retail and other mainstream pharmacies throughout the country (e.g. CVS, Rite Aid, Walgreens)" because "Acthar requires special handling that retail pharmacies are not well equipped to provide." SAC ¶ 83.g.i. This supports a long-acting ACTH submarket

Based on the <u>Brown Shoe</u> factors, the Court concludes Plaintiff has adequately pled a submarket for long-acting ACTH drugs.<sup>5</sup>

# 2. Antitrust Injury

Plaintiff alleges it was harmed by Defendant's unlawful conduct because it otherwise "would have paid for fewer Acthar prescriptions and it would have paid less for those prescriptions" because "increased

<sup>&</sup>lt;sup>5</sup> The Court therefore need not, and does not, address Plaintiff's additional allegations in support of direct proof of market power.

competition [from Synacthen] in the market for long-acting ACTH drugs" would have resulted in "lower prices for Acthar" or more prescriptions for the "lower priced Synacthen." SAC ¶ 137. Defendant contends this presumption depends on a speculative chain of events that if Defendant had not purchased the Synacthen rights, another company "would have secured FDA approval . . . , entered the relevant antitrust market, and gained acceptance among doctors, thereby causing a reduction in the prices that [Plaintiff] paid for Acthar." Mot. at 10.

Plaintiff argues the allegations in the SAC "are beyond sufficient to make it plausible that Synacthen would have been sold in the United States but for Mallinckrodt's conduct." Opp'n at 9-10. Specifically, Plaintiff has alleged that Synacthen has been used safely and effectively outside the United States and therefore "a buyer would not need to begin the research, development, testing, or manufacturing process from scratch," SAC ¶ 70, 75, that Defendant used Synacthen studies to obtain FDA approval for Acthar, id. ¶ 71, that the FDA has approved a short-acting formulation of Synacthen, id. ¶ 75 n.7, and that there were three other bidders seeking the rights to pursue FDA approval for Synacthen and commercialize it in the United States that had the necessary expertise and financing, as well as sufficient business and regulatory plans, to do so, id. ¶¶ 73-74. The Court agrees this is more than sufficient. See Bubar v. Ampco Foods, Inc., 752 F.2d 445, 452 (9th Cir. 1985) (courts consider "[t]he background and experience of [the potential entrant] in his prospective business," "[a]ffirmative action on the part of [a potential entrant] to engage in the proposed business," "ability of [a potential entrant] to finance the business and the purchase of equipment and facilities necessary to engage in the business," and "consummation of contracts" by a potential entrant).

Defendant raises a number of reasons why it believes these allegations are insufficient, none of which the Court finds persuasive. First, Defendant contends that "[c]ourts addressing this issue have required a plaintiff to plead facts establishing the probability and timing of FDA approval for an unapproved drug to be considered a

potential competitor." Mot. at 12 (citing Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 807-08, 815 (D.C. Cir. 2001) and Brotech Corp. v. White Eagle Int'l Techs. Grp., Inc., No. CIV.A.03-232, 2004 WL 1427136, at \*6 (E.D. Pa. June 21, 2004)). This presumably stems from the requirement that to establish causation in a competitor exclusion case, the plaintiff must allege that the potential competitor has an "intent to enter the market and a preparedness to do so." See Bubar, 752 F.2d at 450.6 Under Defendant's view, the probability and timing of FDA approval are necessary to make plausible allegations that a competitor is prepared to enter the market. However, particularly where the plaintiff is a consumer rather than a competitor, and where, as here, the defendant is currently in possession of the "asset package," it would be too exacting a burden to require a plaintiff to allege exactly how long it would take for some other company to get FDA approval. Plaintiff's allegations make it sufficiently plausible that, but for Defendant's purchase of the Synacthen rights, Synacthen would have been approved by the FDA for use in the United States for at least one of the same indications as Acthar. That in Brotech the plaintiff had failed to allege when FDA approval "may be anticipated," 2004 WL 1427136, at \*6, and in Tawfilis v. Allergan, Inc., 157 F. Supp. 3d 853

<sup>&</sup>lt;sup>6</sup> Plaintiff asserts the cases cited by Defendant address antitrust cases brought by competitors and not consumers, for which there are different burdens. Opp'n at 10-11. However, the circuit courts to have considered the issue have concluded that both consumers and competitors must satisfy the intent and preparedness test. See, e.g., Meijer, Inc. v. Biovail Corp., 533 F.3d 857, 862 (D.C. Cir. 2008) ("Just as a would-be entrant suing an incumbent firm for excluding it from a relevant market in violation of the Sherman Act must demonstrate it intended and was prepared to enter that market, . . . so a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply it but for the incumbent firm's exclusionary conduct" (internal citations omitted)); Sunbeam Television Corp. v. Nielsen Media Research, Inc., 711 F.3d 1264, 1273 (11th Cir. 2013) (following Meijer and rejecting position that "proof of a 'willing and able' competitor 'standing in the wings, ready to swoop in' should only apply to *competitor* plaintiffs, not *customer* plaintiffs.").

(C.D. Cal. 2015), the plaintiff had alleged that approval "could have" occurred within two years, <u>id.</u> at 857, does not impose a requirement on all plaintiffs to allege the number of years in which approval is likely to occur. In each of those cases, the court considered the totality of the allegations and concluded that antitrust injury either was or was not plausible. Most of the other cases cited by Defendant were decided at the summary judgment stage and are therefore inapplicable here.

Next, Defendant contends that although it has been three years since it was required to sublicense the rights to Synacthen for infantile spasms and nephrotic syndrome to another company, id. ¶ 82, the complaint contains no allegations that Synacthen has obtained FDA approval, or even that the sublicensee has made progress in obtaining FDA approval. Mot. at 13. According to Defendant, this makes it implausible that Synacthen would have been approved by the FDA if another bidder had purchased it in 2013. However, a potential entrant that has the rights to develop and sell Synacthen for only two indications is not similarly situated to a potential entrant that can develop and sell Synacthen for any indication. This is particularly true here where Plaintiff has alleged that the indications for which Defendant retained rights are the cash cows. See, e.g., SAC ¶ 114 ("[F]ewer than 10% of Acthar's sales come from prescriptions for infantile spasms, and more than 98% of Humana's expenditures for Acthar were made for insureds over the age of 18"). Therefore, this does not make Plaintiff's allegations implausible.

Defendant also contends that because Synacthen is a synthetic drug, it "cannot be presumed to have identical effects on the human body" and therefore would be approved by the FDA for the same 19 indications. Mot. at 11; see also id. at 13 ("Humana makes no specific allegations regarding Synacthen's use and effectiveness as to any particular Acthar indication, let alone its relative safety and effectiveness versus Acthar as to such indications"). However, that Defendant used Synacthen studies when it applied for FDA approval and that Synacthen is used for the same indications outside of the United States makes it plausible that Synacthen would be approved for those indications in the United States. Therefore, the Court need not

simply "guess as to whether . . . Synacthen is a plausible replacement for Acthar as the standard of care for [infantile spasms] in the United States, and whether, for other indications, it would be one of several alternatives for 'first line' treatment or an alternative to Acthar as a 'last line' treatment." Reply at 5. Moreover, the Court agrees with Plaintiff that it "has suffered antitrust injury if it is plausible that a finder of fact could conclude that Synacthen would have been approved for any use, as the introduction of competition would lower the price of all ACTH drugs." Opp'n at 10 n.12. There are no allegations that the price of Acthar differs depending on the indication. Therefore, competition for less than all 19 indications could plausibly lower the price for all indications.

Finally, Defendant argues that Plaintiff has not plausibly alleged that the beginning of the alleged antitrust period should be 2011. See Mot. at 13. The bidding process for the rights to sell Synacthen in the United States did not begin until late 2012 and early 2013, and Defendant did not win the rights until June 11, 2013. SAC ¶¶ 76-77. Plaintiff fails to explain how any harm caused by Defendant's alleged anticompetitive behavior could have occurred prior to Defendant acquiring the Synacthen license. However, the date another bidder could have or would have brought Synacthen to market is a factual question not best resolved at the motion to dismiss stage. Moreover, discovery might reveal that, had it not won the bid, Defendant would have started lowering its prices prior to Synacthen's market entrance in anticipation of future competition.

The Court concludes Plaintiff has adequately alleged an antitrust injury.

## 3. Statute of Limitations

Defendant contends that 22 of the 25 state laws relevant to Plaintiff's state antitrust claims are barred by the statute of limitations because "[a] cause of action for an allegedly anticompetitive acquisition of assets accrues on the date of the acquisition," which in this case was June 11, 2013, and that statute of limitations for those 22 states is four

years or less. Mot. at 14.7 Plaintiff contends its claims were tolled due to fraudulent concealment, the continuing violation doctrine, and <u>American Pipe</u> tolling. Opp'n at 14-19.

## a. Fraudulent Concealment

Plaintiff alleges it "could not have discovered and remained unaware" of Defendant's illegal conduct until the FTC brought these actions to light in 2017 because Defendant "falsely maintained that it would develop and seek FDA approval of Synacthen." SAC ¶¶ 131-132. For example, Defendant's chief scientific officer made public statements that Defendant intended to seek FDA approval for Synacthen in conditions different than Acthar and where Synacthen would "potentially provide a clinical benefit over Acthar." Dkt. 70-2 (RJN Ex. B) (June 2013 Press Release). However, Plaintiff's Section 2 claim explicitly alleges that Defendant's purchase of the license itself, not its failure to commercialize the drug, is the anticompetitive behavior. See SAC ¶ 141 (Section 2 claim alleges that "[b]y intervening in the bidding process for Synacthen and purchasing the exclusive license to market Synacthen in the United States, Mallinckrodt eliminated the potential competitive threat posed by an independently owned Synacthen license"). In other words, as alleged, the "potential competitive threat" was an "independently owned Synacthen license." Plaintiff should have been aware that there would be no independently owned

a statute of limitations defense.

<sup>&</sup>lt;sup>7</sup> Plaintiff agrees that these 22 states have limitations periods of four or fewer years for antitrust claims, but contends that for two of those states, New York and Oregon, the antitrust claim was statutorily tolled "for one year after the conclusion of any proceeding instituted by the United States under federal antitrust laws." Opp'n at 19. Defendant appears to concede that these are not time-barred. <u>See</u> Reply at 6 n.3. Therefore, the parties agree that 20 of 25 states relevant to Plaintiff's state antitrust claim are subject to

<sup>&</sup>lt;sup>8</sup> The Court grants Plaintiff's unopposed request for judicial notice (Dkt. 70) of a press release issued by Defendant in June 2013. Fed. R. Evid. 201(b).

Synacthen license at the time Defendant publicly announced it would be obtaining the license.

Plaintiff's other allegations provide further support for this conclusion. For example, Plaintiff alleged that "given the drugs' similarities, any therapeutic indication that [Defendant] might have pursued with Synacthen could have been pursued with Acthar." Id. ¶ 79. Plaintiff also alleged that "Novartis was not naïve, and could be expected to understand that Questcor would have little interest in developing the only synthetic competitor to Acthar, its extraordina[r]ily lucrative non-synthetic product." <u>Id.</u> ¶ 78. Plaintiff does not explain why it could not have been expected to understand the same thing. Accepting as true the allegation that Defendant falsely stated that it would obtain FDA approval of Synacthen for certain treatments, there are no allegations in the complaint that would support the necessary assumption that had Defendant developed, obtained FDA approval for, and sold Synacthen in the United States, Plaintiff could have reasonably expected to have either paid lower prices for Acthar or that Synacthen would have been offered by Defendant at a materially lower price. Given that Defendant would still control 100% of the alleged product market, whether through one drug or two, the Court cannot plausibly draw the inference that Plaintiff was reasonable in assuming Defendant would have acted to its financial detriment and lowered the price of Acthar or introduced Synacthen at a substantially lower price. See Igbal, 556 U.S. at 679 (Courts must "draw on their judicial experience and common sense" in determining whether allegations in a complaint are plausible). Fraudulent concealment, therefore, does not save Plaintiff's otherwise time-barred claims.9

<sup>&</sup>lt;sup>9</sup> Plaintiff's footnote implicitly arguing that the Court should find fraudulent concealment here because of the Court's conclusion as to Plaintiff's RICO claim, Opp'n at 15 n.20 (citing March Order at 25), is misplaced. The facts necessary to put Plaintiff on inquiry notice of the RICO claims differs materially from the types of facts that would put Plaintiff on inquiry notice of the antitrust claims.

## b. Continuing Violation

Plaintiff also contends that Defendant's actions constitute a continuing violation because "its yearly licensing payments to Novartis have forestalled and continue to forestall the transfer of Synacthen rights to a party that would develop it to compete with Acthar." Mot. at  $18.^{10}$  Specifically, Defendant pays Novartis \$25 million each year to maintain its monopoly in the long-acting ACTH market and Plaintiff contends that "[e]ach payment is anticompetitive in that it forestalls Novartis from licensing its drug to others and enables Mallinckrodt to charge monopoly prices." Id. Essentially, each payment is a new contract preventing Synacthen from being developed to compete with Acthar. The Court agrees.

"To state a continuing violation of the antitrust laws in the Ninth Circuit, a plaintiff must allege that a defendant completed an overt act during the limitations period that meets two criteria: '1) It must be a new and independent act that is not merely a reaffirmation of a previous act; and 2) it must inflict new and accumulating injury on the plaintiff." Samsung Elecs. Co. v. Panasonic Corp., 747 F.3d 1199, 1202 (9th Cir. 2014) (quoting Pace Indus., Inc. v. Three Phoenix Co., 813 F.2d 234, 238 (9th Cir. 1987)). Cases where "all of the harm occurred at the time of the initial violation . . . is the exception, not the rule. Id. at 1202-03. Instead, "[n]on-legal actions taken pursuant to a prelimitations period contract can lead a new cause of action to accrue." Id. at 1203.

Defendant first contends the continuing violation theory does not apply because "[u]nilateral decisions about whether to develop a new product . . . are *not* subject to antitrust scrutiny." Reply at 6. However, Plaintiff is not claiming anticompetitive conduct simply because Defendant chose not to develop an Acthar competitor. The anticompetitive conduct stems from Defendant's decision to prevent

<sup>&</sup>lt;sup>10</sup> The Court grants Plaintiff's unopposed request for judicial notice (Dkt. 70) of Defendant's SEC filings and the license agreement with Novartis (Dkts. 70-1, 70-3 through 70-8). Fed. R. Evid. 201(b).

others from developing an Acthar competitor by continuing to pay Novartis for the Synacthen license. Therefore, the Court finds this argument unconvincing.

Next, Defendant contends the continuing violation theory does not apply because "the license agreement [does not] contain[] a provision requiring [Defendant] to 'shelve' Synacthen." Reply at 7. However, Defendant cites no case law imposing a requirement for the agreement to explicitly compel the anticompetitive conduct. Moreover, the license agreement itself explicitly prevents companies other than Defendant from developing Synacthen for sale in the United States, thereby proscribing any independently owned Synacthen license, the anticompetitive conduct at issue here. And "action taken under a prelimitations contract [i]s sufficient to restart the statute of limitations so long as the defendant had the ability not to take the challenged action, even if that would have required breaching the allegedly anticompetitive contract." Samsung, 747 F.3d at 1203.

Finally, Defendant contends recent cases have held that the continuing violation theory does not apply to antitrust allegations based on price increases after an acquisition. Reply at 7-8 (citing Midwestern Mach., Inc. v. Nw. Airlines, Inc., 167 F.3d 439, 440 (8th Cir. 1999) and Z Techs. Corp. v. Lubrizol Corp., 753 F.3d 594, 603 (6th Cir. 2014)). These cases are factually distinct from the alleged antitrust violations at issue here, which involve more than an incidental price increase ultimately caused by an acquisition. Here, the antitrust conduct is the continuing payments to Novartis to prevent another company from developing an Acthar competitor. A similar arrangement was found to be a continuing violation by the Ninth Circuit in Samsung. 747 F.3d at 1204 (because "the license itself did not permanently and finally control the acts of the SD Defendants[,] [t]heir decision to enforce the contract caused a new anti-competitive harm, and the statute of limitations ran anew from the time that defendants began enforcement."). To the extent the cases cited by Defendant contradict Ninth Circuit law as set forth in Samsung, the Court disregards them.

Therefore, the statute of limitations does not bar Plaintiff from asserting claims based on harms flowing from the alleged anticompetitive license payments made to Novartis during the limitations period.

# c. <u>American Pipe Tolling</u>

Plaintiff contends it is also "entitled to tolling of its claims under *American Pipe* as of [April and October of 2017 when class actions were filed against Defendant], because in those cases [Plaintiff] is a putative member of the classes and its antitrust claims share a common factual and legal basis with the claims asserted." Opp'n at 15 n.21. Defendant notes that only the April 2017 lawsuit would fall within the statute of limitations, but Plaintiff was not included in the proposed class until an amended complaint was filed in December 2017, after the expiration of the four-year limitations period. See Reply at 8. Therefore, American Pipe does not save Plaintiff's state law claims to the extent based on the 2013 license agreement.<sup>11</sup>

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Defendant's motion to dismiss the First and Second Counts is DENIED. Defendant's motion to dismiss the Third Count is DENIED as to claims brought under New York, Oregon, Maine, Vermont, and Wisconsin law. As to the remaining state law antitrust claims, Defendant's motion is GRANTED to the extent Plaintiff seeks to challenge the 2013 license agreement (and any other conduct outside of the relevant limitations period), but DENIED as to Defendant's alleged continuing antitrust violations within the limitations period.

<sup>11</sup> It does not appear that Defendant disputes that the complaints filed on October 30, 2017 and December 8, 2017 would toll the statute of limitations for claims based on conduct that occurred within four years of those dates.

## B. RICO (Counts IV and V)

The Court previously held that Plaintiff had adequately alleged RICO claims based on an alleged "Acthar Enterprise," consisting of Defendant, CDF, and the prescribing doctors, that participated in a pattern of racketeering activity including 1) mail and wire fraud based on Defendant's and prescribing doctors' misrepresentations that they were complying with state and federal law, when in fact a) the co-pay assistance programs violated the Anti-Kickback Statute (AKS) and the False Claims Act (FCA), and b) the doctor payments violated state bribery laws and 2) bribery based on the doctor payments. March Order 13-34. In so deciding, the Court rejected Defendant's contention that any racketeering acts related to the co-pay assistance funds occurred outside the four-year statute of limitations. Id. at 23-25.

Defendant now contends that the Court's "reasoning [on the statute of limitations issue] invites consideration of judicially noticeable facts establishing that the claim is time-barred." Mot. at 3. 13 Defendant identifies a 2013 New York Times article that purportedly establishes that Humana "would have been on notice of its alleged claim" more than four-years before it filed this action. <u>Id.</u> at 4; <u>see also id.</u> at 18 ("the alleged conduct has been public knowledge since 2013"), <u>id.</u> at 19 ("major news media reported – as early as 2013 – about Questcor's alleged contributions to the CDF funds at issue and their purported Acthar-only nature"). However, Defendant does not explain

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<sup>&</sup>lt;sup>12</sup> The Court also held that Plaintiff had not adequately alleged any racketeering activity based on alleged insured misrepresentations or the theory that co-pay assistance was bribery. March Order at 26-28. The Court invited Plaintiff to amend those claims to the extent it wished to continue pursuing them. <u>Id.</u> at 35 n.21. Because Plaintiff chose not to amend those claims, it has abandoned them. For the sake of clarity, the Fourth and Fifth Counts, to the extent they rely on either of these theories, are DISMISSED.

<sup>&</sup>lt;sup>13</sup> Defendant concedes it is not entitled to dismissal based on the allegations in the SAC alone. <u>See</u> Mot. at 19 (Defendant "agrees that [Plaintiff] had not pled admissions on the critical issue of what it knew about the CDF funds at the time").

how the Court's reasoning in the March Order warrants reconsideration of the statute of limitations issue. The Central District of California permits only three grounds on which a motion for reconsideration may be made:

(a) a material difference in fact or law from that presented to the Court before such decision that in the exercise of reasonable diligence could not have been known to the party moving for reconsideration at the time of such decision, or (b) the emergence of new material facts or a change of law occurring after the time of such decision, or (c) a manifest showing of a failure to consider material facts presented to the Court before such decision.

Local Rule 7-18. The new article is at best a material difference in fact, but Defendant makes no argument that it could not have discovered the article in the exercise of reasonable diligence prior to the March Order. Therefore, the Court declines to reconsider its prior determination that Plaintiff had adequately alleged it discovered Defendant's wrongdoing within the limitations period.

Further, as Plaintiff points out, even if the Court were to consider the article, it would not change the outcome. One or two articles are insufficient to show, as a matter of law, that Plaintiff had constructive notice of the facts contained within them. <sup>14</sup> Additionally, the Court previously concluded that because Plaintiff alleged that the donation agreements fraudulently misrepresented that the funds were not limited to patients using Acthar, had Plaintiff inquired into the funds,

<sup>&</sup>lt;sup>14</sup> Defendant contends that its argument is not that the articles themselves should have put Plaintiff on notice, but that the OIG's 2014 SAB, which purportedly singled out the emergence of single-drug funds, should have caused Plaintiff to run some Google searches to see if there were any articles about drugs covered by Plaintiff. Reply at 11. Whether Plaintiff's investigation (or lack thereof) in response to the 2014 SAB was reasonable is a factual issue not best resolved at the motion to dismiss stage.

it would not have discovered that the funds were illegal. March Order at 24-25.

Defendant's motion to dismiss Counts Four and Five to the extent based on allegations regarding co-pay assistance programs is DENIED.

# C. State Law Claims (Counts VI through X)

## 1. Statute of Limitations

Defendant contends that 21 of the 25 states' laws under which Plaintiff brings its unfair competition and consumer fraud and deceptive trade practices claims, as well as four of the five states' laws under which Plaintiff brought an insurance fraud claim are also barred by the relevant statutes of limitations to the extent they are based on the co-pay assistance funds. Mot. at 20. The Court declines to dismiss those claims for the same reason stated in section III.B. and for the additional reason that Defendant did not raise this contention in its prior motion and therefore is prohibited from doing so here under Rule 12(g)(2). See In re Apple iPhone Antitrust Litig., 846 F.3d 313, 317-318 (9th Cir. 2017), aff'd sub nom. Apple Inc. v. Pepper, 139 S. Ct. 1514 (2019) ("a defendant who fails to assert a failure-to-state-a-claim defense in a pre-answer Rule 12 motion cannot assert that defense in a later pre-answer motion under Rule 12(b)(6)").

## 2. Individual Defenses to State Laws

Defendant next contends Plaintiff's claims under Kentucky and New Jersey insurance fraud statutes also fail because the Kentucky statute requires a criminal adjudication of guilt and the New Jersey statute requires "prelitigation notice . . . with which [Plaintiff] has not alleged compliance." Mot. at 15 n.8. Not only does Rule 12(g)(2) prevent Defendant from making these arguments in a successive preanswer motion to dismiss, but it is also legally incorrect. As Plaintiff notes, the Kentucky legislature repealed the requirement of criminal adjudication. See 2018 Kentucky Laws Ch. 178 (HB 323) (removing requirement of a "criminal adjudication of guilt" for a private party to

state a claim for damages). And as to the New Jersey statute, prelitigation notice is not required. <u>See N.J. Stat. § 17:33A-7(c)</u> (notice to be provided at the time of filing). In reply, Defendant appears to concede that Plaintiff can assert its claim under New Jersey law. Reply at 12 ("Mallinckrodt requests that the Court dismiss with prejudice . . . all other claims (except that under New Jersey's Insurance Fraud Statute)").

Defendant attaches to its brief "Appendix B," a chart of legal defenses to Plaintiff's unfair competition and consumer fraud and deceptive trade practices claims. See Mot. at 23-25. That chart includes the following arguments:

- Michigan's statutes do not apply to regulated activities, such as the provision of prescription drugs to Medicare beneficiaries, or alleged misrepresentations not made to customers
- Minnesota's statutes require claims to satisfy the public benefit requirement and therefore do not apply to claims for recovery of private damages
- New Jersey's statutes do not permit claims brought by third-party payors, rather than drug consumers
- North Dakota's statutes do not apply to statements made in connection with coverage, rather than in connection with the sale or advertisement of a drug

Although technically within the 25-page limit, Appendix B skirts the purpose of the page limitation by including additional argument in size 11 font, single-spaced. Moreover, the arguments were not raised in the prior motion and are therefore improper under Rule 12(g)(2). The Court will not consider these additional defenses at this time.

## 3. Tortious Interference

The Court previously dismissed Plaintiff's tortious interference claim because Plaintiff had failed to allege that accepting co-pay assistance caused its members to breach their contract with Plaintiff. March Order at 34. Plaintiff has added allegations that its contracts with its members "provide[] that an insured is 'responsible for' copayments and 'must pay [their] share of the cost when [they] get [a] service or drug." SAC ¶ 202. The contract also states that "when you get a drug through a patient assistance program offered by a drug manufacturer . . . we will not pay for any share of these drug costs." Id. Plaintiff contends that "[i]f the [patient assistance program] uses its funds to pay the member's co-pay, however, then both the letter and the purpose of the [contract] provision are subverted." Id. ¶ 203.

But nothing in the cited provisions can reasonably be read as preventing members from paying their co-pays with money obtained from a co-pay assistance fund. The first provision, as discussed in the March Order, merely requires members to pay their co-pays. It sets no limitations on the source of the funds. The second provision, when read in context, does not prohibit members from doing anything it all. It is only a reminder that if members obtain drugs outside of their plan benefits directly from the drug manufacturer through a patient assistance program, Plaintiff will not reimburse members for any payments made to the patient assistance programs. Here, in contrast, the members do obtain the drugs through their insurance, and simply obtain the funds to pay the co-pays through a co-pay assistance fund. That is not prohibited by the contracts. The contract does not say that if a co-pay assistance fund covers the co-pay, Plaintiff was entitled to deny coverage in the first place, when it otherwise would have provided coverage. Moreover, there is simply nothing in the cited provision that requires members to "identif[y]" whether co-pay assistance "originat[ed] with the manufacturer." Id. Therefore, it does not follow that "it is a breach for the member to use that assistance to procure payment for the manufacturer's drug." Id.; see also id. ("Mallinckrodt is causing Humana members to procure a benefit under the contract to

which the members are not entitled under the contract's plain terms.") $^{15}$ 

Therefore, Plaintiff has still not alleged that its members breached their contracts, and the Court determines that Plaintiff cannot plead any other facts that would cure this deficiency. See Schreiber, 806 F.2d at 1401 (leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency"). Count IX is DISMISSED with prejudice.

## IV. CONCLUSION

Count III, to the extent it relies on laws from states other than New York, Oregon, Maine, Vermont, and Wisconsin and relies on the 2013 license agreement, Counts IV and V, to the extent they rely on purported racketeering activity based on alleged insured

assistance is alternatively "disruption' of the contractual relationship." Opp'n at 21 (citing Redfearn v. Trader Joe's Co., 230 Cal. Rptr. 3d 98, 104 (2018)). This is insufficient to preserve this argument. See Birdsong v. Apple, Inc., 590 F.3d 955, 959 (9th Cir. 2009) ("[A] bare assertion does not preserve a claim, particularly when, as here, a host of other issues are presented for review."); see also Indep. Towers of Washington v. Washington, 350 F.3d 925, 929-30 (9th Cir. 2003) ("However much we may importune lawyers to be brief and to get to the point, we have never suggested that they skip the substance of their argument in order to do so. . . . We require contentions to be accompanied by reasons."); Mahaffey v. Ramos, 588 F.3d 1142, 1146 (7th Cir. 2009) ("Perfunctory, undeveloped arguments without discussion or citation to pertinent legal authority are waived").

misrepresentations or the theory that co-pay assistance was bribery, and Count IX are DISMISSED with prejudice. Defendant's motion is otherwise DENIED.

IT IS SO ORDERED.

Date: August 14, 2020

Dale S. Fischer

United States District Judge