

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS**

**IN RE: EpiPen (Epinephrine  
Injection, USP) Marketing,  
Sales Practices and Antitrust  
Litigation**

**MDL No: 2785**

**Case No. 17-md-2785-DDC-TJJ**

**(This Document Applies to  
Consumer Class Cases)**

**MEMORANDUM AND ORDER**

This Order addresses the pending Motions to Dismiss in one of the two separate tracks of this MDL—the consumer class cases track. The consumer class track consists of cases filed by individual consumers or third-party payors who allege they purchased EpiPens for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries. After the Judicial Panel on Multidistrict Litigation transferred five consumer class cases and one other filed by Sanofi-Aventis U.S. LLC (“Sanofi”) to our court for coordinated and consolidated proceedings (Docs. 1, 5, & 9), the consumer class plaintiffs filed a Consolidated Class Action Complaint (“Class Complaint”) (Doc. 60). The Class Complaint asserts federal and state antitrust claims, federal RICO Act violations, various state consumer protection law violations, and unjust enrichment claims. The Class Complaint also seeks class action certification.

The Class Complaint asserts its claims against two groups of defendants who are either sellers or manufacturers of the EpiPen. One group consists of defendants Mylan N.V., Mylan Specialty L.P., Mylan Pharmaceuticals, Inc., and Mylan’s CEO Heather Bresch (collectively “the

Mylan Defendants”). The other group of defendants consists of Pfizer, Inc., King Pharmaceuticals, Inc., and Meridian Medical Technologies, Inc. (collectively “the Pfizer Defendants”). When referring to both sets of defendants, this Order simply calls them, collectively, “defendants.”

Defendants have filed separate motions asking the court to dismiss the Class Complaint. Doc. 92 (Pfizer Defendants’ Motion to Dismiss Plaintiffs’ Consolidated Class Action Complaint); Doc. 94 (Mylan Defendants’ Motion to Dismiss Plaintiffs’ Consolidated Class Action Complaint). The class plaintiffs have submitted an Omnibus Response to the Motions to Dismiss. Doc. 123. And both sets of defendants have filed Replies. Doc. 216 (Pfizer Defendants’ Reply); Doc. 219 (Mylan Defendants’ Reply). Also, on March 14, 2018, the Mylan Defendants submitted a Notice of Supplemental Authority under D. Kan. Rule 7.1(f). Doc. 394. The class plaintiffs filed a response, objecting to the supplemental submission. Doc. 403. Then, on July 6, 2018, the class plaintiffs filed a Notice of Supplemental Authority (Doc. 765), and the Mylan Defendants submitted a response to their submission (Doc. 785). On July 11, 2018, the class plaintiffs filed another Notice of Supplemental Authority (Doc. 781), and the Mylan Defendants filed a response to that submission as well (Doc. 803). Finally, on August 12, 2018, the class plaintiffs filed another Notice of Supplemental Authority (Doc. 874), and the Mylan Defendants filed a response to that submission (Doc. 889).

Thus, to say the least, the Motions to Dismiss are now thoroughly and fully briefed. After carefully considering the arguments presented by the parties’ filings, the court is prepared to rule.<sup>1</sup> For the reasons explained below, the court grants defendants’ motions in part and denies them in part.

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<sup>1</sup> Mylan has filed a Request for Oral Argument on their Motion to Dismiss under D. Kan. Rule 7.2. Doc. 220. D. Kan. Rule 7.2 provides: “The court may set any motion for oral argument or hearing at the

## I. Factual Background

The following facts come from the Class Complaint. The court accepts the facts asserted in the Class Complaint as true and views them in the light most favorable to the class plaintiffs.

*Mayfield v. Bethards*, 826 F.3d 1252, 1255 (10th Cir. 2016) (citation omitted).

The EpiPen<sup>2</sup> is a disposable, prefilled automatic injection device that delivers epinephrine (also known as adrenaline) to treat severe allergic reactions known as anaphylaxis. Anaphylaxis is a life-threatening allergic reaction that can occur rapidly after exposure to an allergen.

Anaphylaxis manifests in a variety of symptoms, including swelling of the tongue and throat, vomiting, reduced blood pressure, difficulty breathing, and, if untreated, death. Most commonly, anaphylaxis is caused by food allergens, but medications, latex, insect bites, and other unknown substances also can cause anaphylaxis. About 15 million people have food allergies in the United States. One of every 13 children in the United States has serious food allergies. And, each year, allergic reactions account for some 200,000 emergency room visits. Anaphylaxis is always considered a life-threatening medical emergency.

Epinephrine is used to treat anaphylaxis and is available only by prescription. To treat anaphylaxis effectively, one must administer epinephrine immediately. As little as a thirty minute delay in applying epinephrine can cause death. As a result, patients prone to anaphylaxis

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request of a party or on its own initiative.” After reviewing the parties’ written submissions, the court finds that they explain the parties’ positions quite effectively. The court concludes that oral argument will not assist its work and thus, to grant it, would contradict Fed. R. Civ. P. 1. It is, simply, unnecessary. Exercising its discretion, the court denies Mylan’s request.

<sup>2</sup> The Class Complaint uses the term “EpiPen” to refer to the EpiPen®, EpiPen 2-Pak®, EpiPen Jr.®, EpiPen Jr. 2-Pak®, My EpiPen®, LIFE HAPPENS®, EpiPen4Schools®, Never-See-Needle®, and Be Prepared®. Like the Class Complaint, the court refers to these devices collectively as the “EpiPen” and omits the ® for readability.

are advised to carry an epinephrine auto-injector (“EAI”) at all times. By doing so, a patient can use the EAI in an emergency when a risk of a severe allergic reaction presents itself.

In 2007, Mylan acquired the right to market and distribute the EpiPen. Pfizer is the exclusive supplier of EpiPens to Mylan. Pfizer provides Mylan with 100% of its EpiPen supply through two of its wholly owned subsidiaries—King Pharmaceuticals, Inc., and Meridian Medical Technologies, Inc.—who manufacture the epinephrine and hold the EpiPen patents. Since at least 2009, Mylan’s market share of EAI devices in the United States EAI market has remained above 80%. Since 2009, Mylan’s market share consistently has exceeded 90%, and, in 2012, its share was almost 100%. During the same time—and while the cost of the EpiPen’s dose of epinephrine has remained about \$1—Mylan has increased the EpiPen’s price by more than 600%. In 2007, Mylan priced the EpiPen at \$100. By 2016, Mylan was charging more than \$600. In 2015, Mylan announced that the EpiPen had reached \$1 billion in annual sales for the second consecutive year—up from \$200 million in 2007.

The Class Complaint alleges that the Mylan and Pfizer Defendants have maintained a monopoly over the EpiPen market and its profitable revenues by devising an illegal scheme to monopolize the market for EAI devices. The Class Complaint asserts that defendants carried out their illegal scheme through several different avenues. The following paragraphs briefly summarize each one, as the Class Complaint describes them.

***The Mylan Defendants Paid Pharmacy Benefit Managers (PBMs) to Exclude Competition***

Pharmacy Benefit Managers (“PBMs”) are third-party administrators of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans. More specifically, PBMs administer a health coverage provider’s prescription benefit program by

developing the coverage provider's formulary (the list of prescription benefits included in the coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies who provide discounts in exchange for access to a provider's plan participants, and negotiating with manufacturers. The significant majority of patients with prescription drug insurance coverage receive their benefits through a third-party payor whose drug formulary is determined by a PBM. From 2013 to 2015, commercial third-party payors accounted for about 71% of the EAI drug device market in the United States. So, for a competitor to enter and compete vigorously in the EAI drug device market, it is imperative that it access these third-party payors' drug formularies.

Between 2013 and 2015, the Mylan Defendants took advantage of their monopoly power by imposing significant increases in the EpiPen's price. Mylan then used the additional profit margins to offer PBMs significantly higher rebates and percentage discounts conditioned upon exclusive or preferred placement on the PBMs' drug formularies. For example, when Sanofi launched a rival EAI device—Auvi-Q—in 2013, Mylan began taking steps to block Auvi-Q from drug formularies. It did so by offering large rebates to the PBMs who controlled the formularies for third-party payors—30% or higher—and expressly conditioning those rebates on: (a) granting the EpiPen exclusive position on the formulary; and (b) removing (or severely restricting) access to Auvi-Q. Mylan also targeted another rival EAI device—Adrenaclick—with the exclusionary rebate program. Adrenaclick's market share has ranged from only 2% in 2013 to 8% in 2016. Mylan knew that Adrenaclick—as well as Auvi-Q—could not raise prices to inflate their margins sufficiently to offer rebates or discounts similar to those that Mylan was offering to PBMs. In 2014, CVS Caremark added Adrenaclick to its Formulary Drug Removals

List, effectively removing a consumer or other end-payor's opportunity to purchase Adrenaclick as an alternative to the EpiPen.

The class plaintiffs allege that the Mylan Defendants' exclusionary rebate scheme deprives patients of a fair price for EAI devices—the price that would result from normal market forces. Instead of lowering its prices to gain market share, Mylan bargains for its market share by providing ever-larger rebates and other kickbacks to PBMs, conditioned on exclusive relationships with those PBMs. Mylan can position itself on the drug formularies by using its monopoly power to charge consumers higher prices for its product. It then can share these revenues with the PBMs (the ones who create the formularies) through substantially enhanced rebates conditioned on excluding insurance coverage for rival products. This conduct, in turn, inflates the prices that consumers pay for the EpiPens so that Mylan can preserve its net realized price and sales volumes. The class plaintiffs contend that the net effect of this scheme harms both consumers and competitors alike.

***The Mylan Defendants Entered into an Exclusive School Access Scheme***

The class plaintiffs next assert that the Mylan Defendants leveraged the EpiPen's dominant market position to foreclose competition in an EAI submarket—*i.e.*, American public schools. They did so by offering to supply a portion of each school's need for EAI devices on a free or discounted basis but conditioning those discounts on the school entering an exclusive dealing contract. The Mylan Defendants created this important submarket by increasing federal lobbying efforts to gain access to parents, educators, and medical professionals in public schools. As part of the lobbying effort, Mylan spent a reported \$4 million specifically lobbying to pass the School Access to Emergency Epinephrine Act. The law was enacted in 2013. It gives federal funding priority to schools who stockpile EAIs. Mylan's lobbying efforts proved

enormously successful. Now, a majority of states permit their public schools to stockpile EAI while eleven states *require* EAI stockpiling. Given the EpiPen’s dominant market position, the Act not only has provided EpiPen access to schools, but also it has mandated some schools to stockpile the product.

After securing the EAI stockpiling requirement, Mylan acted quickly to exclude competing EAI from this valuable school submarket. As part of the Mylan Defendants’ scheme, Mylan launched the “EpiPen4Schools” program. The program gives away free and discounted EpiPens to school districts—ones subject to the new law now requiring (or strongly encouraging) them to stockpile the devices. But Mylan conditioned the free and discounted EpiPens on the schools entering exclusive dealing agreements with Mylan. The purpose of these exclusive dealing agreements was to exclude competitors—like Auvi-Q and Adrenaclick—from the public school submarket. In the fall of 2016, the New York Attorney General and members of the United States Senate announced investigations into the anticompetitive terms of Mylan’s EpiPen4Schools program. Later, Mylan eliminated the EpiPen4Schools program’s exclusivity requirement.

***Defendants, Working Together, Used the Judicial and Regulatory Processes  
to Protect their Monopoly***

The Class Complaint next asserts that the Mylan and Pfizer Defendants worked “hand-in-hand,” using patent litigation and the Food and Drug Administration (“FDA”) regulatory process to erect barriers to market entry and delay EAI competition. Class Compl. ¶ 314. The Pfizer Defendants own the patents protecting the EpiPen and serve as the contract supplier of the product. The Mylan Defendants own the trademarked brand names and control the worldwide marketing and sale of the product. Together, defendants have a unified interest in protecting the EpiPen monopoly. So, the class plaintiffs allege, defendants collaborated to enhance the

EpiPen’s sales volume and profitability, fend off competitors, and protect the EpiPen patents by using the judicial and regulatory process to restrain competition.

Defendants did so by adding several more patents to the already-patented EpiPen to prevent the launch of competing generics. Defendants have four patents on the EpiPen. According to the class plaintiffs, none of them are designed to enhance the product. Instead, the patents’ purposes are to stop generic competitors. Indeed, Mylan CEO Heather Bresch announced during a public earnings call in 2009 that Mylan was adding another patent to the already-patented EpiPen device that “will also put in another barrier to entry because . . . now that market preferential would be the needle protected device and drug of which we have IP and stuff around. So I just think it is a very, very difficult hurdle to get through, and so feel confident that EpiPen is in good shape.” Class Compl. ¶ 238. On September 14, 2010, Meridian secured U.S. Patent No. 7,794,432—less than three weeks before Intelliject (the inventor of Auvi-Q) submitted its New Drug Application (“NDA”) to the FDA.

Defendants also worked together to stop generic competition to the EpiPen by filing patent infringement lawsuits. They filed such lawsuits against three generic EpiPen rivals—Sandoz, Teva, and Intelliject—and then entered into anticompetitive settlements with impending generic manufacturers.

### ***Teva Settlement***

In December 2008, Teva filed an Abbreviated New Drug Application (“ANDA”) seeking FDA approval to market a generic EpiPen. In August 2009, Pfizer’s subsidiaries—King and Meridian—sued Teva for infringing U.S. Patent No. 7,449,012 (“the Teva Litigation”). In November 2010, King and Meridian filed a First Amended Complaint that included a claim for



infringing the newly secured '432 patent. Later, King and Meridian dropped their claims based on infringing the '012 patent, leaving only the claims for infringing the '432 patent.

After discovery and a bench trial in March 2012, the parties settled the Teva Litigation on April 27, 2012. According to the class plaintiffs, defendants and Teva entered an unlawful settlement agreement that required Teva to delay launching its generic EAI for three years—until June 22, 2015—in exchange for defendants providing significant consideration, incentives, and benefits to Teva. The Class Complaint lists several facts about the Teva settlement that, the class plaintiffs contend, show defendants made a substantial “reverse payment” to Teva to convince it to delay bringing its competing product to market. These facts include:

- E  
1 The court’s Markman rulings interpreting the terms of the '432 patent were favorable to Teva.
- E  
1 The parties settled the litigation after completing a full bench trial, meaning that the parties likely would incur marginal litigation expenses going forward, as compared to the expenses already incurred at settlement.
- E  
1 No rational economic actor with a viable product (and who had spent millions of dollars developing it) would refrain from entering a lucrative market for 36 months unless it received monetary compensation in exchange for non-entry.
- E  
1 In 2012, the Federal Trade Commission reported seeing “a record number of settlements involv[ing] potential pay-for-delay agreements,” and that, in patent settlements involving a “first-filer” like Teva, the majority of the settlements involved explicit compensation in return for delayed entry (Class Compl. ¶¶ 267–68).

☐ On the same day of the Teva settlement, Mylan issued a joint press release announcing the settlement on its own behalf and for Pfizer.

☐ Four days after announcing the Teva settlement, Teva and Mylan settled another lawsuit where Teva had asserted patent infringement claims against Mylan based on Mylan's application to market a generic version of Teva's drug, Nuvigil. With the Nuvigil settlement, Mylan agreed to delay market entry until June 2016. Like the EpiPen, Nuvigil had annual sales hovering near \$1 billion. So, procuring delayed entry of generics for both Nuvigil and the EpiPen was valuable to all parties involved.

☐ The Teva settlement has come under congressional scrutiny as a "pay-for-delay" agreement.

During the same time period, the Teva settlement also prevented competition from any other generic EAI device. Defendants knew that their agreement with Teva would delay market entry because Teva was subject to the Hatch-Waxman Act's 180-day exclusivity award. This provision grants a six-month exclusivity period to the first generic to challenge a brand firm's patent, claiming it is invalid or not infringed. The exclusivity period begins when the first-filing generic enters the market. Here, Teva was the first filer. So, with Teva delaying its market entry under the parties' settlement, Teva's exclusivity period could not begin running until at least three years in the future. As a result, defendants delayed all generics seeking ANDA applications based on the EpiPen.

In a public earnings call, Mylan's CEO Heather Bresch described how the Teva settlement had delayed market competition. Also, she appeared to concede that Mylan had participated in the Teva settlement. In July 2012, she stated publicly: "So we certainly have

seen a benefit [to growing the EpiPen market] and obviously, now with the runway absolutely clear for us through 2015, through *our* settlement with Teva, I can assure you, we are going to continue as we see [the] response continue to invest in EpiPen as a franchise.” Class Compl. ¶ 277 (emphasis added).

### ***Intelliject Settlement***

Defendants initiated another patent lawsuit against Intelliject—the inventor of Auvi-Q—when Intelliject sought FDA approval for its competing EAI. In 2009, Sanofi announced it had acquired the rights to Intelliject’s EAI and that under its license, Sanofi would manufacture and commercialize the product while Intelliject would continue developing the product and work to secure regulatory approval. On January 11, 2011, defendants—through King—filed a patent infringement lawsuit against Intelliject seeking to block FDA approval of its NDA for its product—one that later became known as Auvi-Q. King’s lawsuit alleged that Intelliject’s EAI infringed the ’432 patent—a patent that Meridian secured more than a year after Intelliject began developing its product and less than three weeks before Intelliject filed its NDA.

On August 1, 2011—less than eight months after King filed its lawsuit—the FDA announced that it was giving Intelliject’s EAI tentative final approval, pending resolution of the patent litigation that King filed. Six months later, the parties announced that they had settled the Intelliject litigation. Again, Mylan announced the settlement jointly for itself and Pfizer. Although the parties did not make public the specific terms of the agreement, they announced that the agreement prevented Intelliject and Sanofi from launching their EAI product for another nine months—until November 15, 2012. Intelliject and Sanofi made the agreement not to enter the market until November 15, 2012, in exchange for valuable consideration. Through the

Intelliject litigation, defendants effectively blocked competition from Intelliject’s competing device for almost two years.

### ***Sandoz Settlement***

In 2010, another EAI competitor—Sandoz, Inc. (“Sandoz”)—attempted to enter the EAI market by filing an ANDA for its own generic EpiPen alternative. Similar to the other lawsuits against Teva and Intelliject, defendants—through King—filed a patent infringement suit against Sandoz. According to the class plaintiffs, defendants’ approach to Sandoz was to stall its ANDA by staying the action. The court administratively terminated the Sandoz litigation, giving the parties the ability to reopen the case by letter request. No party has reopened the case. So, to date, Sandoz’s FDA approval and any definitive ruling on the EpiPen patents are stayed indefinitely. The class plaintiffs allege that defendants entered an agreement with Sandoz to stay the case in exchange for valuable consideration paid to Sandoz.

### ***FDA Citizen Petition***

The Class Complaint next alleges that, with Teva’s generic EAI entry into the market looming, defendants took another step to block generic competition from the market by filing an FDA Citizen Petition. An FDA Citizen Petition provides the public with an avenue to present safety concerns to the FDA. But here, the class plaintiffs allege, defendants used the FDA Citizen Petition process to delay—further—Teva’s entry into the market and to prevent Teva’s product from competing with the EpiPen.

On January 16, 2015, Mylan filed a Citizen Petition “a mere six months before Teva was scheduled (pursuant to the settlement) to enter the market.” Class Compl. ¶ 311. Antitrust scholar Michael Carrier of Rutgers Law School described Mylan’s Petition in this fashion:

In its petition, Mylan contended that Teva should be required to demonstrate that its product was the “same as” Mylan’s EpiPen. In other words, even though the

parties had already agreed through settlement to delay Teva's generic entry for more than three years, Mylan sought to further delay the entry of Teva's generic through its citizen petition.

In addition to its January 2015 petition, the company waited almost five months after filing and only weeks before the FDA was required to respond, until May 2015, to supplement its petition with a 48-page independent study purportedly showing that patients would not use Teva's generic product correctly.

Given that Teva's generic product had been in development for at least six years before the petition's filing, this late-filing of a supplemental study implicates significant timing questions. Why would such a study be submitted only weeks before the FDA was required to respond under the FDA's 150-day clock?

*Id.* (quoting Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 *Cardozo L. Rev.* 249, 279 (2012)). According to the class plaintiffs, Mylan's submissions to the FDA rested on fundamentally flawed studies and the medical opinions of a doctor whom Mylan had paid some \$95,000 in fees.

According to the class plaintiffs, without defendants' use of the FDA Citizen Petition process, Teva would have entered the market much sooner after addressing any FDA concerns and securing FDA approval. The class plaintiffs also assert that, from 2009 to present, defendants' actions deterred not only Teva, but also many more potential generics companies from developing and launching competing products.

### ***Defendants Implement a Pricing Scheme***

The Class Complaint next alleges that the Mylan Defendants implemented a pricing scheme that defrauded U.S. consumers into paying an inflated price for the EpiPen—one that climbed by more than 500%. The Mylan Defendants allegedly implemented this pricing scheme working alongside PBMs. Mylan is a generics company that typically makes low margins on drug sales. But the EpiPen—a specialty branded drug—represented a unique and highly profitable revenue stream for Mylan. Recognizing this opportunity, Mylan CEO Heather Bresch

and other executives decided to exploit the EpiPen to generate billions of dollars in revenue for Mylan. According to the class plaintiffs, the Mylan Defendants and the PBMs distracted consumers and regulators from the reality that defendants were raising the price of the EpiPen from \$100 to \$600 by launching a campaign of false and misleading statements and actions.

One of the ways that the Mylan Defendants allegedly implemented their pricing scheme was changing the way Mylan sold the EpiPen. On August 24, 2011, Mylan announced that it no longer would sell individual EpiPens in the U.S. Instead, Mylan forced U.S. consumers to purchase EpiPens in pairs with the EpiPen 2-Pak. The class plaintiffs refer to this change as the “hard switch.” And the class plaintiffs allege that the “hard switch” forced consumers and third-party payors to overpay for the EpiPen 2-Pak because the switch, in effect, doubled the EpiPen’s price.

From 1987 to 2011, Mylan and others had sold the EpiPen one at a time in the U.S. without incident. Nothing changed in 2011 that required Mylan to sell the EpiPen as a 2-Pak. The EpiPen 2-Pak is just two individual EpiPens connected by a grey piece of plastic. The class plaintiffs allege that no medical reason exists to force customers to purchase a 2-Pak instead of a single EpiPen. Instead, Mylan deceptively suggested that the 2-Pak was medically required even though EpiPens are sold individually in every other country besides the United States. Also, Mylan’s packaging offers no medical instructions or guidelines for patients to know whether, or when, to administer the second back-up EpiPen.

Beginning in 2011, Mylan began raising the price of the EpiPen while forcing customers to buy EpiPens in the 2-Pak. In October 2011, Mylan increased the price of an EpiPen 2-Pak to \$181. And by May 2016, the price of an EpiPen 2-Pak jumped to \$608.

***The Mylan Defendants Have Made Various Misrepresentations and Omissions in an Effort to Conceal Their Anticompetitive Conduct***

Finally, the Class Complaint alleges that the Mylan Defendants have spread false and misleading information and omitted material information as part of their scheme to monopolize the EAI market. They spread, the Class Complaint alleges, four broad categories of false and misleading information.

*First*, the class plaintiffs allege, Mylan created and spread misinformation about a competing EAI device—Auvi-Q. Although the FDA had determined that the epinephrine in Auvi-Q is a bioequivalent to the epinephrine in the EpiPen, Mylan funded and promoted a study entitled, “Auvi-Q versus EpiPen Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve.” Class Compl. ¶ 229. Mylan intended the study to undermine the FDA’s conclusion that Auvi-Q had demonstrated bioequivalence to the epinephrine in the EpiPen—in direct contradiction to the FDA’s conclusion.

The class plaintiffs also allege that Mylan made false and misleading statements about Auvi-Q’s formulary status. According to the class plaintiffs, Mylan’s anticompetitive conduct caused major health plans either to limit their coverage of Auvi-Q or to exclude Auvi-Q from coverage altogether. Mylan did so by paying formularies to exclude Auvi-Q from coverage. But then, Mylan marketed to physicians the fact that Auvi-Q was not covered by formularies and suggested that the decision to exclude Auvi-Q from coverage was based on clinical recommendations—and not Mylan’s large, conditional rebate offers.

*Second*, the class plaintiffs allege that Mylan made false and misleading statements about the “hard switch” to the EpiPen 2-Pak. On August 24, 2011, Mylan issued a news release entitled “Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively.” Class Compl. ¶

336. The press release’s subheadline provided: “Decision aligns with recent clinical guidelines for patients at risk for or who have experienced anaphylaxis to have immediate access to two doses of epinephrine.” *Id.* The Class Complaint alleges that the press release was fraudulent and misleading for several reasons. They include:

- The press release cited a National Institute of Allergy and Infectious Diseases (“NIAID”) study that did not apply to the general population. Instead, it applied only to a narrow subset: allergy sufferers who had already (1) been hospitalized for (2) a food allergy.
- Mylan purported to rely on the World Allergy Organization (“WAO”) global standard in making the switch, but Mylan did not require sale of the EpiPen 2-Pak globally. Indeed, the press release states that the single EpiPen Auto-Injector package configuration will remain available outside of the U.S.
- The switch to the 2-Pak did not change patient access to two doses of epinephrine. Doctors could write, and often did write, prescriptions for two EpiPens. So, no need existed for Mylan to mandate something patients could purchase already.
- The medical guidelines recited did not state that providers must sell two doses of epinephrine. Instead, Mylan used the WAO’s vague statement as a false pretext for selling only the 2-Pak.
- No mandates required Mylan to sell the EpiPen exclusively as a 2-Pak, or not at all.
- No medical studies support the decision to sell the EpiPen exclusively as a 2-Pak.
- From 1987 until 2011, the EpiPen was sold individually without incident.  
Nothing changed suddenly in 2011 that required Mylan to sell only the 2-Pak.



FO  
b7  
When Mylan switched to the 2-Pak in 2011, it did not order a recall or insist that all U.S. EpiPen patients immediately go buy a second EpiPen.

FO  
b7  
Although the press release relies on the WAO, the U.S. is the only country where Mylan required customers to purchase a 2-Pak of the EpiPen.

FO  
b7  
According to a study conducted by the American Academy of Allergy, Asthma & Immunology, only a small number of patients require a second dose. The reason for selling the device solely in packs of two is to account for user error due to the imperfect product design, *i.e.*, 14% of parents accidentally stick the needle in their own thumb instead of in their child's leg.

FO  
b7  
Mylan offers no medical guidelines or instructions to EpiPen 2-Pak consumers in its packaging or on the device to explain how or when to use (or even how to store) the second EpiPen in the 2-Pak.

FO  
b7  
Mylan states that between 1–20% of patients might need a second device. But, according to class plaintiffs, the margin of 1–20% is so wide that it is meaningless and provides a false justification for the “hard switch” to the 2-Pak.

Class Compl. ¶ 339. The class plaintiffs also allege that the NIAID panel Mylan relied on to justify the change to the 2-Pak was influenced and tainted by Mylan's financial contributions.

The August 24, 2011, press release quotes Dr. Phillip Lieberman, a member of the NIAID panel, as stating that up to 20% of patients will require more than one dose of epinephrine to relieve symptoms. According to the class plaintiffs, Dr. Lieberman's statement does not explain why a 2-Pak is necessary for 100% of patients when only “up to 20%” require more than one dose.

Also, his statement never explains why all patients must purchase two EpiPens instead of having

a prescription that allows two doses. The class plaintiffs allege that Dr. Lieberman made his statement justifying the switch to the 2-Pak because Mylan paid him to do so.

*Third*, the class plaintiffs allege, Mylan made false statements about coupons, rebates, and generics. Mylan has stated publicly on its website and to the media throughout at least 2016 that 80% of consumers with insurance pay nothing for the EpiPen. According to the class plaintiffs, this statement is false because third-party payors end up paying the bulk of the cost for the EpiPen and, in turn, the third-party payors pass on the costs to patients with increased premiums. Mylan also announced recently that it will begin offering a \$300 generic version of the EpiPen. The class plaintiffs assert that Mylan's admission that it can make a \$300 generic using the same factories and components used to make the \$600 EpiPen shows that Mylan is price gouging consumers with its current list price for the EpiPen.

*Finally*, the Class Complaint alleges that Mylan made false statements to Congress under oath to help cover up its fraud and to deceive the public about the EpiPen price increases. The Class Complaint asserts that CEO Heather Bresch falsely testified to Congress on September 21, 2016, when she: (1) misrepresented Mylan's profit on the EpiPen as \$50 per device, but, according to a *Wall Street Journal* article, Mylan's profits were 60% higher than that amount; (2) misrepresented that Mylan had invested more than \$1 billion in the EpiPen when, in fact, Mylan acquired the EpiPen in 2007 without incurring any research and development expenses; (3) misrepresented that Mylan had provided free EpiPens to more than 66,000 U.S. schools with "no strings attached," but Mylan, in fact, did attach strings to the free EpiPens by requiring the schools to sign a contract agreeing not to purchase any products from Mylan's competitors for a twelve-month period; (4) misrepresented that Mylan had reduced U.S. healthcare costs by about

\$180 billion; and (5) misrepresented that 85% of EpiPen patients pay less than \$100 for a 2-Pak and a majority pay less than \$50.

## II. Legal Standard

Fed. R. Civ. P. 8(a)(2) provides that a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Although this Rule “does not require ‘detailed factual allegations,’” it demands more than “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action’” which, as the Supreme Court explained, “will not do.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must assume that the factual allegations in the complaint are true. *Id.* (citing *Twombly*, 550 U.S. at 555). But the court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Id.* (quoting *Twombly*, 550 U.S. at 555). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” to state a claim for relief. *Bixler v. Foster*, 596 F.3d 751, 756 (10th Cir. 2010) (quoting *Iqbal*, 556 U.S. at 678). Also, the complaint’s “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555 (citations omitted).

For a complaint to survive a motion to dismiss under Rule 12(b)(6), the pleading “must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Iqbal*, 556 U.S. at 679 (quoting *Twombly*, 550 U.S. at 570). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 678 (citing *Twombly*, 550 U.S. at 556). “The plausibility standard is not akin to a ‘probability requirement,’ but it asks

for more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (quoting *Twombly*, 550 U.S. at 556); *see also Christy Sports, LLC v. Deer Valley Resort Co., Ltd.*, 555 F.3d 1188, 1192 (10th Cir. 2009) (“The question is whether, if the allegations are true, it is plausible and not merely possible that the plaintiff is entitled to relief under the relevant law.” (citation omitted)).

In the antitrust context, the Supreme Court observed in *Twombly* that “proceeding to antitrust discovery can be expensive.” *Twombly*, 550 U.S. at 558 (applying the plausibility pleading standard to Sherman Act claims). So, courts must “‘insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.’” *Id.* (quoting *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 528 n.17 (1983)). But still, antitrust cases are not subject to a standard requiring “heightened fact pleading of specifics.” *Id.* at 570. Instead, an antitrust Complaint must allege “only enough facts to state a claim to relief that is plausible on its face” sufficient to “nudge[ ] the[ ] claims across the line from conceivable to plausible.” *Id.*; *see also In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1074 (D. Kan. 2009) (explaining on a Rule 12(b)(6) motion to dismiss antitrust claims that “the Court must ensure that plaintiffs have alleged facts to support those elements sufficient to provide the ‘heft’ to show an entitlement to relief and to ‘nudge’ plaintiffs’ claims over the line from mere[ ] possibility or speculation to plausibility” (quoting *Twombly*, 550 U.S. at 557, 570)).

The court’s analysis, below, applies this governing standard to defendants’ Rule 12(b)(6) dismissal arguments.

### **III. Analysis**

The Class Complaint asserts nine claims against the Mylan Defendants: (1) Sherman Act §§ 1 and 2 violations (Count I); (2) Clayton Act § 3 violations (Count II); (3) conspiracy

violating state antitrust statutes (Count III); (4) monopolization violating state antitrust statutes (Count IV); (5) attempted monopolization violating state antitrust statutes (Count V); (6) tying violating state antitrust statutes (Count VI); (7) RICO Act violations (Count VII); (8) violation of state consumer protection laws (Count VIII); and (9) unjust enrichment (Count IX). The Class Complaint asserts just Counts I–V and VII jointly against the Mylan and Pfizer Defendants.

Both the Mylan and Pfizer Defendants move the court to dismiss each claim asserted in the Class Complaint. The court addresses each of defendants’ arguments in the subsections, below. The first section addresses whether the Class Complaint states plausible claims of federal and state antitrust violations. The second section discusses whether the class plaintiffs have alleged viable RICO claims. The third section addresses whether the Class Complaint states plausible claims for relief under state consumer protection laws. Finally, the fourth section considers whether the class plaintiffs have stated a claim for unjust enrichment.

#### **A. Antitrust Claims**

Defendants assert eight different arguments why the class plaintiffs’ factual allegations never state a plausible antitrust claim under either federal or state law. The court addresses each one of the eight arguments, in turn, below.

##### **1. Have the class plaintiffs alleged a plausible tying claim based on the EpiPen 2-Pak?**

The Mylan Defendants<sup>3</sup> argue that the Class Complaint fails to allege a plausible tying claim because it never alleges the existence of two distinct products. Instead, the Mylan Defendants contend, the class plaintiffs premise their tying claim on the EpiPen 2-Pak, *i.e.*

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<sup>3</sup> The class plaintiffs assert their tying claim just against the Mylan Defendants—not the Pfizer Defendants.

selling two EpiPen devices in one package. Defendants assert that this practice—because it involves selling two identical products—is not an unlawful tying arrangement.

Tying is an arrangement involving the sale of “two distinct products or services as a package.” *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 33 (1984) (Brennan, J., concurring), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (further citation omitted). “[T]he essential characteristic of an invalid tying arrangement lies in the seller’s exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms.” *Id.* at 12. But “a tying arrangement cannot exist unless two separate product markets have been linked.” *Id.* at 21. And “the question whether one or two products are involved turns not on the functional relation between them, but rather on the character of the demand for the two items.” *Id.* at 19; *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 456 (1992) (“[T]o be considered two distinct products, there must be sufficient consumer demand so that it is efficient for a firm to provide [one] separately from [the other].”).

The class plaintiffs respond that they have alleged a tying arrangement involving two separate product markets—one for the primary EAI device, and the other for a “spare” (or “back-up”) EAI device. Class Compl. ¶¶ 575–79. The Class Complaint describes how Mylan and others sold the EpiPen individually in the U.S. from 1987 to 2011 without incident. But, in 2011, Mylan imposed the “hard switch,” requiring patients to purchase EpiPens in pairs in the EpiPen 2-Pak. The class plaintiffs allege that, before the “hard switch,” “[t]here was sufficient independent demand for some patients to either not purchase a second EpiPen at all or to purchase an EpiPen and a cheaper, alternative back-up.” *Id.* ¶ 577. But, after the hard switch,

Mylan forced patients to buy two separate devices—the primary EAI device and back-up EAI device—even though “each EpiPen expires annually and the vast majority of EpiPens expire before they can be used.” *Id.* ¶ 577. As the Class Complaint describes: “Consumers no longer had the choice or ability to purchase a back-up or spare device from another manufacturer, or to decline to purchase a second EpiPen based on whether they needed it, chose to purchase it, or were prescribed it by a doctor.” *Id.* ¶ 579.

Viewing these allegations in the class plaintiffs’ favor, the Class Complaint alleges a “sufficient consumer demand” in the U.S. to purchase a primary EAI device separately from a back-up device or none at all “so that it is efficient for a firm to provide [one] separately from [the other].” *Eastman Kodak Co.*, 504 U.S. at 456; *see also Multi-State Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof’l Pubs., Inc.*, 63 F.3d 1540, 1547–48 (10th Cir. 1995) (holding that the case’s summary judgment facts presented a factual dispute whether “enough consumer demand [existed] in Colorado” for one product such that it was efficient to sell the two products separately).

The court recognizes that the class plaintiffs have alleged a tying relationship based on two products that are functionally identical. The Mylan Defendants assert that the two products thus are interchangeable. For example, a patient could use either one of the two EpiPens in a 2-Pak as the primary device and the other one as the back-up device. The Mylan Defendants thus argue that it is not plausible that the primary EAI device and backup EAI device belong to separate markets. Indeed, the Tenth Circuit has defined the “relevant product market in any given case” as one ““composed of products that have reasonable *interchangeability* for the purposes for which they are produced—price, use and qualities considered.”” *Buccaneer Energy (USA) Inc. v. Gunnison Energy Corp.*, 846 F.3d 1297, 1313 (10th Cir. 2017) (quoting *SCFC ILC*,

*Inc. v. Visa USA, Inc.*, 36 F.3d 958, 966 (10th Cir. 1994)) (emphasis added). Although the two products here have the same qualities, the Class Complaint defines how patients *use* them in a functional sense as two separate products. A patient uses one EpiPen as the primary EAI device and the other as the back-up device.

The parties do not cite, and the court’s research has not revealed, any tying cases involving identical products with different and distinct uses—what the class plaintiffs allege here. The Mylan Defendants cite two cases where courts refused to find two separate products to support a tying claim, but those cases involved preliminary injunction motions where the factual record failed to demonstrate the existence of two separate product markets. *See Metromedia Broad. Corp. v. MGM/UA Entm’t Co.*, 611 F. Supp. 415, 422–24 (C.D. Cal. 1985) (recognizing that questions existed whether “the demand for first runs [of TV series] is separate from that for reruns,” but refusing to “carve up” a copyright for the purposes of licensing “a single intellectual property” because both the first runs and reruns shared the “same copyright and uniqueness,” which “was the product from which market power derives”); *Paul v. Pulitzer Publ’g Co.*, No 74-327C(A), 1974 WL 887, at \*5 (E.D. Mo. May 24, 1974) (holding that “different issues of the same newspaper are not separate products” but never discussing whether consumer demand existed for selling weekday editions separately from the Saturday edition).

In contrast here, the Class Complaint asserts facts that plausibly allege two separate product markets—one for EAI primary devices and the other for back-up devices. These allegations are sufficient to state a claim at this stage of the litigation. Ultimately, to prevail on their tying claim, the class plaintiffs must adduce admissible evidence to support a reasonable finding that two separate product markets exist. But, to survive the Motions to Dismiss,



plaintiffs need only make plausible factual allegations of two different product markets. They have satisfied that requirement.

**2. Have the class plaintiffs alleged plausible exclusive dealing claims based on Mylan’s exclusive dealing contracts with PBMs and schools?**

The Mylan Defendants assert that the class plaintiffs have failed to allege plausible antitrust claims based on Mylan’s exclusive dealing contracts with PBMs and schools.

Defendants offer five arguments to support their assertion.

*First*, the Mylan Defendants argue, the Class Complaint never alleges that Mylan’s rebates and discount offers resulted in EpiPen prices below the cost of their production. Six days after the Mylan Defendants filed their Motions to Dismiss the Class Complaint, the court issued a Memorandum and Order in the other of the two separate tracks in this MDL—the Sanofi track. The court’s Order granted Mylan’s Motion to Dismiss the *Sanofi* Complaint in part, and denied that motion in part (“the *Sanofi* Order”). Doc. 98. In the *Sanofi* Order, the court rejected the same argument asserted here—*i.e.*, that Sanofi’s exclusive dealing claims fail as a matter of law because the *Sanofi* Complaint never alleges that Mylan’s rebate offers resulted in prices that were below its costs to produce the EpiPen. *See id.* at 10–15. The court recognized that the price-cost test does not apply to bar exclusive dealing claims when price itself is not the clearly predominant mechanism of exclusion. *Id.* at 12–13 (citing *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 277 (3d Cir. 2012) (further citations omitted)). And, viewing the allegations in Sanofi’s favor, the court concluded that the *Sanofi* Complaint “does not rely ‘solely on the exclusionary effect of [Mylan’s] prices’ to support its exclusive dealing claim based on Mylan’s rebate program.” *Id.* at 13 (quoting *ZF Meritor*, 696 F.3d at 277).

The same is true of the Class Complaint.<sup>4</sup> The Class Complaint alleges that Mylan leveraged its greater-than-90% market share by offering large rebates to PBMs to exclude Auvi-Q from the formularies. Class Compl. ¶ 177. The Class Complaint asserts that no legitimate business reason existed for Mylan’s deep conditional rebates except blocking Auvi-Q from the market. *Id.* ¶ 178. Also, it asserts that Mylan’s rebates effectively prevented competitors from accessing formularies of the two largest PBMs—Express Scripts and CVS Caremark—that combine to cover more than 50% of the PBM market in the United States. *Id.* ¶¶ 162, 168. The Class Complaint alleges that Mylan’s conditional rebates unlawfully increased Sanofi’s cost to enter the market if it wanted to match Mylan’s rebates. *Id.* ¶ 182. And, the Class Complaint alleges, after Mylan successfully excluded Auvi-Q from coverage, it sent misleading marketing materials to physicians asserting that EpiPen was the “preferred” EAI device for 99% of patients while Auvi-Q was “preferred” for only 2% of patients. According to the class plaintiffs, the marketing materials suggested that the reason for Auvi-Q’s exclusion was based on clinical recommendations—and not the large, conditional rebate offers. *Id.* ¶¶ 232–35. These allegations assert that Mylan’s rebate program involved anticompetitive conduct—beyond pricing itself—that was designed to exclude competition in the EAI drug market.

*Second*, the Mylan Defendants contend that the Class Complaint never alleges that Mylan’s rebates harmed the class plaintiffs by excluding Auvi-Q from the market because Sanofi’s decision not to compete with the EpiPen was based on other factors, all unrelated to Mylan’s conduct. The Mylan Defendants cite a paragraph from the *Sanofi* Complaint asserting that Sanofi voluntarily recalled Auvi-Q in October 2015 following reports of manufacturing

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<sup>4</sup> Mylan’s Reply—filed after the court issued its *Sanofi* Order—concedes that the *Sanofi* Order decided against this argument and states that Mylan is not relitigating the issue. Doc. 219 at 18 n.5. But Mylan’s Reply incorporates the arguments made in its opening brief and preserves the issue for further review. *Id.*

issues. Doc. 95 at 44. But, as the court concluded in the *Sanofi* Order, the *Sanofi* Complaint plausibly alleges that Mylan's conduct forced Sanofi to exit the EAI drug market. Doc. 98 at 40. The Class Complaint contains similar allegations. As the court already has held, Mylan's arguments that the voluntary recall—and not Mylan's alleged anticompetitive conduct—caused Sanofi's injuries present a factual dispute that the court cannot resolve on a motion to dismiss. *Id.* For the same reasons as the *Sanofi* Order discussed, the court declines to dismiss the class plaintiffs' exclusive dealing claims based on Mylan's argument that Sanofi's decision to exit the EAI market was based on factors other than Mylan's anticompetitive conduct.

*Third*, the Mylan Defendants assert that the Class Complaint never alleges that Mylan's exclusive dealing contracts harmed competition. The court rejected this same argument in the *Sanofi* Order. It rejects it again here for the same reasons. The Class Complaint, construed in favor of the class plaintiffs, plausibly alleges that Mylan's anticompetitive conduct harmed competition. The Class Complaint alleges that defendants implemented a pricing scheme that raised the price of the EpiPen from a little over \$100 for two EpiPens in 2007 to more than \$600 for the same two EpiPens in 2016. Class Compl. ¶¶ 349–60. According to the class plaintiffs, the price increases allowed Mylan to share its monopoly profits with PBMs through larger rebates for excluding competing products. *Id.* ¶¶ 165–66. Mylan's exclusionary contracts then prevented consumers in a substantial share of the market from accessing or choosing competing EAI devices such as the Auvi-Q and others. *Id.* at ¶¶ 168, 491. These allegations, if true, are capable of supporting a finding or inference of harm to competition, and thus, they state a plausible antitrust claim.

*Fourth*, the Mylan Defendants assert that the class plaintiffs' claims based on discounts or rebates Mylan offered to states or state agencies are barred by the *Noerr-Pennington* doctrine.

The *Noerr-Pennington* doctrine “‘exempts from antitrust liability any legitimate use of the political process by private individuals, even if their intent is to eliminate competition.’” *Tal v. Hogan*, 453 F.3d 1244, 1257 n.13, 1259–60 (10th Cir. 2006) (quoting *Zimomra v. Alamo Rent-A-Car, Inc.*, 111 F.3d 1495, 1503 (10th Cir. 1997)). The scope of the *Noerr-Pennington* doctrine depends “on the source, context, and nature of the anticompetitive restraint at issue.” *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988).

But “*Noerr-Pennington* immunity does not apply if the purported effort to influence or obtain government action is in fact only an attempt to interfere with the business relationships of a competitor.” *Classic Commc’ns, Inc. v. Rural Tel. Serv. Co.*, 956 F. Supp. 910, 917 (D. Kan. 1997) (first citing *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); then citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972)). “This is the so-called ‘sham’ exception to the *Noerr-Pennington* doctrine.” *Id.* The sham exception applies “when ‘persons use the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.’” *GF Gaming Corp. v. City of Black Hawk*, 405 F.3d 876, 884 (10th Cir. 2005) (quoting *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991)). “The exception thus ‘involves a defendant whose activities are not genuinely aimed at procuring favorable government action at all,’ such as a defendant who files ‘frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay.’” *Id.* (quoting *City of Columbia*, 499 U.S. at 380).

In the *Sanofi* Order, the court held that the *Noerr-Pennington* doctrine barred Sanofi’s exclusive dealing claims based on Mylan’s discounts or rebates to state-based Medicaid agencies. Doc. 98 at 22–24. The court reasoned that Sanofi’s allegations accused Mylan of

using the *outcome* of the government process—*i.e.*, exclusion of Auvi-Q from the drug formularies—*not the process itself*, to harm a competitor. *Id.* at 22. Thus, the court concluded, *Noerr-Pennington* immunity applied to Sanofi’s claims based on discounts or rebates offered to state-based Medicaid agencies. *Id.*

The class plaintiffs argue the court should reach a different result here because, they contend, the Class Complaint’s allegations differ from Sanofi’s. First, the class plaintiffs contend that their antitrust claims are premised on Mylan’s misclassification of the EpiPen and that this misclassification influenced decisions by state-based Medicaid agencies to exclude Auvi-Q. The Class Complaint alleges that Mylan’s misclassification of the EpiPen allowed it to “amass millions of dollars each year in unpaid rebates to cash-strapped state Medicaid agencies.” Class Compl. ¶ 187. And, according to the Class Complaint, these “outstanding underpaid rebates led benefit managers to continue favoring the EpiPen over competitors in the expectation of receiving a large make-up payment if and when Mylan was forced to classify the EpiPen as a brand.” *Id.* ¶ 188. The class plaintiffs assert that the *Noerr-Pennington* doctrine does not shield Mylan’s misrepresentations about the EpiPen’s classification from antitrust liability because “[m]isrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process.” *Cal. Motor Transp.*, 404 U.S. at 513.

The court disagrees that the class plaintiffs’ allegation about the EpiPen’s misclassification—in this one paragraph of their 1,429 paragraph Class Complaint—places the claim outside of *Noerr-Pennington* immunity. Indeed, “[n]ot every fraudulent misrepresentation during an adjudicative or administrative proceeding can give rise to antitrust liability.” *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 843 (7th Cir. 2011). “[A] misrepresentation renders an adjudicative proceeding a sham only if the misrepresentation (1) was intentionally

made, with knowledge of its falsity; and (2) was material, in the sense that it actually altered the outcome of the proceeding.” *Id.* at 843; *see also Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 123 (3d Cir. 1999) (“While we do not condone misrepresentations in a judicial setting, neither will we deprive litigants of immunity derived from the First Amendment’s right to petition the government if the alleged misrepresentations do not affect the core of the litigant’s . . . case.”).

Here, the class plaintiffs’ allegation never asserts explicitly that the misclassification caused any state-based Medicaid agencies to exclude EpiPen rivals from the formularies. Instead, the allegation refers generally to “benefit managers.” And it recites that these benefit managers continued to “favor” the EpiPen over competitors. Also, the allegation asserts that the benefit managers knew about the misclassification and thus anticipated a large make-up payment when Mylan was forced to reclassify the EpiPen. Thus, according to the allegation, the benefit managers never made their decisions based on any false representations that Mylan made to them. To the contrary, the allegation asserts that the benefit managers understood that Mylan had misclassified the EpiPen. So, nothing about the misclassification affected the decision-making abilities of benefit managers when they chose which EAI devices to include in the formularies. Construed in the class plaintiffs’ favor, the exclusive dealing allegations based on Mylan’s discounts or rebates to state-based Medicaid agencies assert that Mylan’s conduct violated the antitrust laws by offering the rebates in exchange for exclusivity. The *Noerr-Pennington* doctrine precludes liability for this type of conduct, even if the intent was to exclude competition. Thus, the Class Complaint fails to allege a plausible antitrust claim based on Mylan’s discounts or rebates to state-based Medicaid agencies.

Finally, the Mylan Defendants argue that the Class Complaint never alleges that Mylan’s EpiPen4Schools program foreclosed competitors from a substantial share of the relevant market.<sup>5</sup> To assert a plausible exclusive dealing claim, a plaintiff must plead facts capable of supporting a finding or inference that the “probable effect” of “performance of the contract will foreclose competition in a substantial share of the line of commerce affected.” *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961); *see also Perington Wholesale, Inc. v. Burger King Corp.*, 631 F.2d 1369, 1374 (10th Cir. 1979) (“Thus, a complaining trader must allege and prove that a particular arrangement unreasonably restricts the opportunities of the seller’s competitors to market their product.”).

The Supreme Court has instructed lower courts “[t]o determine substantiality in a given case” by “weigh[ing] the probable effect of the contract on the relevant area of effective competition, taking into account the relative strength of the parties, the proportionate volume of commerce involved in relation to the total volume of commerce in the relevant market area, and the probable immediate and future effects which pre-emption of that share of the market might have on effective competition therein.” *Tampa Elec.*, 365 U.S. at 329. When considering whether the contract at issue in *Tampa Electric* tended to foreclose a substantial volume of competition, the Supreme Court considered several things. *Id.* at 334–35. They include the relative dominance of a seller’s position in the market, whether the market has “myriad outlets

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<sup>5</sup> The Mylan Defendants also assert that “[a]t best, Plaintiffs allege that Mylan engaged in legitimate state and federal lobbying efforts to allow schools to participate in the program” and that the *Noerr-Pennington* doctrine shields such conduct from antitrust liability. Doc. 95 at 46. But the class plaintiffs do not base their antitrust claims on Mylan’s lobbying activities. Instead, the claims are premised on Mylan’s alleged anticompetitive conduct in offering free and discounted EpiPens to school districts but making those offers contingent on the school districts entering into illegal exclusive dealing agreements with Mylan. The Mylan Defendants never argue that the *Noerr-Pennington* doctrine immunizes that alleged anticompetitive conduct—*i.e.*, the conduct on which the class plaintiffs base their antitrust claims for the EpiPen4Schools program.

with substantial sales volume,” the prevalence in the industry of exclusive contracts, the duration of the contract, and the existence of any pro-competitive justifications for the contract. *Id.*

The class plaintiffs assert that the Class Complaint plausibly alleges facts capable of supporting a finding or inference of substantial market foreclosure. The Class Complaint alleges that Mylan’s exclusionary contracts with PBMs prevented competitors from accessing formularies covering more than 50% of the PBM market in the U.S. Also, the Class Complaint alleges that Mylan created a substantial, additional need for EpiPens by adding school districts to the market for EAI devices. Class Compl. ¶ 208. More than 67,000 school districts now purchase EpiPens, and the districts usually are “bulk” purchasers. *Id.* For example, the public schools in Fairfax County, Virginia, order about 1,100 EpiPen 2-Paks annually to have them on hand for their 180,000 students. *Id.* The Class Complaint also alleges that Mylan gained another advantage by opening up the school market—gaining access to nursing staff and creating familiarity with the EpiPen among parents. *Id.* ¶ 209.

Although these allegations never assert definitively that the EpiPen4Schools program’s exclusionary contracts foreclosed a substantial share of the market, the court declines to conclude at the motion to dismiss stage that these facts fail to plead adequate foreclosure. Indeed, our court has recognized that *Tampa Electric* provides a “number of other factors which may be relevant to a rule of reason analysis in an exclusive dealing claim,” and thus it has refused to “decide at the pleading stage that plaintiff had failed to plead adequate foreclosure levels” to state an exclusive dealing claim. *Suture Express, Inc. v. Cardinal Health 200, LLC*, 963 F. Supp. 2d 1212, 1229 (D. Kan. 2013) (Rogers, J.). The court comes to the same conclusion here. To determine whether the EpiPen4Schools program’s exclusionary contracts foreclosed a substantial share of the market, the court must weigh the various factors outlined in *Tampa Electric*. The



court cannot engage in such an analysis at the pleading stage. Instead, the court considers the Class Complaint's allegations in the light most favorable to the class plaintiffs. And it concludes that the class plaintiffs plausibly have alleged facts supporting a finding or inference that the probable effect of Mylan's exclusionary contracts in the EpiPen4Schools program substantially foreclosed competition. The court thus concludes that the class plaintiffs have stated a plausible exclusive dealing claim based on Mylan's EpiPen4Schools program.

**3. Have the class plaintiffs alleged causation to support their antitrust claims based on the patent litigation settlements?**

Next, defendants argue that the class plaintiffs lack standing to assert their antitrust claims based on the patent litigation settlements with potential competitors. This argument asserts that the class plaintiffs have alleged no facts capable of supporting a finding or inference of causation. To establish antitrust standing, a plaintiff must allege "(1) an 'antitrust injury'; and (2) a direct causal connection between that injury and a defendant's violation of the antitrust laws." *Tal v. Hogan*, 453 F.3d 1244, 1253 (10th Cir. 2006) (citations and internal quotation marks omitted); *see also Sharp v. United Airlines, Inc.*, 967 F.2d 404, 406 (10th Cir. 1992) (explaining that antitrust standing requires "the causal connection between the antitrust violation and the plaintiff's injury").

Defendants contend that the class plaintiffs have not alleged plausibly that they caused any delay in the sale of potential competitors' EAI devices by initiating the patent lawsuits and entering into settlement agreements with potential competitors.<sup>6</sup> Instead, defendants provide two

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<sup>6</sup> The Mylan Defendants also argue that the Class Complaint never alleges that Mylan was a party to or participated in the patent litigation with Teva, Intelliject, or Sandoz. Thus, the Mylan Defendants argue, the Class Complaint fails to state a claim against them based on the patent litigation and settlements. As explained in the following subsection (*see infra* Part III.A.4.), the court concludes that plaintiffs have alleged a plausible conspiracy between Mylan and Pfizer that included their coordinated scheme to initiate patent litigation against potential competitors in the EAI market, and then, to settle those lawsuits by agreeing to pay those potential competitors to postpone entry into the market. The court

reasons—unrelated to the patent litigation and settlements—that prevented potential competitors Teva, Intelliject, and Sandoz from entering the EAI market. First, defendants assert, Teva and Sandoz never entered the market because they never secured FDA approval for their EAI devices. Second, defendants contend, these potential competitors could not enter the market lawfully without infringing Pfizer’s EpiPen device patents—ones that don’t expire until 2025. The class plaintiffs respond, asserting that both arguments require the court to make factual determinations—something it cannot do on a motion to dismiss. Instead, the class plaintiffs argue, the Class Complaint alleges facts from which one could infer plausibly that defendants’ conduct prevented potential competitors from entering the EAI market. The court agrees with them, for reasons explained below.

In response to defendants’ first argument, the class plaintiffs concede that the Class Complaint recites that Teva and Sandoz never secured FDA approval for their competing EAI devices. Class Compl. ¶¶ 302, 319. But it also alleges that Teva and Sandoz were anticipating imminent launches into the EAI market and taking the steps to gain FDA approval of their generic, competing products so that they could enter the market. *See id.* ¶¶ 251–52 (reciting that defendants’ alleged “pay-for-delay” settlements were designed “to stop Teva’s imminent generic competition” after Teva had filed an ANDA in December 2008 seeking approval to market a generic EpiPen); *see also id.* ¶ 302 (reciting that “[i]n 2010, Sandoz . . . made a similar attempt to enter the market through a generic alternative to EpiPen” by filing an ANDA). And, the Class Complaint alleges, defendants’ unlawful conduct—*i.e.*, filing the lawsuits and entering into reverse payment settlements for purposes of delaying these potential competitors’ entry into the market—caused Teva and Sandoz’s failure to secure FDA approval.

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thus rejects the Mylan Defendants’ argument that the Class Complaint never alleges that they participated in the patent litigation and settlements.

Indeed, the Class Complaint recognizes that the “FDA ultimately rejected Teva’s generic product when it was under review.” *Id.* ¶ 319. But it also alleges that “it is likely that Teva may have been able to fix those problems if the patent lawsuit had not delayed its ability to enter the market.” *Id.* (citation and internal quotation marks omitted). The Class Complaint also alleges: “But for Mylan’s anti-competitive assault campaign, Teva would have entered the market much sooner and fixed the deficiencies that led to the FDA’s rejection of Teva’s generic.” *Id.* ¶ 322. And it contends: “By sidelining Teva from 2012 to 2015, Mylan, King, and Meridian disrupted Teva’s trajectory toward FDA approval and also gained a three-year guaranteed monopoly period in which Mylan could raise prices on consumers without any fear of generic competition from Teva.” *Id.*

Also, the Class Complaint alleges that Sandoz never secured FDA approval because defendants’ litigation has resulted in “the court entering an order staying the FDA process and administratively terminating the action, to be reopened upon letter request by any of the parties.” *Id.* ¶ 302. And, to date, “[n]o party has reopened the case.” *Id.*

The class plaintiffs argue that these allegations plausibly assert causation because the delay for potential competitors entering the market “was a foreseeable consequence of the original antitrust violation.” *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 630 (E.D. Pa. 2011); *see also id.* at 629–33 (denying summary judgment against antitrust claims because, among other things, plaintiffs presented sufficient evidence to raise genuine issues of material fact whether the FDA’s deficiency notices sent to a potential competing generic “was indeed proximately caused by, or was the foreseeable consequences of, [defendant’s] alleged antitrust violations”). The court agrees with this argument. Viewing the allegations in the class plaintiffs’ favor, the Class Complaint asserts that defendants’ alleged unlawful reverse payment

settlements caused both the potential competitors' delay in entering the EAI device market and their delay in securing FDA approval.

Defendants cite several cases where district courts have dismissed antitrust claims based on reverse payment settlements for lack of causation because, those courts held, the absence of FDA approval had caused the generic's delay in entering the market—not defendants' alleged conduct. Defendants urge the court to apply the same reasoning here. But these cases differ from this one because the complaints in those cases never alleged that defendants had *caused* the delay to secure FDA approval. *See, e.g., In re Asacol Antitrust Litig.*, No. 15-cv-12730-DJC, 2016 WL 4083333, at \*7 (D. Mass. July 20, 2016) (dismissing antitrust claim based on alleged reverse payment settlements because “the amended complaint contains no plausible allegation that [defendants] sought to delay or sabotage FDA approval” and, instead, “the lack of FDA approval today remains ‘the limiting factor’ in [the generic’s] ability to bring its generic drug to market”); *In re Sologyn (Minocycline Hydrochlorine) Antitrust Litig.*, No. 14-md-02503-DJC, 2015 WL 5458570, at \*9 (D. Mass. Sept. 16, 2015) (holding that plaintiffs’ allegations that a reverse payment settlement delayed entry of a competing product never asserted a “plausible allegation of delay by defendants” because the competing product never received FDA approval to launch its product before the parties’ agreed entry date under the settlement); *Brotech Corp. v. White Eagle Int’l Tech. Grp., Inc.*, No. Civ.A.03-232, 2004 WL 1427136, at \*6 (E.D. Pa. June 21, 2004) (holding that a counterclaim alleged no antitrust injury when it “[did] not allege facts establishing [a competitor’s] intent and preparedness to enter the market for its [competing] product, that it would be prepared to enter the market for said product in the absence of the instant lawsuit, or that FDA approval of said products is probable). The facts alleged here differ. The class plaintiffs have alleged that defendants’ reverse payment settlements delayed competing

products—not only from entering the market but from securing FDA approval. *See* Class Compl. ¶¶ 302, 319, 322. These allegations suffice to state a claim for relief at the pleading stage.

In response to defendants’ second argument—that a generic competitor could not enter the market lawfully without infringing Pfizer’s patents—the class plaintiffs assert the Class Complaint plausibly alleges that Pfizer’s patent rights were not sufficient to preclude generic competition (even though the patents did not expire until 2025). The class plaintiffs contend that, without defendants’ alleged unlawful settlements, defendants faced a high probability of generic competition because it was likely that the courts would find the patents invalid or conclude that the generic competing devices were non-infringing. Indeed, the Class Complaint alleges that “given the trial court’s previous rulings [in the Teva Litigation] it requires no great leap to infer that, had the parties waited for a decision, the ‘432 patent would have been found invalid.” *Id.* ¶ 284. It goes on to allege: “That, in turn, would have removed the most significant barrier to entry for Teva—or any other putative generic manufacturer, making it more likely that at least one would have entered or attempted to enter the market.” *Id.* The Class Complaint also alleges facts about the trial court proceedings that allow a plausible finding or inference of invalidity or non-infringement. These alleged facts include: (1) the trial court issued Markman rulings interpreting the ‘432 patent favorable to Teva; (2) the parties settled after the trial court had held a full bench trial, meaning that the parties’ additional litigation expenses were minimal compared to the expenses they already had incurred when they settled; and (3) “[n]o rational economic actor with a viable product (and who had spent millions of dollars developing it) would refrain from entering a lucrative ‘blockbuster’ market for 36 months unless it received monetary compensation in exchange for non-entry.” *Id.* ¶ 265.

Defendants assert that these allegations fail to state a plausible claim because they merely speculate that a generic would have proved invalidity or non-infringement in a patent lawsuit. For support, defendants cite two cases where district courts dismissed antitrust claims based on alleged unlawful reverse payments because the plaintiffs never asserted plausible allegations about a generic's ability to prevail in patent litigation with the patent holders. *See, e.g., FTC v. AbbVie, Inc.*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015) (holding that plaintiff's allegations that the patent litigation was a sham "is merely speculation" because "[n]o judicial determination of the sham issue had been made when the parties settled the case"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 201–02 (E.D.N.Y. 2003) (holding that plaintiff's allegations that a generic would have prevailed in patent litigation were too speculative, especially because of judicially noticed facts about "post-settlement affirmations of the . . . [p]atent's validity").

The court disagrees that the class plaintiffs' allegations here are merely speculative. In contrast to defendants' cited cases, the class plaintiffs here allege facts capable of supporting a finding or inference that a potential generic competitor could have shown that Pfizer's patents were invalid, or that its competing device did not infringe the patents. These factual allegations include ones about what transpired in the Teva Litigation—*i.e.*, that the trial court issued a Markman ruling that was allegedly favorable to Teva and that the timing of the parties' settlement suggests the patent holders recognized the risk of the trial court finding the patents invalid or the competing product non-infringing.

Recently, the Massachusetts federal district court denied summary judgment against an antitrust claim based on a reverse payment settlement. Analyzing the causation issue, that court noted, "the Supreme Court [has] explained that 'it is normally not necessary to litigate patent

validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)’ because ‘[a]n unexplained large reverse payment itself would normally suggest that the patentee has some serious doubts about the patent’s survival.’” *In re Sologyn (Minocycline Hydrochlorine) Antitrust Litig.*, No. 14-md-02503-DJC, 2018 WL 563144, at \*14 (D. Mass. Jan. 25, 2018) (quoting *FTC v. Actavis, Inc.*, 570 U.S. 136, 157 (2013)). Also, the court recognized “as a general matter, ‘[i]t is well established that the burden of proving infringement generally rests upon the patentee.’” *Id.* (quoting *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. 191, 198 (2014)). The Massachusetts court thus concluded that, on summary judgment, “the standard requiring Plaintiffs to produce ‘some evidence’ of invalidity or noninfringement does not require Plaintiffs ‘to prove that the generic defendant would have won, only that it could have.’” *Id.* (quoting *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1155 (N.D. Cal. 2017)).

Applying that reasoning here,<sup>7</sup> the class plaintiffs need not allege that Teva *would* have prevailed in the patent litigation—it merely needs to allege that it *could* have. The Class Complaint’s allegations assert plausibly that Teva could have prevailed in the patent litigation if the parties has not resolved the case through an alleged reverse payment settlement. These allegations thus sufficiently assert that Pfizer’s patents did not bar a generic competitor from entering the market. And the class plaintiffs have stated a plausible antitrust claim based on the alleged unlawful reverse payment settlements. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 755 (E.D. Pa. 2014) (denying motion to dismiss antitrust claim for lack of an injury caused by a patent litigation settlement because, the court concluded, plaintiffs “plausibly alleged that,

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<sup>7</sup> The parties do not cite, and the court’s research has not located, any Tenth Circuit cases discussing the viability of antitrust claims based on reverse payment settlements. The court predicts that the Tenth Circuit, if presented with this issue, would find *In re Sologyn* persuasive and apply its reasoning to the facts alleged here.

but for the anticompetitive settlement agreements, [the generic] would have prevailed in the underlying patent litigation against [the patent holder]”).

**4. Have the class plaintiffs alleged a plausible conspiracy between Mylan and Pfizer?**

Defendants next assert that the class plaintiffs have failed to allege a plausible conspiracy between the Mylan and Pfizer Defendants under the antitrust laws. Defendants concede that the Class Complaint alleges that “[b]eginning in 2012 with the settlement of the Teva Litigation, Defendants [Mylan, King, Meridian] engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to prevent the sale of a generic version of the EpiPen in the United States . . . .” Class Compl. ¶ 543 (Count III alleging state law antitrust violations); *see also id.* ¶ 530 (“By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in a per se violation of § 1 of the Sherman Act . . . .” (Count I, alleging violations of federal antitrust law)). But, defendants contend, the Class Complaint alleges no facts capable of supporting a finding or inference of an agreement or conspiracy to exclude competing devices in the EAI market.<sup>8</sup>

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<sup>8</sup> The Mylan Defendants’ opening brief asserts that the class plaintiffs’ claims—premised on alleged reverse payment settlements—are evaluated under a rule of reason analysis—not the per se rule. Doc. 52 at 106–07; *see also FTC v. Actavis, Inc.*, 570 U.S. 136, 159 (2013) (holding that courts must apply a rule of reason analysis to reverse payment settlement agreements alleged to violate the antitrust laws). The class plaintiffs’ response concedes that an individual reverse payment settlement is analyzed under a rule of reason analysis. Doc. 64 at 151 n.203. But, the class plaintiffs assert, their conspiracy claims are not based just on the reverse payment settlements. *Id.* Instead, they argue, that the court must look to the totality of the conduct allegedly supporting the conspiracy claims. *Id.* But they never cite any case law showing that the per se rule applies to that other conduct that, they contend, supports their conspiracy claim. *Id.*

Nevertheless, at this stage of the litigation, the court need not decide what rule to apply to analyze the reasonableness of the alleged restraints of trade supporting the class plaintiffs’ conspiracy claims. *See CSR Ltd. v. Fed. Ins. Co.*, 40 F. Supp. 2d 559, 564 (D.N.J. 1998) (“At this early [motion to dismiss] stage of the proceeding, the court does not find it necessary to determine which mode of analysis [per se or rule of reason] it will ultimately employ in evaluating the defendants’ activities.”); *see also Swarthmore Radiation Oncology, Inc. v. Lapes*, 812 F. Supp. 517, 520 (E.D. Pa. 1992) (“[The court] need not decide, at this stage of the proceedings, whether a per se rule or a ‘rule of reason’ applies.”). In ruling the



To state a claim under Sherman Act § 1, a complaint must allege “enough factual matter (taken as true) to suggest that an agreement was made.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007); *see also TV Commc’ns Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1027 (10th Cir. 1992) (“To state a claim for a violation of section one [of the Sherman Act] the plaintiff must allege facts which show: the defendant entered a contract, combination or conspiracy that unreasonably restrains trade in the relevant market.”).

“An agreement or conspiracy under federal antitrust laws is said to exist when ‘there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme.’” *Suture Express, Inc. v. Cardinal Health 200, LLC*, 963 F. Supp. 2d 1212, 1223 (D. Kan. 2013) (quoting *W. Penn Allegheny Health Sys. v. UPMC*, 627 F.3d 85, 99 (3d Cir. 2010)). “‘A plaintiff may plead an agreement by alleging direct or circumstantial evidence, or a combination of the two,’ but allegations of direct evidence, that are adequately detailed, are sufficient alone.” *Id.* (quoting *W. Penn Allegheny*, 627 F.3d at 99). However, “[b]are bones accusations of a conspiracy without any supporting facts are insufficient to state an antitrust claim.” *Tal v. Hogan*, 453 F.3d 1244, 1261 (2006) (citation omitted).

Here, the class plaintiffs contend that they have alleged facts which one can use to infer plausibly that defendants conspired to exclude competing EAI devices from the market. The Class Complaint asserts that defendants engaged in a “multi-faceted, fraudulent scheme to obtain and maintain a monopoly” in the EAI market. Class Compl. ¶ 6. The Class Complaint alleges that defendants effectuated their scheme by combining and conspiring to: assert and prosecute invalid patents to dissuade competitors from entering the EAI market; intervene in regulatory

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pending motion, the court just needs to determine whether the class plaintiffs have alleged a plausible conspiracy under the antitrust laws. The class plaintiffs have shouldered that burden here.

proceedings to delay competitors’ entry in the EAI market; and enter into unlawful “pay-for-delay” settlement agreements with competitors to maintain Mylan’s power. *Id.*<sup>9</sup>

The Class Complaint alleges that the Mylan and Pfizer Defendants engaged in this scheme to fend off EpiPen competitors because they had a “unified interest” to protect their monopoly. *Id.* ¶ 241. It asserts that the Pfizer Defendants (as the EpiPen patent holders and suppliers) and the Mylan Defendants (as the EpiPen sellers) worked collaboratively to enhance the EpiPen’s sales volume and profitability because their related revenues rise and fall together. *Id.* ¶ 241.

The Class Complaint, construed in the class plaintiffs’ favor, also alleges that defendants worked together to secure patents solely for the purpose of preventing generic competition. *Id.* ¶¶ 236–39. It describes how Mylan CEO Heather Bresch announced during a public earnings call in 2009, that *Mylan* was adding another patent to the already-patented EpiPen device that “will also put in [place] another barrier to entry . . . .” *Id.* ¶ 238 (emphasis added). Shortly afterward, Meridian—not Mylan—secured the ’432 patent. Also, the Class Complaint alleges that Mylan Specialty LP took over as sponsor of the EpiPen patents in the Orange Book<sup>10</sup> from

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<sup>9</sup> This paragraph of the Class Complaint asserts other alleged unlawful conduct supported the alleged conspiracy—such as the EpiPen misclassification, the exclusivity contracts offered through the EpiPen4Schools Program, deceptive marketing practices, the “hard switch” to the EpiPen 2-Pak, and false testimony to Congress. But the Pfizer Defendants argue that the Class Complaint makes no factual allegations capable of supporting a finding or inference that Pfizer *participated* in any of this other alleged conspiratorial conduct. The court agrees. The court thus confines its discussion to the factual allegations supporting Pfizer’s alleged involvement in an antitrust conspiracy to exclude EpiPen competitors—*i.e.*, the Class Complaint’s allegations about Pfizer’s involvement in securing patents, initiating patent infringement litigation, and entering into unlawful reverse payment settlements.

<sup>10</sup> The Orange Book is the common name for the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*. See *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, U.S. Food & Drug Administration, (2018), <https://www.fda.gov/drugs/informationondrugs/ucm129662.htm>. According to the FDA, the Orange Book “identifies drug products approved on the basis of safety and effectiveness by the [FDA] under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.” *Id.*

Meridian. *Id.* ¶ 247. The Class Complaint asserts that this sponsorship change shows “concerted action by Mylan and Pfizer to share the burdens and rewards of their EpiPen monopoly.” *Id.* ¶¶ 247, 314.

The Class Complaint also alleges that the Mylan Defendants and Pfizer Defendants worked together to prevent competitors from entering the market by filing patent infringement lawsuits and entering into “pay-for-delay” settlement agreements. *Id.* ¶¶ 236–303. While Mylan was not a party to the patent litigation lawsuits, one can infer plausibly from the Class Complaint’s allegations that Mylan was participating in the concerted action. Indeed, the class plaintiffs allege that Mylan CEO Heather Bresch appeared to concede that Mylan participated in the Teva settlement by publicly referring to it as “*our* settlement with Teva.” *Id.* ¶ 277 (emphasis added). Mylan also issued joint press releases with Pfizer announcing the Teva and Intelliject settlements. *Id.* ¶¶ 270, 298. The Class Complaint also quotes an antitrust scholar who has concluded “[a]t the time (and to this day), Mylan was working hand-in-hand with Meridian/King, with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.” *Id.* ¶ 314. The Class Complaint also describes that Congress has questioned whether the Teva settlement is an unlawful “pay-for-delay” settlement. *Id.* ¶ 280. In the inquiry, Congress directed questions about the settlement to Mylan, even though Mylan was not a party to the lawsuit. *Id.*

Defendants assert that all of class plaintiffs’ allegations merely amount to “loosely parallel conduct” that cannot state a plausible conspiracy claim. Doc. 95 at 53 (citing *Twombly*, 550 U.S. at 556 (“[A]n allegation of parallel conduct and a bare assertion of conspiracy will not suffice.”)). Defendants assert that the allegations about patent infringement lawsuits and settlements involve different cases with different patents and different parties—and sometimes

different products. Defendants contend that one cannot infer plausibly from these allegations that defendants agreed to join a conspiracy. Instead, defendants assert, these allegations just show unilateral and independent conduct—not a horizontal agreement—and thus, defendants argue, the allegations do not suffice to state a conspiracy claim.

Indeed, the Supreme Court requires: “[W]hen allegations of parallel conduct are set out in order to make a § 1 claim, they must be placed in a context that raises a suggestion of preceding agreement, not merely parallel conduct that could just as well be independent action.” *Twombly*, 550 U.S. at 557. This is so because “lawful parallel conduct fails to bespeak unlawful agreement.” *Id.* at 556. *See also Mitchael v. Intracorp, Inc.*, 179 F.3d 847, 859 (10th Cir. 1999) (“While consciously parallel behavior may contribute to a finding of antitrust conspiracy, it is insufficient, standing alone, to prove conspiracy.”); *Cayman Express Corp. v. United Gas Pipe Line Co.*, 873 F.2d 1357, 1361 (10th Cir. 1989) (“[C]onscious parallel business behavior, standing alone, is insufficient to prove conspiracy.”). Thus, “an allegation of parallel conduct and a bare assertion of conspiracy will not suffice. Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality.” *Twombly*, 550 U.S. at 556. Instead, a plaintiff must allege “conspiracy evidence [that] tend[s] to rule out the possibility that the defendants were acting independently.” *Id.* at 554.

The Tenth Circuit has held that “parallel behavior may, however, support the existence of an illegal agreement ‘when augmented by additional evidence from which an understanding among the parties may be inferred.’” *Mitchael*, 179 F.3d at 859 (quoting *Monument Builders of Greater Kansas City, Inc. v. Am. Cemetery Ass’n*, 891 F.2d 1473, 1481 (10th Cir. 1989) (further citation and internal quotation marks omitted)). “Such evidence may include a showing that the

parties are acting against their own individual business interests, or that there is motivation to enter into an agreement requiring parallel behavior.” *Id.* (quoting *Monument Builders*, 891 F.2d at 1481 (further citation and internal quotation marks omitted)); *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 321–22 (3d Cir. 2010) (explaining that “[s]ome courts have denominated these [additional] facts, the presence of which may indicate the existence of an actionable agreement, as ‘plus factors’” and identifying “at least three such plus factors: (1) evidence that the defendant had a motive to enter into a price fixing conspiracy; (2) evidence that the defendant acted contrary to its interests; and (3) evidence implying a traditional conspiracy” (citations and internal quotation marks omitted)).

Here, the Class Complaint alleges parallel conduct by asserting, plausibly, that both the Mylan and Pfizer Defendants participated in a scheme to secure invalid EpiPen patents, initiate patent infringement litigation, and then settle those lawsuits with reverse payment settlements. The court also concludes that the Class Complaint, construed in the class plaintiffs’ favor, alleges sufficient “plus factors” and thus allows one to infer plausibly that an actionable agreement existed. The class plaintiffs allege facts supporting a plausible inference that defendants were motivated to enter an agreement to exclude competitors from entering the EAI market. *See* Class Compl. ¶¶ 241 (alleging that defendants’ EpiPen-related revenues rise and fall together), 244 (alleging that, when Pfizer acquired King and Meridian, “Mylan was rightly concerned that Pfizer might try to compete with Mylan by marketing the same device to consumers under a different trade name. But rather than compete with Mylan, Pfizer agreed to continue supplying the device to Mylan under terms that are not publicly available.”). The class plaintiffs also allege that defendants worked together to effectuate this scheme by securing patents, litigating patent infringement lawsuits, and entering into reverse payment settlements. *Id.* ¶¶ 238–39, 247, 270,

277, 298, 314, 632. The court recognizes that “each of [these] allegations of circumstantial agreement standing alone may not be sufficient to imply agreement,” but, “taken together, they provide a sufficient basis to plausibly contextualize the agreement necessary for pleading a § 1 claim.” *Evergreen Partnering Grp., Inc. v. Pactiv Corp.*, 720 F.3d 33, 47 (1st Cir. 2013).

Defendants argue that the Class Complaint asserts no allegations supporting at least one of the plus factors—*i.e.*, that defendants acted against their own economic interest. Defendants assert that the Class Complaint alleges that the Mylan and Pfizer Defendants had a “unified interest” in protecting the EpiPen monopoly and “work[ed] collaboratively to enhance the product[’s] sales volume and profitability.” Class Compl. ¶ 241. According to defendants, these allegations allow only an inference of lawful parallel conduct—not an unlawful agreement. But the class plaintiffs respond that the Class Complaint alleges that Pfizer also participates in the EAI market through its generic division Greenstone’s distribution of the Adrenaclick generic EAI. *Id.* ¶ 101 n.16. So, the class plaintiffs contend, Pfizer was able to control a portion of the small amount of the EpiPen’s competition. From these allegations, one could reasonably infer that Pfizer acted against its own interests by conspiring with Mylan to exclude EpiPen competition—competition that includes the generic Adrenaclick that Pfizer also distributes through its Greenstone division.

The court thus concludes that the Class Complaint sufficiently alleges facts capable of supporting a finding or inference of requisite “plus factors.” Combined with defendants’ alleged parallel business behavior, they state a plausible antitrust claim. The court thus denies defendants’ Motions to Dismiss on this basis.

Finally, in a footnote, defendants assert that the *Copperweld* doctrine bars the class plaintiffs’ conspiracy claims because the Mylan and Pfizer Defendants are parties with a unified

interest and thus incapable of conspiring with each other for purposes of Sherman Act § 1. *See Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 777 (1984) (holding that a parent and its wholly owned subsidiary are incapable of conspiring with each other under the Sherman Act); *see also Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499, at \*5 (D. Del. May 26, 2011) (recognizing that “district courts have held that other parties with unified interests, such as a patent holder and licensee, are incapable of conspiring”). But *Copperweld* does not hold that a patent holder and licensee never can conspire to violate the antitrust laws. Indeed, as other courts have recognized, a patent holder and its licensee can conspire in violation of the antitrust laws “only if [the conspiracy] deprives the marketplace of independent actors.” *Levi Case Co., Inc. v. ATS Prods., Inc.*, 788 F. Supp. 428, 431 (N.D. Cal. 1992); *see also In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, at \*8–9 (E.D. Pa. Oct. 30, 2017) (rejecting argument that alleged co-conspirators were “a single economic entity as patent licensor and licensee” and refusing to apply the *Copperweld* doctrine because the complaint alleged “two separate entities that engaged in concerted action to jointly advance their economic interests”); *Townshend v. Rockwell Int’l Corp.*, No. C99-0400SBA, 2000 WL 433505, at \*6 (N.D. Cal. Mar. 28, 2000) (denying Rule 12(b)(6) motion to dismiss conspiracy claims because the case law did not establish that patent holder and licensee are “legally incapable of entering into a conspiracy” and concluding that defendants’ capability of entering a conspiracy was a “question of fact” that the court could not resolve on a motion to dismiss).

Likewise, here, the court finds that the Class Complaint sufficiently alleges facts capable of supporting a finding or inference that the Mylan and Pfizer Defendants are “two separate entities that engaged in concerted action to jointly advance their economic interests.” *In re*

*Suboxone*, 2017 WL 4910673, at \*9. Although the Class Complaint alleges that the Mylan and Pfizer Defendants shared a “unified interest” in protecting the EpiPen monopoly (Class Compl. ¶ 241), it also alleges that defendants had separate interests—Mylan through its sale of the EpiPen and Pfizer with its control of a portion of the small amount of the EpiPen’s competition through its Greenstone division’s distribution of the generic Adrenaclick. Indeed, the Class Complaint alleges that both compete in the EAI market. The Class Complaint also alleges “anticompetitive conduct at the heart of the alleged conspiracy”—*i.e.*, the concerted effort to procure patents, initiate patent infringement litigation, and enter into reverse payment settlements in an effort to prevent EpiPen competitors from entering the EAI market—that is “ancillary” to the patentee/licensee relationship. *In re Suboxone*, 2017 WL 4910673, at \*9. For these reasons, the court refuses to apply the *Copperweld* doctrine here.

**5. Have the class plaintiffs alleged a viable antitrust claim based on the “reverse” patent litigation settlements?**

Next, defendants argue that the class plaintiffs have failed to allege plausible antitrust claims based on alleged reverse payment settlements. The Supreme Court has held that reverse payment settlements “can sometimes violate the antitrust laws.” *FTC v. Actavis, Inc.*, 570 U.S. 136, 141 (2013). A reverse payment settlement refers to an agreement by a brand-name manufacturer and patent holder to compensate a generic manufacturer and alleged patent infringer in exchange for settling patent infringement litigation, thus delaying the generic’s market entry. *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 41 (1st Cir. 2016) (citing *Actavis*, 570 U.S. at 145). “When a brand-name manufacturer pays to delay the first filer’s generic launch, that reverse payment postpones not only the first filer’s product but also those of all other generic manufacturers, who must wait out the 180-day exclusivity period before going to market.” *Id.* Because a reverse payment settlement effectively delays generic



competition in the market, *Actavis* recognized that “a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects.” *Actavis*, 570 U.S. at 158.

To determine whether a reverse payment settlement has anticompetitive effects, the Supreme Court has instructed that “a detailed exploration of the validity of the patent itself” is not necessary. *Id.* at 158. Instead, the anticompetitive effects of a reverse payment depend on “its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” *Id.* at 159. The Supreme Court also recognized that “[t]he existence and degree of any anticompetitive consequence may also vary as among industries.” *Id.* Because of “[t]hese complexities,” the Supreme Court has held that courts must analyze alleged unlawful reverse payment settlements under the rule of reason. *Id.*

Here, defendants assert that the Class Complaint fails to plead facts showing that defendants actually made any payments in the patent litigation settlements with Teva, Intelliject, and Sandoz. Thus, defendants contend, the class plaintiffs fail to state a plausible claim based on any of these settlements. The court addresses each of the three settlements separately, below.

#### **a. Teva Settlement**

The class plaintiffs assert that one plausibly can infer from the Class Complaint’s allegations that defendants made a large and unjustified reverse payment settlement in the Teva Litigation. The Class Complaint alleges that one reasonably can infer “[f]rom the facts surrounding the settlement” that “King and Meridian made a substantial ‘reverse payment’ to Teva to convince it to delay bringing its competing generic auto-injector to market.” Class Compl. ¶ 265. According to the Class Complaint, these facts include: (1) the district court in the

Teva Litigation had issued a Markman ruling interpreting the '432 patent favorable to Teva; (2) the parties settled after a full bench trial, meaning that the parties already had expended significant litigation expenses compared to the marginal ones they would incur going forward; and (3) it makes little sense that a “rational economic actor with a viable product (and who had spent millions of dollars developing it) would refrain from entering a lucrative ‘blockbuster’ market for 36 months unless it received monetary compensation in exchange for non-entry.” *Id.*

The Class Complaint never alleges the amount of the alleged settlement payment, but it explains that the terms of the Teva settlement are confidential and not publicly available. *Id.* ¶ 264. At least one court has held that a plaintiff need not plead a precise monetary settlement amount, recognizing that “very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis, and that these issues are sufficiently factual to require discovery.” *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 244 (D. Conn. 2015). Instead, to plead that a large and unjustified reverse payment occurred, a plaintiff must assert “specific allegations about the terms of the settlement and their relative value that are plausible on their face.” *Id.*; *see also King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 410 (3d Cir. 2015) (reversing a district court’s Rule 12(b)(6) dismissal of antitrust claims because “plaintiffs’ allegations, and the plausible inferences that can be drawn from them, are sufficient to state a rule-of-reason claim under *Twombly* and *Iqbal* for violation of the Sherman Act on the ground that [defendant] sought to induce [a generic] to delay its entry into the lamotrigine tablet market by way of an unjustified no-AG agreement”); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016) (declining to “require heightened fact pleading of specifics” such as “precise figures and calculations at the pleading stage” but holding that “the plaintiffs must allege facts

sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*”).

Defendants assert that the class plaintiffs’ allegations here fall short of this pleading standard. For support, defendants rely on *FTC v. AbbVie, Inc.*, 107 F. Supp. 3d 428 (E.D. Pa. 2015), where the court held that plaintiff had failed to state a plausible antitrust claim because the patentees “did not make any payment, reverse or otherwise, to the claimed infringer . . . .” *Id.* at 436. *AbbVie*’s facts differ significantly from the ones alleged here. The class plaintiffs specifically allege that defendants “provided significant consideration, incentives, and benefits to Teva to delay bringing their competing product to market.” Class Compl. ¶ 263. And, the court concludes, the allegations assert specific facts—described above—that are capable of supporting a reasonable inference that the consideration provided as part of the Teva settlement constituted a substantial reverse payment. *Id.* ¶ 265.

Defendants disagree. They argue that the asserted facts cannot support a plausible inference of a reverse payment settlement. But their arguments invite the court to weigh the Class Complaint’s factual allegations—something it cannot do on a motion to dismiss. For example, defendants assert that the Teva settlement was not the product of an unlawful reverse payment but, instead, a settlement that the trial court expressly encouraged. Doc. 93 at 14. Defendants also disagree with the class plaintiffs’ assertion that the parties settled after they had already incurred the most significant attorney’s fees through a bench trial. Defendants argue that the Teva Litigation was “subject to the uncertainty, expense, and burden of protracted appeals and possible remands.” *Id.* at 15. And, defendants contend, the Markman ruling was not favorable to Teva but instead was more of a “mixed conclusion,” with the court rejecting two of Teva’s proposed constructions. *Id.* (citations and internal quotations omitted).

All these arguments require the court to consider disputed factual allegations. And that function is not a proper one on a Rule 12(b)(6) motion to dismiss. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003) (affirming district court’s denial of a motion to dismiss because “[t]he defendants’ claim that [the generic manufacturer’s] decision to stay off the market was motivated not by the [reverse payment], but by its fear of damages in the pending patent infringement litigation, merely raise[d] a disputed issue of fact that cannot be resolved on a motion to dismiss”). Instead, viewing the allegations in the class plaintiffs’ favor, the court concludes that the Class Complaint alleges “enough facts” to allow a reasonable inference that the Teva settlement constituted an unlawful reverse payment and thus is sufficient to “nudge[ ] the[ ] claims across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570.

#### **b. Intelliject Settlement**

Defendants next argue that the class plaintiffs assert conclusory allegations to support their theory that the Intelliject settlement constitutes an unlawful reverse payment settlement. Thus, defendants contend, the class plaintiffs fail to state a plausible claim for relief based on it. For the same reasons already discussed, the court rejects defendants’ argument.

Viewing the Class Complaint’s allegations in the class plaintiffs’ favor, one can infer plausibly that defendants made a reverse payment in the Intelliject settlement. The Class Complaint alleges that, in February 2012, Mylan and Pfizer jointly announced settlement of the Intelliject litigation. Class Compl. ¶ 298. Like the Teva settlement, the terms of the Intelliject settlement are confidential. *Id.* But Mylan and Pfizer publicly stated that “the agreement prevented Intelliject and Sanofi from launching their e-cue device for another nine months, until November 15, 2012.” *Id.* The Class Complaint asserts that “[t]he relatively short duration of delay before entry of the e-cue likely indicates the strength of Intelliject’s defenses to the patent

litigation.” *Id.* The Class Complaint also contends, “on information and belief, Intelliject and Sanofi agreed not to enter the market until November 15, 2012[,] in exchange for valuable consideration.” *Id.* ¶ 299. These allegations can support a plausible inference that defendants settled the Intelliject litigation by making a reverse payment.

Defendants contend that these facts won’t allow such an inference because the settlement granted Intelliject a market entry date that was 13 years before the EpiPen patents expire. Defendants argue that this allegation shows just that the Intelliject settlement is a traditional settlement agreement involving a negotiated *early* entry date. And that type of settlement agreement is not subject to antitrust scrutiny. *Actavis*, 570 U.S. at 158. With this argument, defendants again ask the court to weigh disputed factual allegations. The court cannot engage in such fact-finding on a motion to dismiss. For these reasons, the court finds that the Class Complaint plausibly asserts that the Intelliject settlement constituted a large and unjustified reverse payment settlement sufficient to support an antitrust claim.

### **c. Sandoz Settlement**

Finally, defendants assert that the Class Complaint fails to allege that the Sandoz settlement involved a large and unjustified reverse payment settlement. The Class Complaint alleges that, in 2010, Sandoz attempted to enter the EAI market with a generic alternative to the EpiPen. Class Compl. ¶ 302. The Class Complaint asserts that “defendants conspired to have King file a patent infringement suit against Sandoz in response to its ANDA filing.” *Id.* Pfizer filed a Form 10-Q with the SEC in 2016. *Id.* It recited that Sandoz’s ANDA is ongoing and the litigation is stalled because the court had entered an order staying the FDA process and administratively terminating the action, subject to the parties seeking to reopen the case by letter request. *Id.* To date, no party has reopened the case. *Id.* The Class Complaint describes how

staying the litigation also stays a definitive ruling on any challenge to the EpiPen patents. *Id.* And it asserts “[o]n information and belief” that defendants “entered into an agreement with Sandoz to stay the case indefinitely in exchange for valuable consideration to Sandoz.” *Id.* at ¶ 303.

Although the class plaintiffs cannot provide the precise terms of the Sandoz agreement without the benefit of discovery, one plausibly can infer from Sandoz’s actions that it received significant consideration in exchange for its actions—*i.e.*, agreeing to stay its ANDA application for its generic product. Indeed, one also could infer the opposite conclusion—that Sandoz agreed to stay its ANDA application because it considered the patent infringement claims valid and appreciated the risk that it would lose the patent infringement litigation. But, at the pleading stage, the court cannot make that determination. Instead, the court must consider the facts alleged in the class plaintiffs’ favor and draw reasonable inferences from them. Applying that standard here, the court concludes that the class plaintiffs have asserted a plausible antitrust claim based on their allegations that the Sandoz settlement involved an unlawful reverse payment settlement.

**6. Have the class plaintiffs stated a plausible antitrust claim based on the FDA Citizen Petition?**

Next, the Mylan Defendants argue that the class plaintiffs’ allegations about the FDA Citizen Petition fail to state a plausible antitrust claim. The Mylan Defendants assert two arguments supporting dismissal.

*First*, the Mylan Defendants contend, the Class Complaint never alleges that the Citizen Petition caused any delay in the FDA approval process. The Mylan Defendants explain that a federal statute requires the FDA to take final agency action on a Citizen Petition within 150 days (about five months). 21 U.S.C. § 355(q)(1)(F). And, 21 U.S.C. § 355(q)(1)(A) provides that the

Secretary “shall not delay approval” of a pending ANDA based on the filing of a Citizen Petition. But, as Mylan concedes, this statute also contains an exception. It authorizes “the Secretary, upon reviewing the petition,” to determine whether a further delay is necessary to protect public health. 21 U.S.C. § 355(q)(1)(A)(ii). And, as the Class Complaint alleges, legal scholars and Congress have recognized the “dangerous potential” of Citizen Petitions (such as Mylan’s) to extend brand monopolies and delay approval of generics. Class Compl. ¶¶ 306, 308.

The Class Complaint asserts that Mylan filed a Citizen Petition on January 16, 2015, “a mere six months before Teva was scheduled (pursuant to the settlement) to enter the market.” *Id.* ¶ 311. It also alleges that Mylan waited until May 2015—almost five months after filing its Citizen Petition and only weeks before the FDA was required to respond—to supplement its Petition with a 48-page independent study purportedly showing that patients would not use Teva’s generic product correctly. *Id.* ¶ 311. The Class Complaint quotes a legal scholar who has questioned the timing of Mylan’s Citizen Petition and suggested that it was part of a strategy to delay Teva’s ANDA approval. *Id.* ¶¶ 311, 314. And, the Class Complaint asserts, “[b]ut for Mylan’s anti-competitive assault campaign” that included the FDA Citizen Petition, “Teva would have entered the market much sooner and fixed the deficiencies that led to the FDA’s rejection of Teva’s generic.” *Id.* ¶ 322.

At least one court has concluded that allegations similar to those asserted here—ones that asserted, generally, that citizen petitions can delay the FDA approval process, and, more specifically, that a defendant had delayed approval of a generic competitor—“plausibly pleads that the citizen petition resulted in delay of the FDA’s approval of the generic ANDAs.” *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 3967911, at \*18 (E.D. Pa. Sept. 8, 2017) (denying a Rule 12(b)(6) motion to dismiss

antitrust claims based on alleged delay caused by FDA citizen petition because the Amended Complaint plausibly pleaded delay and “[w]hether such a delay actually occurred in this case is a subject more properly left for resolution after discovery”). For the same reasons, the court finds that the class plaintiffs plausibly have alleged that Mylan’s Citizen Petition delayed the FDA approval process.<sup>11</sup>

*Second*, the Mylan Defendants assert that the *Noerr-Pennington* doctrine bars the class plaintiffs’ claims based on the FDA Citizen Petition. As discussed, the *Noerr-Pennington* doctrine “exempts from antitrust liability any legitimate use of the political process by private individuals, even if their intent is to eliminate competition.” *Tal v. Hogan*, 453 F.3d 1244, 1259 (10th Cir. 2006) (citation and internal quotations marks omitted). But *Noerr-Pennington* immunity does not apply to “sham” activities. *Prof’l Real Estate Inv’rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993). Petitioning the government is a “sham” activity if: (1) it is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits,” and (2) it “uses the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.” *Id.* (citations and internal quotation marks omitted).

The Mylan Defendants assert that the Class Complaint’s allegations don’t satisfy these two requirements to plead adequately that Mylan’s Citizen Petition falls within the sham exception to the *Noerr-Pennington* doctrine. First, the Mylan Defendants argue that the

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<sup>11</sup> In the same vein, the Mylan Defendants argue that the Citizen Petition never delayed the FDA approval process because the FDA ultimately denied Teva’s application. But, for reasons explained in Part III.A.3. above, the Class Complaint adequately alleges “[b]ut for Mylan’s anticompetitive assault campaign”—described in the Class Complaint as the patent settlement litigation, reverse payment settlements, and FDA Citizen Complaint—“Teva would have entered the market much sooner and fixed the deficiencies that led to the FDA’s rejection of Teva’s generic.” Class Compl. ¶ 322. As the court concluded already, these allegations sufficiently allege causation. They also support the class plaintiffs’ claim that Mylan’s FDA Citizen Petition delayed Teva’s entry into the market.



allegations don't plead facts capable of supporting a finding or inference that Mylan's Citizen Petition was objectively baseless. Some courts have found that the question "[w]hether petitioning activity is a sham is generally [one] for the jury." *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 689 (E.D. Pa. 2014) (citing *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011)). But "'a court may decide probable cause as a matter of law' where 'there is no dispute over the predicate facts of the underlying . . . proceeding.'" *Id.* (quoting *Prof'l Real Estate Inv'rs, Inc.*, 508 U.S. at 63).

The Class Complaint asserts facts supporting a plausible inference that the Citizen Petition was objectively baseless because of its timing and contents. Mylan waited until January 2015—six months before Teva was scheduled to enter the market—to file the Citizen Petition even though Teva had been developing the drug for six years, the parties had litigated the patent infringement suit for three years, and the parties settled that litigation three years before the Petition's filing. Class Compl. ¶¶ 311, 314. The Class Complaint also asserts that Mylan's Citizen Petition relied on a medical statement from a doctor who Mylan paid to render the opinion. *Id.* ¶¶ 317, 318. And Mylan's Citizen Petition never disclosed that it had made such a payment. *Id.* ¶ 318.

The Class Complaint also alleges that Mylan waited just weeks before the FDA was required to respond to the ANDA to supplement its Citizen Petition by submitting a study. *Id.* ¶ 311. The Class Complaint asserts that this study had "numerous flaws that demonstrate that Mylan was not acting in good faith" by submitting it to the FDA. *Id.* ¶ 313. The Class Complaint identifies specific flaws: the study lacked a control group; it did not use the actual generic device, but a prototype; it used a small number of participants; the researchers failed to

provide proper instructions to the study's participants for using the prototype; and the researchers told the participants to watch a video instead of actually use the prototype. *Id.*

The Mylan Defendants respond with various arguments attacking these allegations. They explain the legitimacy of the filings' timing, the doctor's medical statement, the payments the doctor received (noting that the doctor received payments from other pharmaceutical companies, including Teva), and the supplemental study. But these arguments present disputed fact issues that the court cannot decide at the pleading stage. On a motion to dismiss, the court considers the allegations in the class plaintiffs' favor and concludes they sufficiently allege that Mylan's FDA Citizen Petition was objectively baseless. *See In re Suboxone Antitrust Litig.*, 2017 WL 3967911, at \*17 (explaining that federal antitrust claims "based on the filing of a sham citizen petition survived dismissal" because the complaint "sets forth multiple facts which could create an inference that the petition was objectively baseless"); *see also La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ.7343(HB), 2008 WL 169362, at \*5 (S.D.N.Y. Jan. 18, 2008) (denying motion to dismiss antitrust claims based on an alleged sham petition because plaintiff alleged triable fact issues about "the reasonability and viability" of the citizen petition and was entitled to additional discovery to prove the allegations).

The court also finds that the Class Complaint plausibly alleges that Mylan used the *process* of filing the FDA Citizen Petition—not the *outcome* of that proceeding—to restrain competition. The Class Complaint repeatedly alleges that Mylan used the FDA Citizen Petition process as a means to delay Teva's market entry. Class Compl. ¶¶ 304, 310, 311, 316, 319, 321. These allegations suffice to state an antitrust claim based on Mylan's Citizen Petition that falls within the sham exception to the *Noerr-Pennington* doctrine.

**7. Have the class plaintiffs alleged a plausible antitrust claim based on allegedly misleading statements?**

The Mylan Defendants next argue that the Class Complaint fails to allege plausible antitrust claims based on the Mylan Defendants’ misrepresentations about Auvi-Q’s bioequivalence and not-covered status.<sup>12</sup> Deceptive speech can support Sherman Act claims because “in some cases, such defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts.” *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010); *see also Caldera, Inc. v. Microsoft Corp.*, 87 F. Supp. 2d 1244, 1249 (D. Utah 1999) (holding that alleged misleading statements about the plaintiff’s product viewed with other anticompetitive behavior supported a Sherman Act § 2 claim sufficient to survive summary judgment).

The Tenth Circuit presumes that allegedly false speech “bears only a *de minimis* effect on competition.” *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1127 (10th Cir. 2014); *see also Nat’l Ass’n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 916 (2d Cir. 1988) (“[A] plaintiff asserting a monopolization claim based on misleading advertising must overcome a presumption that the effect on competition of such a practice was *de minimis*.” (citation and internal quotation marks omitted)).<sup>13</sup> An antitrust plaintiff “may rebut this

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<sup>12</sup> The Mylan Defendants also recognize another type of deceptive speech that the Class Complaint appears to allege to support an antitrust claim. The class plaintiffs assert that Mylan failed to disclose the “bought-and-paid-for” physician statements supporting the EpiPen 2-Pak. Doc. 95 at 60. The Mylan Defendants assert that these allegations cannot support an antitrust claim based on deceptive speech because they involve omissions—not deceptive statements. The class plaintiffs’ Opposition never responds to this argument. Doc. 123 at 58–60. And instead, it confines its arguments to allegedly false statements that Mylan made about the Auvi-Q. *Id.* The court thus concludes that the class plaintiffs have abandoned any attempt to base their deceptive speech claims on Mylan’s failure to disclose that it allegedly paid physicians for their statements supporting the EpiPen 2-Pak. The court thus dismisses any of the class plaintiffs’ antitrust deceptive speech claims based on this alleged failure to disclose.

<sup>13</sup> The class plaintiffs assert that the *de minimis* test applies only to competitors asserting a deceptive speech claim—not consumers like the class plaintiffs here. But they cite no case law supporting this argument. And the Mylan Defendants respond that the Ninth Circuit has applied the *de*

presumption by satisfying a six-factor test, showing that the disparagement was: (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offset by rivals. *Lenox*, 762 F.3d at 1127 (citing *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997)); see also *Ayerst Labs.*, 850 F.2d at 916 (quoting III P. Areeda & D. Turner, *Antitrust Law* ¶ 738a, at 278–79 (1978)). The Tenth Circuit has not decided whether a plaintiff must satisfy all six factors to overcome the *de minimis* presumption. *Lenox*, 762 F.3d at 1128 n.9; see also *Duty Free Ams., Inc. v. Estee Lauder Cos.*, 797 F.3d 1248, 1269 (11th Cir. 2015) (holding that it need not determine whether a plaintiff must allege all six factors because the complaint failed to allege falsity).

In *Ayerst*, the Second Circuit held that a district court had erred by dismissing a Sherman Act § 2 claim. Plaintiff there based its claim on an allegedly false and deceptive letter that defendant had sent to customers. The court found that plaintiff's Complaint alleged several of the factors required to overtake the *de minimis* presumption—including that the letter was clearly false, clearly material, and clearly likely to induce reasonable reliance. *Id.* But the court also agreed with defendant: plaintiff had not alleged other certain factors because the Complaint asserted that defendant sent the letter to pharmacists—persons likely to have knowledge about the subject matter—and that defendant only could have made the misrepresentations for a short time period. *Id.* at 917. Nevertheless, the court concluded, “several factors . . . cannot be

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*de minimis* presumption to competitors and consumers alike. See *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997) (explaining that the court “insist[s] on a preliminary showing of significant and more-than-temporary harmful effects on competition (and not merely upon a competitor or *customer*) before [disparaging of a rival product] can rise to the level of exclusionary conduct” (emphasis added)). Without any authority supporting the class plaintiffs' position, the court declines to hold the *de minimis* test does not apply to their claims here.

adequately evaluated until the discovery process has moved forward to a greater extent than it has thus far.” *Id.* The court thus held that the Complaint pleaded a Sherman Act § 2 claim sufficient to survive Rule 12(b)(6) dismissal.

Viewing the facts alleged here in the light most favorable to the class plaintiffs, the Class Complaint alleges several of the factors required to overcome a presumption that deceptive statements have had a *de minimis* effect on competition. The class plaintiffs allege that Mylan: (1) created and spread misinformation about the Auvi-Q and its bioequivalence to the EpiPen; (2) funded and promoted a study that was intended to undermine the FDA’s conclusion that Auvi-Q demonstrated bioequivalence to the epinephrine in the EpiPen; and (3) made misleading statements to physicians that the EpiPen was the “preferred” brand based on Auvi-Q’s coverage exclusions when Mylan itself produced the exclusion with its large, conditional rebate offers. Class Compl. ¶¶ 229, 232–34. The class plaintiffs assert that these allegedly false and misleading statements blocked Auvi-Q from competing in the market, thus excluding competition. *Id.* ¶¶ 229–31, 235.

The Mylan Defendants contend that the class plaintiffs’ allegations fail to assert that Mylan’s allegedly deceptive statements were “clearly false,” as the first factor of the six-factor test requires. The court disagrees. One plausibly can infer from the Class Complaint’s allegations that Mylan’s statements about Auvi-Q were clearly false. Although the Class Complaint does not use those precise words, it calls the statements “misinformation” and so “misleading” that they “ensur[ed] that physicians would think that the EpiPen was the only realistic choice for their patients.” *Id.* ¶¶ 229, 234–35. Of course, to prevail on their speech-based claims, the class plaintiffs must come forward with evidence showing that these alleged statements produced anticompetitive effects in violation of the antitrust laws. But, at the

pleading stage, the court applies *Ayerst*'s rationale and concludes that the class plaintiffs "should be allowed to go forward with the discovery process to substantiate [their] claim" that Mylan's allegedly deceptive speech violated the antitrust laws. *Ayerst Labs.*, 850 F.2d at 917.

Also, following *Ayerst*, the court need not decide whether the Class Complaint alleges facts capable of supporting each factor before it could overtake the *de minimis* presumption. The *Ayerst* plaintiff did not satisfy such an obligation at the pleading stage. The court finds persuasive *Ayerst*'s conclusion that these factors require factual development through the discovery process. Here, the court cannot evaluate several of the factors adequately without the facts that discovery may or may not produce. So, the court denies the motion to dismiss the class plaintiffs' deceptive speech claim at the pleading stage. *See id.* at 917.

**8. Have the class plaintiffs stated plausible claims for relief under state antitrust laws?**

Finally, defendants argue that the Class Complaint fails to allege any plausible claims under all the state antitrust laws invoked by the Class Complaint. Defendants contend that the state antitrust claims fail for the same reasons that the federal claims fail. But, as discussed above, the court concludes that the Class Complaint states plausible claims for relief under the federal antitrust laws. It reaches the same conclusion about defendants' repackaged arguments attacking the state law claims.

Also, defendants advance three other arguments that, they say, warrant dismissal of certain state antitrust claims. *First*, defendants argue that the court should dismiss state antitrust claims asserted under the laws of Alaska, Arizona,<sup>14</sup> the District of Columbia, Iowa, New

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<sup>14</sup> The Class Complaint names only one plaintiff who resides in Arizona—Cassandra Bredek. Class Compl. ¶ 14. But Ms. Bredek voluntarily dismissed her claims on February 7, 2018. Doc. 139. So, no Arizona plaintiffs remain in the case.

Mexico, North and South Dakota, Oregon,<sup>15</sup> Puerto Rico, Rhode Island, Vermont,<sup>16</sup> and Wisconsin<sup>17</sup> because the Class Complaint includes no named plaintiff who resides in any of these states. Our court has recognized that “[s]everal courts, including other district courts in the Tenth Circuit, have determined that the plaintiffs in a putative class action may only assert a state law claim if a named plaintiff resides in, does business in, or has some other connection to that state.” *Roco, Inc. v. EOG Res., Inc.*, No. 14-1065-JAR-KMH, 2014 WL 5430251, at \*3 (D. Kan. Oct. 24, 2014) (first citing *Griffin v. Dugger*, 823 F.2d 1476, 1483 (11th Cir. 1987); then citing *Thomas v. Metro. Life Ins. Co.*, 540 F. Supp. 2d 1212, 1226–27 (W.D. Okla. 2008) (other citations omitted)). Because the Class Complaint names no plaintiff who resides in the 12 states listed above, the court agrees with defendants. The named class plaintiffs lack standing to assert claims under the antitrust laws of these states.

The class plaintiffs argue that a number of courts have refused to dismiss antitrust state law claims at the motion to dismiss stage simply because the complaint includes no named plaintiff from that particular state. But the class plaintiffs cite district court cases from outside the Tenth Circuit to support this position. In contrast, the Tenth Circuit has held: “Prior to class certification, the named plaintiffs’ failure to maintain a live case or controversy is fatal to the case as a whole—that unnamed plaintiffs might have a case or controversy is irrelevant.”

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<sup>15</sup> The Class Complaint names just one plaintiff who resides in Oregon—David Smith. Class Compl. ¶ 50. But Mr. Smith voluntarily dismissed his claims on February 7, 2018. Doc. 139. So, no Oregon plaintiffs remain in the case.

<sup>16</sup> The Class Complaint names just one plaintiff who resides in Vermont—John Dodge. Class Compl. ¶ 58. But Mr. Dodge voluntarily dismissed his claims on February 7, 2018. Doc. 139. So, no Vermont plaintiffs remain in the case.

<sup>17</sup> The Class Complaint names just one plaintiff who resides in Wisconsin—Heather Rutland. Class Compl. ¶ 63. But Ms. Rutland voluntarily dismissed her claims on February 7, 2018. Doc. 139. So, no Wisconsin plaintiffs remain in the case.

*Thomas v. Metro. Life Ins. Co.*, 631 F.3d 1153, 1159 (10th Cir. 2011) (citations omitted); *see also Roco*, 2014 WL 5430251, at \*4 (“Where the only named plaintiff in a putative class action lacks standing from the outset of the case, and a class is yet to be certified, the proper course is dismissal.” (citations omitted)); *Smith v. Pizza Hut, Inc.*, No. 09-cv-1632-CMA-BNB, 2011 WL 2791331, at \*9 (D. Colo. July 14, 2011) (holding, “Plaintiff lacks standing to bring claims under state laws to which Plaintiff has never been subjected and the class action claim must therefore be dismissed for lack of standing”). Based on this authority, including the binding Circuit precedent, the court dismisses the antitrust state law claims for which the Class Complaint includes no named plaintiff from that state.

Alternatively, the class plaintiffs seek leave to amend the Class Complaint to cure the absence of certain states’ representatives. The court finds it premature to grant such relief. The class plaintiffs provide no information about these additional representatives, including whether they have located any representative from any of these 12 states. To the extent the class plaintiffs identify class representatives from any of these states, they may file an appropriate motion seeking leave to amend the Class Complaint to add them as parties.

*Second*, defendants argue, the class plaintiffs are indirect purchasers who cannot assert claims for relief under the antitrust laws of Alaska, Arkansas, Illinois, Massachusetts, Missouri, Puerto Rico, Rhode Island, and West Virginia. Defendants assert that these state laws bar indirect purchaser claims.

In *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1997), the Supreme Court held that only direct purchasers may bring claims for damages under the federal antitrust laws. *Id.* at 737. To avoid the *Illinois Brick* rule, some states have passed “repealer” statutes allowing indirect purchasers to recover under state antitrust laws. *See In re Broiler Chicken Antitrust Litig.*, 290 F.



Supp. 3d 772, 818 (N.D. Ill. 2017). Here, defendants contend, the class plaintiffs assert claims under certain state laws that still bar indirect purchaser claims consistent with the rule in *Illinois Brick*.

In response to this argument, the class plaintiffs concede that Alaska does not permit indirect purchaser claims. But they stand on their claims asserted under the other seven states' laws. For two of those seven states—Puerto Rico and Rhode Island—the Class Complaint includes no named plaintiff. The court dismisses those claims for the same reason already discussed. Thus, the court need not address defendants' argument that these state laws bar indirect purchaser claims.

For Illinois, defendants assert that the Illinois Antitrust Act specifically provides: “[N]o person other than the Attorney General of this State shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act.” 740 Ill. Comp. Stat. § 10/7(2); *see also In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 539 (E.D. Pa. 2010) (prohibiting plaintiffs from asserting class action claims under the Illinois Antitrust Act because “the Act does not provide relief to indirect purchasers through class actions”). But several courts have concluded that the class action prohibition in the Illinois Antitrust Act is procedural in nature and that Rule 23 applies to determine whether a claim may be brought as a class action. So, because “[t]he availability of the class action procedure does not change the substantive rights or remedies available to [plaintiffs] under Illinois law,” courts have refused to dismiss Illinois Antitrust Act claims “on the basis of the Illinois’s class action bar.” *In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d at 818; *see also, e.g., In re Propranolol Antitrust Litig.*, 249 F. Supp. 3d 712, 728 (S.D.N.Y. 2017); *In re Aggrenox Antitrust Litig.*, No. 14-MD-2516(SRU), 2016 WL 4204478, at \*6 (D. Conn. Aug. 9, 2016); *In re Lithium Ion Batteries*

*Antitrust Litig.*, No. 13-MD-2420-YGR, 2014 WL 4955377, at \*21 (N.D. Cal. Oct. 2, 2014); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, No. M 07-1827-SI, 2011 WL 13152270, at \*5 (N.D. Cal. Aug. 24, 2011). Although these cases are not binding precedent in our Circuit,<sup>18</sup> the court finds their reasoning persuasive. And, for the same reason, the court concludes that the class plaintiffs' Illinois antitrust claims survive dismissal at the pleading stage.

For the West Virginia claim, defendants argue that the state's Code includes a harmonization provision, directing courts to construe the state's Antitrust Act "in harmony with ruling judicial interpretations of comparable federal antitrust statutes." W. Va. Code § 47-18-16. Defendants contend that the West Virginia legislature enacted this provision one year after the Supreme Court decided *Illinois Brick* and that it has not otherwise abrogated *Illinois Brick* by statute. But, plaintiffs respond, the West Virginia Attorney General has issued a Legislative Rule providing that "[a]ny person who is injured directly or indirectly by reason of a violation of the West Virginia Antitrust Act may bring an action for damages." W. Va. Code St. R. § 142-9-2. Relying on this rule, several federal courts have held that the West Virginia Antitrust Act permits indirect purchaser claims. *See, e.g., In re Broiler Chicken Antitrust Litig.*, 290 F. Supp. 3d at 812; *In re Chocolate Confectionary Antitrust Litig.*, 602 F. Supp. 2d 538, 582 n.55 (M.D. Pa. 2009); *In re Dynamic Random Access Memory (Dram) Antitrust Litig.*, 516 F. Supp. 2d 1072, 1097 (N.D. Cal. 2007); *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 350 F. Supp. 2d 160, 173–75 (D. Me. 2004); *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1376, n.8 (S.D. Fla. 2001). Following the reasoning of these decisions, the court joins them and denies defendants' motion to dismiss the West Virginia antitrust claims.

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<sup>18</sup> The parties do not cite, and the court has not located, a Tenth Circuit decision addressing this issue, or even one from a district court within our Circuit.

For the other state antitrust laws, the class plaintiffs rely on case law that does not support their argument that indirect purchasers may bring a cause of action under these state statutes. Instead, the authority that defendants cite establishes that indirect purchasers may not bring a cause of action under the antitrust laws of Arkansas,<sup>19</sup> Massachusetts,<sup>20</sup> and Missouri.<sup>21</sup> The court thus dismisses these state law antitrust claims.

*Third*, defendants argue that the court must dismiss the California, Kansas, New York, and Tennessee antitrust claims brought in Counts IV, V, and VI (monopolization, attempted monopolization, and tying) because these states do not recognize unilateral conduct claims. The class plaintiffs' response concedes that the New York claims are not viable. Doc. 123 at 83 n.282. The court thus dismisses the New York claims asserted under Counts IV, V, and VI.

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<sup>19</sup> Plaintiffs assert their Arkansas antitrust claim under Ark. Code Ann. § 4-75-212(b). Class Compl. ¶ 562.d. That statute authorizes the Attorney General to sue on behalf of persons injured “directly or indirectly.” Ark. Code Ann. § 4-75-212(b). Other courts have dismissed indirect purchaser claims brought under similar provisions in the Arkansas Unfair Practices Act because they do “not provide for a private individual to bring an action and only permit[ ] actions by the Attorney General.” *In re Cast Iron Soil Pipe & Fittings Antitrust Litig.*, No. 1:14-md-2508, 2015 WL 5166014, at \*22 (E.D. Tenn. June 24, 2015). See also *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 599 F. Supp. 2d 1179, 1181 (N.D. Cal. 2009) (holding that plaintiffs could not “circumvent the restrictions on antitrust claims under Arkansas . . . law by reframing those claims as unjust enrichment actions”).

<sup>20</sup> The Massachusetts Supreme Court has held that “indirect purchasers can assert claims for price-fixing or other anticompetitive conduct under [Mass. Gen. Laws ch.] 93A § 9, *where they have no standing* [otherwise] to bring such claims under the Massachusetts Antitrust Act [Mass. Gen. Laws ch.] 93 §§ 1-14A.” *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 762 N.E.2d 303, 306 (Mass. 2002) (emphasis added). Here, the class plaintiffs assert their state antitrust claim under the latter chapter that *Ciardi* discusses, *i.e.* Mass. Gen. Laws Ch. 93, § 1 *et seq.* Class Compl. ¶ 562.l. And, as *Ciardi* holds, an indirect purchaser has no standing to sue under this chapter. *Ciardi*, 762 N.E.2d at 306.

<sup>21</sup> The class plaintiffs' response asserts that the Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.020, does not bar indirect purchaser suits. But that's not the Missouri antitrust statute that the Class Complaint asserts to support its state antitrust claim. Instead, the Class Complaint relies on Mo. Rev. Stat. § 416.011, *et seq.* And, as several courts have held, “Missouri's antitrust laws . . . prohibit recovery by indirect purchasers.” *In re Lithium Ion Batteries Antitrust Litig.*, No. 13-MD-2420-YGR, 2014 WL 4955377, at \*19 (N.D. Cal. Oct. 2, 2014); see also *In re Asacol Antitrust Litig.*, No. 15-cv-12730-DJC, 2016 WL 4083333, at \*12 (D. Mass. July 20, 2016); *In re Pool Prods. Distrib. Mkt. Antitrust Litig.*, 946 F. Supp. 2d 554, 570 (E.D. La. 2013); *Duvall v. Silvers, Asher, Sher & McLaren, M.D.'s*, 998 S.W.2d 821, 824 (Mo. Ct. App. 1999).

For the California claim, the Class Complaint asserts state antitrust claims under California’s Cartwright Act (Cal. Bus. & Prof. Code §§ 16700, *et seq.*) and California’s Unfair Competition Law (Cal. Bus. & Prof. Code §§ 17200 *et seq.*). Class Compl. ¶ 562.e. The Cartwright Act does not prohibit unilateral conduct. *Dimidowich v. Bell & Howell*, 803 F.2d 1473, 1478 (9th Cir. 1986); *see also Bondi v. Jewels by Edwar, Ltd.*, 73 Cal. Rptr. 494, 498 (Cal. Ct. App. 1968) (concluding that Cartwright Act prohibits *agreements* in restraint of trade). But, in contrast, the class plaintiffs may assert a claim based on unilateral conduct under California’s Unfair Competition Law. *See, e.g., In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 283 (D. Mass. 2004); *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1379 (S.D. Fla. 2001). However, the class plaintiffs’ remedies under that provision are “generally limited to injunctive relief and restitution.” *Cel-Tech Commc’ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 539 (Cal. 1999); *see also In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d at 1379 (explaining that the “Unfair Competition Law does not authorize awards of damages at law”). The court thus denies defendants’ motion to dismiss the claims asserted under California’s Unfair Competition Law but dismisses the state antitrust claims based on unilateral conduct and asserted in Counts IV, V, and VI under California’s Cartwright Act.

For Kansas, the class plaintiffs assert that Kan. Stat. Ann. § 50-161(b) permits indirect purchasers to recover if “damaged or injured by any agreement, *monopoly*, trust, conspiracy or combination . . . .” *Id.* (emphasis added). But, as one court has observed, “the Kansas Monopolies and Unfair Trade Act . . . by its terms prohibits combinations and conspiracies only.” *In re Relafin Antitrust Litig.*, 221 F.R.D. 260, 283 (D. Mass. 2004) (citing Kan. Stat. Ann. § 50-132 (“No person, servant, agent or employee of any person doing business within the state of Kansas shall *conspire or combine* with any other persons, within or without the state for the

purpose of monopolizing any line of business . . . .” (emphasis added))). Thus, *In re Relafin* reasoned, the Kansas Restraint of Trade Act does not permit unilateral conduct claims. *Id.* Finding no other case law addressing this issue and finding *In re Relafin*’s reasoning persuasive, the court dismisses the class plaintiffs’ Kansas antitrust law claims based on unilateral conduct and asserted in Counts IV, V, and VI.

For Tennessee, the class plaintiffs assert their state antitrust claims under the Tennessee Trade Practices Act, Tenn. Code Ann. § 47-25-101. Class Compl. ¶ 562.cc. The Tennessee statute “declare[s]” that certain anticompetitive conduct is “against public policy, unlawful, and void.” Tenn. Code Ann. § 47-25-101. Such conduct includes “all arrangements, contracts, agreements, trusts, or combinations *between persons or corporations* designed, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer of any such product or article.” *Id.* (emphasis added). As one court has explained, “[n]one of these terms appears to include unilateral conduct.” *In re Relafin Antitrust Litig.*, 221 F.R.D. at 283 (citing 6 Julian O. von Kalinowski, *Antitrust Laws and Trade Regulation* § 116.03 (2d ed. 2003)). Likewise, at least two other courts have held that the Tennessee Trade Practices Act does not cover unilateral conduct claims. *See, e.g., In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 415–16 (E.D. Pa. 2009); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1108–09 (N.D. Cal. 2007).

The class plaintiffs cite only one case where a federal court has permitted antitrust claims asserted under the Tennessee Trade Practices Act to survive a motion to dismiss. *See In re Asacol Antitrust Litig.*, No. 15-12730-DJC, 2016 WL 4083333, at \*15 (D. Mass. July 20, 2016). The *Asacol* court relied on two Tennessee cases allowing antitrust claims to proceed under the Act. *Id.* But, as *Asacol* recognized, the two Tennessee cases never addressed whether the statute

permits claims based on unilateral conduct. *Id.* The court is not persuaded by *Asacol's* reasoning, at least not as applied to the unilateral conduct claimed here. Instead, it finds persuasive the federal district court cases cited above. These cases considered the plain language of the Tennessee statute, specifically addressed whether it applies to unilateral conduct, and determined that it does not reach such claims. For this reason, the court dismisses the class plaintiffs' Tennessee antitrust claims based on unilateral conduct, as asserted in Counts IV, V, and VI.

### **B. RICO Claim**

The court now considers whether the class plaintiffs have asserted a plausible RICO claim against defendants. Subsection 1962(c) of RICO makes it:

unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

18 U.S.C. § 1962(c). Subsection 1962(d) makes it “unlawful for any person to conspire to violate” subsection 1962(c). *Id.* § 1962(d). RICO also provides a private civil cause of action for those who are injured by violations of § 1962 and allows recovery of treble damages, costs, and attorney fees. *Id.* § 1964(c).

When addressing plaintiffs' RICO claim below, the court is mindful that “RICO is to be read broadly.” *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 497 (1985). “To successfully state a RICO claim, a plaintiff must allege four elements: (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.” *Robbins v. Wilkie*, 300 F.3d 1208, 1210 (10th Cir. 2002) (citations and internal quotation marks omitted). And, to have standing to assert a RICO claim, the plaintiff must allege that the RICO violation proximately caused plaintiff's injuries. *Bixler v. Foster*, 596 F.3d 751, 756 (10th Cir. 2010).

Defendants assert eight reasons why the class plaintiffs' RICO claim fails to state a plausible claim as a matter of law. The court concludes that none of these arguments warrant dismissal at the pleading stage. The court explains why in the eight subsections that follow.

### **1. RICO Enterprise**

First, defendants assert that the Class Complaint fails to assert a plausible RICO claim because it never alleges facts capable of supporting a finding or inference of a RICO enterprise. Instead, defendants contend, the Class Complaint alleges only that defendants engaged in arms-length business activities that do not suffice to state a RICO claim.

As already described, RICO prohibits a "person" who is associated with an "enterprise" to conduct its affairs through a pattern of racketeering activity. *See* 18 U.S.C. § 1962(c). "RICO broadly defines 'enterprise' as 'any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.'" *George v. Urban Settlement Servs.*, 833 F.3d 1242, 1248 (10th Cir. 2016) (quoting 18 U.S.C. § 1961(4)).

Here, the class plaintiffs allege that the RICO enterprise is an "association-in-fact enterprise," consisting of the RICO Defendants (Mylan N.V., Mylan Specialty, LP, Heather Bresch, Pfizer, King Pharmaceuticals, and Meridian) and the PBM Conspirators (defined as at least four PBMs: CVS Health Corporation, Express Scripts Inc., Optum Rx Inc., and Prime Therapeutics LLC ), "formed for the purpose of engaging in a scheme to defraud the public regarding the pricing of the EpiPen, the medical necessity, quality, and characteristics of EpiPens and the EpiPen 2-Pak, and Mylan's profits and efforts to control the price of the EpiPen." Class Compl. ¶ 604.

The Supreme Court has explained that “‘an enterprise includes any union or group of individuals associated in fact[,]’ and that ‘RICO reaches ‘a group of persons associated together for a common purpose of engaging in a course of conduct.’” *Boyle v. United States*, 556 U.S. 938, 944 (2009) (quoting *United States v. Turkette*, 452 U.S. 576, 580, 583 (1981)). An association-in-fact enterprise requires: (1) “a purpose,” (2) “relationships among those associated with the enterprise,” and (3) “longevity sufficient to permit these associates to pursue the enterprise’s purpose.” *Id.* at 946.

The class plaintiffs assert that their Class Complaint alleges all three requirements of an association-in-fact enterprise. *First*, they assert, the Class Complaint alleges that the common purpose of the “EpiPen Pricing Enterprise” was to overcharge consumers for the EpiPen to enrich defendants. Doc. 123 at 99; Class Compl. ¶¶ 600, 604, 643, 648.

*Second*, the Class Complaint alleges relationships between the Mylan and Pfizer Defendants and that they worked together to operate and manage the EpiPen Pricing Enterprise. Also, the Class Complaint alleges that the Mylan and Pfizer Defendants worked together to stop generic competition for the EpiPen by filing patent infringement lawsuits between 2009 and 2012 against at least three generic rivals—Teva, Sandoz, and Intelliject. Class Compl. ¶ 629; *see also id.* ¶¶ 236–324. Also, the Class Complaint alleges that Pfizer (through Meridian) and Mylan “jointly” settled the Teva Litigation by entering a settlement agreement that secretly restrained competition and ensured that the EpiPen Pricing Enterprise could continue successfully without facing competition from Teva. *Id.* ¶¶ 630–31; *see also id.* ¶ 270 (describing how Mylan and Pfizer issued a joint press release about the Teva settlement); *see also id.* ¶ 277 (describing how Mylan CEO Heather Bresch referred to the Teva settlement as “our settlement with Teva”) (emphasis added). The Class Complaint also alleges that Mylan Specialty LP took



over for Meridian as sponsor of the EpiPen patents in the Orange Book. *Id.* ¶ 247. Although the class plaintiffs don't assert exactly why or how this change occurred, they allege that it shows "concerted action by Mylan and Pfizer to share the burden and rewards of their EpiPen monopoly." *Id.*

The Class Complaint also describes how Mylan and Pfizer's relationship is not completely clear because they never have asserted publicly that they share more than a manufacturer/seller relationship. *Id.* ¶ 632. But, as the Class Complaint describes, commenters have noted that Pfizer received significant revenues from its relationship with Mylan based on EpiPen sales. *Id.* And, the Class Complaint asserts, this shared interest in generating revenues has caused Mylan and Pfizer to work together to ward off competition through patent litigation and unlawful reverse payment settlements. *Id.* ¶ 241 (asserting that Mylan and Pfizer's "divided intellectual property ownership of the EpiPen and their licensing agreements for it have caused the two companies to work collaboratively to enhance the products sales volume and profitability" because their "EpiPen-related revenues rise (or fall) together").

Defendants argue that these allegations only describe how Pfizer defended its patent rights and provided Mylan products subject to a routine commercial arrangement. Defendants characterize these allegations as "routine business relationships" that cannot establish a RICO claim. Doc. 95 at 67 (first citing *Robins v. Glob. Fitness Holdings, LLC*, 838 F. Supp. 2d 631, 652–53 (N.D. Ohio 2012); then citing *Brannon v. Boatmen's First Nat'l Bank of Okla.*, 153 F.3d 1144, 1148 (10th Cir. 1998) (affirming dismissal of a RICO claim because plaintiffs' "allegations do nothing more than define a legitimate corporate and financial relationship between [defendant] and its holding company.") (further citations omitted)). But, construing the Class Complaint as describing just "routine business relationships" requires the court to draw

inferences against the class plaintiffs' allegations. And that is not a proper endeavor for the court on a motion to dismiss. Instead, the court must take plaintiffs' allegations as true and view them in the light most favorable to the class plaintiffs. *Mayfield v. Bethards*, 826 F.3d 1252, 1255 (10th Cir. 2016). Applying that standard, one plausibly can infer from the Class Complaint's allegations that the Mylan and Pfizer Defendants—persons or entities associated with the enterprise—formed relationships sufficient to satisfy the pleading requirements for a RICO enterprise.

Defendants also argue that the class plaintiffs' allegations about PBMs fail to allege adequately their participation in a RICO enterprise. The Class Complaint alleges, during the past decade, “the PBM Conspirators and other PBMs began to exert influence in their role as insurance-industry middle-men to dictate the success or failure of certain drugs in the marketplace by offering to include or threatening to exclude certain medications from some or all of their formularies and, in the process, extracting hundreds of millions of dollars in the form of ‘discounts’ or ‘rebate’ payments from drug manufacturers in exchange.” Class Compl. ¶ 636. The class plaintiffs assert that PBMs and drug manufacturers engage in negotiations during “complex, closed-door meetings, during which PBMs sell access to their formularies in exchange for large rebates or discounts, a substantial portion of which they pocket as pure profit.” *Id.* ¶ 637. During those negotiations, the class plaintiffs contend, the RICO Defendants “participated in a scheme *with the PBM Conspirators* to increase the list price of the EpiPen.” *Id.* ¶ 638 (emphasis added). The purpose of the RICO Defendants' scheme was to “[t]o facilitate the payment of ‘rebates’ to PBMs, and ensure their position on certain formularies without impacting their bottom line.” *Id.* And also, the scheme “increase[d] the profits of PBMs through artificially increasing the list price of EpiPens” to the detriment of consumers. *Id.* ¶ 639.

The Class Complaint describes how the RICO Defendants and PBM Conspirators advanced the goals of the EpiPen Pricing Enterprise allegedly by “affirmatively misrepresent[ing] or conceal[ing] the existence of the inflated and fraudulent nature of these list price increases as well as the existence, amount, and purpose of the discounts given to the PBM Conspirators to Plaintiffs, the Classes, consumers, health care payers, and the general public.” *Id.* ¶ 641. Also, the Class Complaint alleges that the PBM Conspirators “exerted substantial control over the EpiPen Pricing Enterprise, and participated in the affairs of the enterprise” through a variety of specific actions. *Id.* ¶ 651. This conduct includes the PBM Conspirators’ negotiating and offering to discount the EpiPen; misrepresenting and concealing the existence, amount, and purpose of the EpiPen discounts; misrepresenting and concealing the true nature of the relationship and agreements between the enterprise’s members as well as its effect on the pricing of the EpiPen; and, ensuring that the other RICO Defendants and members of the EpiPen Pricing Enterprise concealed the fraudulent scheme. *Id.*

Defendants characterize these allegations as “[a] commercial negotiation, where the parties have their own independent business interests and one party demands higher rebates and lower prices from the other.” Doc. 95 at 69. And, they contend, “[t]o recognize a RICO enterprise here would be tantamount to holding that negotiating strategies by PBMs, insurers, state Medicaid agencies, and other healthcare payors throughout the U.S. amount to organized criminal conduct—which obviously cannot be, and is not, the law.” *Id.* Perhaps a factfinder would accredit defendants’ characterization of these interactions. But it might not, and the court cannot accept defendants’ characterization of the allegations at the pleading stage. Instead, when one accepts the allegations as true and views them in the class plaintiffs’ favor, one reasonably can infer that the PBMs’ alleged conduct amounted to far more than a commercial negotiation.

Instead, the Class Complaint alleges that the PBMs formed relationships with defendants sufficient to plead a plausible RICO enterprise.

*And finally*, the Class Complaint alleges an enterprise with longevity sufficient to permit the associates to pursue the enterprise’s purpose. The class plaintiffs assert that, beginning at least on January 1, 2009, to the present, the associates have engaged in various activities to pursue the enterprise’s purpose. Class Compl. ¶¶ 601, 629 (discussing how the Mylan and Pfizer Defendants worked together to stop generic competition for the EpiPen by filing patent infringement lawsuits throughout 2009 to 2012); 642, 655–56. The Class Complaint plausibly pleads a RICO enterprise.

## **2. Conducted the Affairs of a RICO Enterprise**

Next, defendants assert that the Class Complaint never alleges that defendants “conduct[ed] or participate[d], directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity . . . .” 18 U.S.C. § 1962(c). As the Supreme Court has explained, RICO liability “‘depends on showing that the defendants conducted or participated in the conduct of the “enterprise’s affairs,” not just their *own* affairs.’” *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001) (quoting *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993)).

Our Circuit has described *Reves*’s “operation and management test” as a standard requiring the defendant to have “‘some part in directing’ the enterprise’s affairs.” *George v. Urban Settlement Servs.*, 833 F.3d 1242, 1251 (10th Cir. 2016) (quoting *Reves*, 507 U.S. at 179). “But importantly, the defendant need not have ‘primary responsibility for the enterprise’s affairs,’ ‘a formal position in the enterprise,’ or ‘significant control over or within an enterprise.’” *Id.* (quoting *Reves*, 507 U.S. at 179 & n.4, 184). This test requires less. “Instead,

even ‘lower rung participants in the enterprise who are under the direction of upper management’ may be liable under RICO if they have ‘some part’ in operating or managing the enterprise’s affairs.” *Id.* (quoting *Reves*, 507 U.S. at 179, 184). Yet, allegations that simply describe a defendant’s conduct “through its regular course of business, goods and services that ultimately benefit the enterprise” do not suffice to state a RICO claim. *Id.* (citing *BancOklahoma Mortg. Corp. v. Capital Title Co.*, 194 F.3d 1089, 1101–02 (10th Cir. 1999)).

Here again, defendants assert that the Class Complaint alleges nothing more than two corporations pursuing routine, arms-length business activities. And, they contend, these activities fail to allege conduct or participation in the RICO *enterprise’s* affairs instead of simply their *own* affairs. The court disagrees with defendants’ construction of the Class Complaint’s allegations.

Instead, as the court already has described, one plausibly can infer from the Class Complaint’s allegations that the Mylan and Pfizer Defendants worked together to operate and manage the EpiPen Pricing Enterprise. Class Compl. ¶ 600. Specifically, the Class Complaint alleges that the Mylan Defendants committed various acts as part of a scheme to defraud the public about the EpiPen’s pricing, the medical necessity, quality, and characteristics of the EpiPen, and the EpiPen 2-Pak. *See, e.g., id.* ¶ 604; *see also id.* ¶¶ 152, 229, 325–47, 354. And the Class Complaint alleges that the Mylan and Pfizer Defendants, working together, participated in various conduct designed to stifle generic competition, *e.g.*, filing patent infringement lawsuits and then resolving those lawsuits through unlawful reverse payment settlements. *Id.* ¶¶ 629–31; *see also id.* ¶¶ 236–324. These alleged facts permit a reasonable inference that both the Mylan and Pfizer Defendants “played some part—even a bit part—in conducting the enterprise’s

affairs.” *George*, 833 F.3d at 1252. And these allegations suffice to support a plausible RICO claim.

### 3. Pattern of Racketeering Activity

Defendants next argue that the Class Complaint never alleges a “pattern of racketeering activity,” as 18 U.S.C. § 1962(c) requires. The RICO statute defines a “pattern” of racketeering as “at least two acts of racketeering activity, . . . which occurred within ten years” of one another. 18 U.S.C. § 1961(5). But “proof of two or more predicate acts [is] not sufficient to prove a pattern unless there is a relationship between the predicate acts and a threat of continuing activity.” *Tal v. Hogan*, 453 F.3d 1244, 1267 (10th Cir. 2006) (first citing *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 239 (1989); then citing *Duran v. Carris*, 238 F.3d 1268, 1271 (10th Cir. 2001)). “Continuity of threat requires both proof of ‘a series of related predicates extending over a substantial period of time,’ as well as a ‘showing that the predicates themselves involve a distinct threat of long-term racketeering activity . . . or that the predicates are a regular way of conducting the defendant’s ongoing legitimate business or the RICO enterprise.’” *Id.* (quoting *Resolution Tr. Corp. v. Stone*, 998 F.2d 1534, 1543 (10th Cir. 1993)).

Defendants assert that the Class Complaint, at best, makes conclusory allegations of a pattern of racketeering activity. Defendants describe the Class Complaint to allege unrelated predicate acts with just one thing in common—they simply involve Mylan and the EpiPen. Defendants thus assert that these allegations lack the common thread tying them together, as required to support a plausible RICO claim.

This simply is wrong. Defendants read the class plaintiffs’ allegations disjunctively. But, when one views the Class Complaint’s allegations in the class plaintiffs’ favor and collectively, the allegations describe predicate acts made as part of the EpiPen pricing scheme—

*i.e.*, defendants’ fraudulent scheme caused American consumers to pay artificially inflated prices for the EpiPen. As defendants recognize, the Class Complaint alleges that defendants used the mails and the wires to disseminate fraudulent information and corrupted an official proceeding. *See, e.g.*, Class Complaint ¶¶ 655.a. (describing how Ms. Bresch made several statements about Mylan’s intent to add more patents in a 2009 quarterly earnings call), 655.c. (describing Mylan and Pfizer’s joint announcement of its settlement agreement with Teva which, the class plaintiffs contend, really was a pay-for-delay settlement), 655.g. (asserting that Ms. Bresch made several false statements when she testified before Congress on September 21, 2016). One can infer from these alleged facts that the common thread among the predicate acts is that defendants made these communications to advance their EpiPen pricing scheme. *See id.* ¶ 659 (asserting that “[t]o effectuate the goals of the EpiPen Pricing Enterprise, including but not limited to maximizing profit and controlling a dominant market position, the RICO Defendants . . . launched a campaign of false and misleading statements and actions to distract consumers and regulators from the reality that the RICO Defendants were raising the price of the EpiPen from \$100 to \$600” that included Mylan’s false statements about competitors, Mylan and Pfizer’s “pay-for-delay” settlements, and Ms. Bresch’s alleged false testimony to Congress about Mylan’s profits). These facts suffice to allege a pattern of racketeering activity. *See George v. Urban Settlement Servs.*, 833 F.3d 1242 1254–57 (10th Cir. 2016) (holding that plaintiffs adequately alleged a pattern of racketeering activity because their complaint asserted defendants committed several acts of mail and wire fraud while executing a fraudulent scheme to deny Home Affordable Modification Program loans to eligible borrowers); *see also Resolution Tr. Corp.*, 998 F.3d at 1543 (holding that sufficient evidence of a pattern of racketeering activity existed to support the

jury’s finding because the “jury could find that the wire fraud activity was associated with on-going acts of fraud”).

Also, our Circuit recognizes that “[w]hether a pattern [of racketeering activity] exists is a question of fact for the jury to determine.” *Resolution Tr. Corp.*, 998 F.2d at 1543; *see also Tal*, 453 F.3d at 1268 (holding that “because the extensiveness of the threat is a question of fact” the court would “assume for the purposes of this opinion that the predicate acts alleged . . . establish a pattern of racketeering activity”). Here, the Class Complaint sufficiently alleges facts that, if true, would permit a jury to find or infer a pattern of racketeering activity and thus support a RICO claim.

#### 4. RICO Causation

Defendants next assert that the class plaintiffs’ RICO claim fails because the Class Complaint never alleges causation. To state a plausible RICO claim, a plaintiff must allege that he was a “person injured in his business or property by reason of a violation of section 1962 of this chapter.” 18 U.S.C. § 1964(c). The Supreme Court has interpreted this provision as one requiring a RICO plaintiff’s damages to “flow from the commission of the predicate acts.” *Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 497 (1985); *see also Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 13 (2010) (“[T]he compensable injury flowing from a [RICO] violation . . . necessarily is the harm caused by [the] predicate acts.” (citations and internal quotation marks omitted)).

Section 1964(c)’s causation requirement requires a RICO plaintiff to allege “that the defendant’s violation not only was a “but for” cause of his injury, but was the proximate cause as well . . . .” *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654 (2008) (quoting *Holmes v. Sec. Inv’r Prot. Corp.*, 503 U.S. 258, 268 (1992)). The Supreme Court has defined RICO



proximate causation as “a flexible concept that does not lend itself to ‘a black-letter rule that will dictate the result in every case.’” *Id.* (quoting *Holmes*, 503 U.S. at 272 n.20 (further citations and internal quotation marks omitted)). Instead, proximate cause provides a “‘label generically [for] the judicial tools used to limit a person’s responsibility for the consequences of that person’s own acts . . . .’” *Id.* (quoting *Holmes*, 503 U.S. at 268). And it includes “a particular emphasis on the ‘demand for some direct relation between the injury asserted and the injurious conduct alleged.’” *Id.* (quoting *Holmes*, 503 U.S. at 268).

Thus, “[w]hen a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff’s injuries.” *Safe Streets All. v. Hickenlooper*, 859 F.3d 865, 889 (10th Cir. 2017) (quoting *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 461 (2006)). The Supreme Court has instructed that “no need [exists] to broaden the universe of actionable harms to permit RICO suits by parties who have been injured only indirectly.” *Id.* (quoting *Anza*, 547 U.S. at 460).

But, in the context of RICO claims premised on predicate acts of mail fraud, the Supreme Court has held that “a plaintiff is not required to plead that he is a victim of the defendant’s underlying crime (*e.g.*, that he relied on the fraudulent mailings) to establish a direct injury.” *Id.* (citing *Bridge*, 553 U.S. at 649–50). “Rather, a plaintiff may establish proximate causation by plausibly pleading that his business or property has been directly injured as a result of the defendants’ § 1962 violation.” *Id.* (citing *Bridge*, 553 U.S. at 649–50).

Here, the Class Complaint alleges, defendants’ pattern of racketeering activity has injured the class plaintiffs in their business or property. Class Compl. ¶¶ 680, 682. The Class Complaint also asserts that defendants’ fraudulent scheme has allowed them to “illegally extract[ ] revenues of millions or billions of dollars from Plaintiffs and the Class.” *Id.* ¶ 602. More precisely, the

class plaintiffs allege, “but for” defendants’ unlawful conduct, the class plaintiffs “would have paid less for both branded and generic versions of EpiPen by: (a) substituting their purchases of EpiPen with less-expensive generic versions of EpiPen; (b) purchasing generic EpiPen at lower prices sooner; (c) purchasing individual, rather than pairs, of EpiPen injectors; (d) buying spare auto-injectors that were generic or cheaper brands; and (e) purchasing branded EpiPen at a reduced price.” *Id.* ¶ 492.

One reasonably can infer from these allegations that defendants’ actions produced the alleged harm—*i.e.*, paying inflated prices for the EpiPen. Defendants disagree, asserting the Class Complaint alleges no plausible relationship between defendants’ alleged false and fraudulent statements and the class plaintiffs’ purchasing decisions. *See* Doc. 219 at 36. The court reads the Class Complaint quite differently. As *Bridge* held, to state a plausible RICO claim, the class plaintiffs need not plead that they relied on the alleged false statements when purchasing the EpiPen. *Bridge*, 553 U.S. at 649–50. Instead, they must allege plausibly that defendants’ RICO violation injured their business or property directly. Here, the class plaintiffs’ allegations satisfy that pleading burden.

The class plaintiffs allege that the fraudulent statements advanced defendants’ pricing scheme in several ways. They include forcing consumers to purchase the EpiPen 2-Pak (instead of individual EpiPens), restricting access to generic competition, and driving up the EpiPen’s price (from \$100 in 2007 to more than \$600 in 2016). Class Compl. ¶¶ 600, 655, 657, 659, 664. It is plausible to infer from these allegations that defendants’ conduct injured the class plaintiffs directly. With this conduct, the class plaintiffs allege, defendants effectively limited consumers’ purchasing decisions by restricting consumer access to competing products—all while hiking the price of the EpiPen and thus forcing consumers to pay inflated prices.

The class plaintiffs are suing to recover for their own injuries—as EpiPen consumers or third-party payors—from having to pay the inflated prices for the EpiPen. *See Safe Streets*, 859 F.3d at 890 (holding that plaintiffs stated a RICO claim because they sought “to recover for injuries to their own land, not harms to third parties”); *In re Neurontin Mktg. and Sales Practices Litig.*, 712 F.3d 21, 37 (1st Cir. 2013) (affirming RICO verdict because the jury could infer from the evidence that plaintiff was a “primary and intended victim” of defendants’ “scheme to defraud”). And one plausibly can infer from the Class Complaint that the class plaintiffs’ alleged injuries were “a foreseeable and natural consequence of [defendants’] scheme” to defraud the public about the EpiPen’s price. *See Bridge*, 553 U.S. at 658 (concluding that the “alleged injury—the loss of valuable liens—is the direct result of petitioner’s fraud” because “[i]t was a foreseeable and natural consequence of petitioners’ scheme to obtain more liens for themselves that other bidders would obtain fewer liens”); *see also In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633, 645 (3d Cir. 2015) (holding plaintiffs pleaded direct injury sufficient to satisfy the RICO proximate causation requirement—regardless of whether plaintiffs had relied on the alleged misrepresentations because the alleged “fraudulent scheme could have been successful only if plaintiffs paid for [a drug used to treat Type II diabetes], and this is the very injury that plaintiffs seek recovery for”); *Safe Streets*, 859 F.3d at 890 (holding that plaintiffs stated a plausible RICO claim because the complaint alleged “[n]o intermediary break[ ] [in] the casual chain” between the enterprise’s RICO violations and the plaintiffs’ injuries). The court finds the class plaintiffs’ allegations sufficient to allege RICO causation.

### **5. Predicate Acts of Racketeering Activity**

Next, defendants assert that the Class Complaint never alleges any racketeering activity sufficient to support a RICO claim. “RICO is founded on the concept of racketeering activity.”

*Safe Streets*, 859 F.3d at 882 (quoting *RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2096 (2016)). This statute “defines ‘racketeering activity’ to encompass dozens of state and federal offenses, known in RICO parlance as predicates.” *Id.* (quoting *RJR*, 136 S. Ct. at 2097). “These predicates include any act “indictable” under specified federal statutes . . . .” *Id.* (quoting *RJR*, 136 S. Ct. at 2096 (quoting 18 U.S.C. § 1961(1))). Such predicates include those “indictable” under 18 U.S.C. “section 1341 (relating to mail fraud),” “section 1343 (relating to wire fraud),” and “section 1512 (relating to tampering with a witness, victim, or an informant).” 18 U.S.C. § 1961(1)(B).

Here, the Class Complaint alleges that defendants engaged in a pattern of racketeering activity involving mail and wire fraud, violating 18 U.S.C. §§ 1341 & 1343. Class Compl. ¶¶ 652, 654.a., 654.b. It also alleges that the Mylan Defendants corrupted an official proceeding, violating 18 U.S.C. § 1512(c)(2), by having Ms. Bresch testify falsely before Congress on September 21, 2016. *Id.* ¶¶ 653, 654.c.

“To support the mail and wire fraud allegations, the plaintiffs must plausibly allege ‘the existence of a scheme or artifice to defraud or obtain money or property by false pretenses, representations or promises,’ and that [defendants] communicated, or caused communications to occur, through the U.S. mail or interstate wires to execute that fraudulent scheme.” *George v. Urban Settlement Servs.*, 833 F.3d 1242, 1254 (10th Cir. 2016) (quoting *Tal v. Hogan*, 453 F.3d 1244, 1263 (10th Cir. 2006)). “And because Fed. R. Civ. P. 9(b) requires a plaintiff to plead mail and wire fraud with particularity, the plaintiffs must ‘set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof.’” *Id.* (quoting *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1236 (10th Cir. 2000)) (emphasis added).

Defendants assert that the Class Complaint never identifies the consequences of the alleged fraudulent communications. More specifically, they contend that the class plaintiffs' allegations never identify how defendants' fraudulent mail and wire communications advanced the alleged scheme to defraud. *See* Doc. 219 at 36. Separately, the Pfizer Defendants assert that the RICO claim fails to state a plausible claim because the class plaintiffs never alleged any predicate acts by any of the Pfizer Defendants, as required to support the claim. *See* Doc. 93 at 20. The court rejects defendants' arguments.

The class plaintiffs have alleged that defendants made various false representations using the mails and wires—including press releases and earnings calls. The Class Complaint describes the time, place, contents, and identity of the person making the allegedly false statements. Class Compl. ¶ 655. And, the class plaintiffs allege, the purpose of the communications was “to fraudulently mislead and deceive American consumers to purchase the EpiPen at an inflated price, to purchase the EpiPen as a 2-Pak only, and to cause consumers to pay an artificially inflated price for EpiPens.” *Id.* ¶ 600. These communications include various representations about the medical necessity of the EpiPen 2-Pak. The class plaintiffs allege that these representations were false and misleading because they relied on flawed medical studies and paid-for medical opinions. The communications also include various representations about Mylan's efforts to provide “free” EpiPens to schools and to encourage anaphylaxis awareness. *Id.* ¶¶ 655.d., 655.e., 659.a. But, the class plaintiffs allege, these representations were fraudulent because Mylan actually used the school program as an anticompetitive means to implement exclusive dealing contracts, hook consumers on the EpiPen, and then raise the EpiPen price. *Id.* ¶¶ 655.d., 655.e., 655.g.iii.

The alleged fraudulent communications also include jointly issued statements about Mylan and Pfizer’s patent litigation settlements. The Pfizer Defendants assert that their settlement of patent litigation cannot support a predicate act. The court doesn’t read the class plaintiffs’ allegations that way. Instead, the class plaintiffs allege that Mylan and Pfizer entered into unlawful reverse payment settlements, but then—together—issued false press releases describing the settlements as a legitimate means to resolve patent litigation. One reasonably can infer the Class Complaint to allege that defendants advanced their scheme to inflate the price of the EpiPen by fraudulently representing to the public that they were resolving valid patent litigation. But the class plaintiffs allege that defendants, in reality, used the patent litigation and resulting “pay-for-delay” settlements as a means to prevent generic competition, to protect the EpiPen monopoly, and to continue raising prices on the EpiPen. Indeed, the Class Complaint alleges that the “pay-for-delay” settlements “concealed from consumers the true, anti-competitive aims of its pay-for-delay arrangements.” *Id.* ¶ 659.e.

It is reasonable to infer from these allegations that defendants’ communications fraudulently misled, deceived, and caused American consumers to purchase the EpiPen at an inflated price. These allegations sufficiently set forth the “time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof” and thus state a plausible RICO claim. *George*, 833 F.3d at 1254.

Defendants also assert that the Class Complaint fails to plead facts capable of supporting a violation of 18 U.S.C. § 1512(c)(2) for corrupting an official proceeding. This statute makes it unlawful to “obstruct[ ], influence[ ], or impede[ ] any official proceeding, or attempt[ ] to do so,” and imposes a “fine[ ] under this title or imprison[ment] not more than 20 years, or both.” 18 U.S.C. § 1512(c)(2). The Class Complaint alleges that Ms. Bresch corruptly influenced an

official proceeding by giving false testimony before Congress. Class Complaint ¶¶ 654.c., 655.g., 659.h., 659.i. Defendants assert that the class plaintiffs provided “no evidence” and only “bald assertions” to support the allegation that Ms. Bresch’s testimony was false. Doc. 95 at 77. Defendants characterize the class plaintiffs’ allegations as merely “subjective disagree[ment]” with Ms. Bresch’s testimony that cannot support an obstruction violation. Doc. 219 at 38. At the pleading stage, the court cannot weigh the class plaintiffs’ allegations and determine whether they describe false testimony or simply report subjective disagreement with Ms. Bresch’s statements. Instead, taking the allegations as true, the class plaintiffs assert that Mr. Bresch testified before Congress on September 21, 2016, and that she repeatedly gave false testimony about a number of topics in an effort to advance defendants’ ongoing scheme to defraud consumers into purchasing the EpiPen at inflated prices. These allegations are sufficient to state a plausible § 1512(c)(2) violation.

## 6. Standing

Defendants assert that the class plaintiffs lack standing to assert a RICO claim for two reasons. Neither one permits the court to dismiss the RICO claim at the pleading stage.

*First*, defendants contend that the class plaintiffs—as indirect purchasers—lack standing to assert a RICO claim. The Tenth Circuit has recognized, albeit in the antitrust context, that “only the direct purchaser, and no other [person] in the distribution chain, is the ‘party injured’” who “may sue for and recover the full amount of the illegal overcharge.” *In re Wy. Tight Sands Antitrust Cases*, 866 F.2d 1286, 1290 (10th Cir. 1989) (first citing *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968); then citing *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977)). Citing cases from outside the Tenth Circuit, defendants argue that the court should

apply this rule to civil RICO claims. *See* Doc. 95 at 77–78 (citing *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 855 (3d Cir. 1996) (further citations omitted)).

The class plaintiffs respond that such a rule defies the Tenth Circuit’s most recent guidance about standing—*i.e.*, a RICO plaintiff has standing if he has pleaded proximate causation. *See Safe Streets*, 859 F.3d at 887 (holding that “RICO standing” is determined under “the usual pleading-stage inquiry: whether the plaintiff has plausibly pled a cause of action under RICO”); *see also id.* at 885 (explaining that a RICO claim requires “(1) injuries to [plaintiffs’] property (2) that were caused by those [RICO] violations”); *Bixler v. Foster*, 596 F.3d 751, 756 (10th Cir. 2010) (“A plaintiff has standing only if his injuries were proximately caused by the RICO violation.”). The class plaintiffs also assert that applying the indirect-purchaser rule is contrary to the Supreme Court’s decision in *Bridge*, holding that first-party reliance is not required to allege RICO causation. *See Bridge*, 553 U.S. at 649–50.

Indeed, the Supreme Court has recognized in the RICO context that its requirements for “antitrust injury” have “no analogue in the RICO setting.” *Holmes v. Sec. Inv’r Prot. Corp.*, 503 U.S. 258, 269 n.15 (1992). And, the Court has cautioned, “our use of the term ‘direct’ should merely be understood as a reference to the proximate-cause enquiry that is informed by the concerns set out in the text. We do not necessarily use it in the same sense as courts before us have and [we] intimate no opinion on results they reached.” *Id.* at 272 n.20; *see also Israel Travel Advisory Serv., Inc. v. Israel Identity Tours*, 61 F.3d 1250, 1257 (7th Cir.), *cert. denied*, 517 U.S. 1220 (1995) (“The Supreme Court observed that it did not mean to preclude all possibility of recovery for injury that was transmitted indirectly; the holding of *Holmes* is no more than that common law ideas about proximate causation inform the understanding of RICO.” (citation omitted)). Instead, the Supreme Court has recognized that “the infinite variety



of claims that may arise [under RICO] make it virtually impossible to announce a black-letter rule that will dictate the result in every case” for determining whether an alleged RICO violation was the proximate cause of a plaintiff’s injuries. *Id.*

Because defendants just cite cases from outside the Tenth Circuit to support their argument that indirect purchasers lack RICO standing,<sup>22</sup> the court declines to apply that rule here. Instead, applying the guidance from our Circuit in *Safe Streets*, the court already has determined that the class plaintiffs adequately have alleged that defendants’ RICO violations proximately caused their injuries. *See supra* Part III.B.4. These allegations suffice to confer RICO standing. *See Safe Streets*, 859 F.3d at 886–890; *see also Bixler*, 596 F.3d at 756.

*Second*, defendants assert the class plaintiffs lack RICO standing because they cannot assert a claim based on overpaying for pharmaceuticals when they received the benefit of their bargain, *i.e.*, effective drugs. To support this argument, defendants cite two cases from the District of New Jersey. *See In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at \*10 (D.N.J. July 10, 2009) (dismissing plaintiffs’ RICO claims for failing to allege a plausible injury based on paying an inflated price for pharmaceuticals because “purchasers of pharmaceutical products have no private cause of action where they receive the benefit of their bargain in the form of effective drugs”); *see also Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 519 (D.N.J. 2011) (dismissing RICO claim because “[p]laintiffs’ injury theory based on financial losses of

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<sup>22</sup> Although defendants cite a District of New Mexico case to support their argument, the cited case never holds that indirect purchasers lack RICO standing. *See N.M. Oncology & Hematology Consultants, Ltd. v. Presbyterian Healthcare Servs.*, 54 F. Supp. 3d 1189 (D.N.M. 2014). Instead, the New Mexico court applied Supreme Court and Tenth Circuit precedent to determine whether plaintiff had alleged proximate causation because “proximate cause is necessary to confer [RICO] standing.” *Id.* at 1244; *see also id.* at 1245 (“To have standing to pursue these claims, Plaintiff must allege facts that support a finding of proximate cause.”).

overpayment” for pharmaceuticals “is inadequate for sustaining a RICO injury, absent allegations that Defendants’ drug was on some level inferior and therefore worth less than what [Plaintiffs] paid for it” (citations and internal quotation marks omitted)).

The persuasive value of these two cases is tempered by the Third Circuit’s more recent decision, *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015). In that case, a defendant pharmaceutical manufacturer argued that plaintiffs lacked standing to bring RICO claims because plaintiffs never alleged that they received unsafe or ineffective prescriptions. Instead, defendant argued, plaintiffs “received exactly what they bargained for” and thus had “not suffered a concrete injury.” *Id.* at 639. The Third Circuit disagreed. *Id.* at 639–40. It held that plaintiffs’ “damages do not depend on the effectiveness of the [drug] that they purchased, but rather on the inflationary effect that [defendant’s] allegedly fraudulent behavior had on the price of [the drug].” *Id.* at 640. The court thus held that plaintiffs had alleged a concrete RICO injury in the form of overpaying for pharmaceutical products. *Id.*

In reaching this conclusion, the Third Circuit explained that defendant’s reliance on *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action* was misplaced. It recognized that the district court in that case “held that the plaintiffs lacked standing to assert [an injury based on economic loss] because they failed to allege that any consumers or beneficiaries received inadequate drugs or suffered personal injuries.” *Id.* (citing *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at \*16). But, on appeal, the Third Circuit “affirmed the District Court on causation grounds.” *Id.* (citing *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 246 (3d Cir. 2012)). The Third Circuit explained its reasoning this way: “To the extent we agreed with the District Court’s injury analysis in that case, we did so in dictum, not in binding precedent.” *Id.* (citing *In re*

*Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d at 246). For the same reasons, defendants’ reliance on that case here is misplaced.

And just as importantly, defendants cite no cases from the Tenth Circuit holding that a RICO plaintiff lacks standing to assert a claim for overpaying for pharmaceuticals when the plaintiff receives the benefit of the bargain in the form of purchasing effective drugs, even at inflated prices. The court declines to apply the holdings from the District of New Jersey cases here, as defendants urge. Instead, the court predicts that the Tenth Circuit would find more persuasive the Third Circuit’s reasoning in the *Avandia Marketing Sales Practices & Product Liability Litigation* case and adopt it. And, the court believes, the Circuit would conclude that the class plaintiffs have alleged a plausible injury here by asserting that they paid inflated prices for the EpiPen—prices that defendants produced with alleged unlawful conduct. *See, e.g.*, Class Compl. ¶ 492 (asserting that “but for defendants’ unlawful conduct . . . Plaintiffs and Class Members would have paid less for both branded and generic versions of EpiPen” and that “Plaintiffs and other members of the Class have sustained substantial losses and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.”).

## **7. RICO Conspiracy**

Subsection 1962(d) makes it “unlawful for any person to conspire to violate” subsection 1962(c). 18 U.S.C. § 1962(d). Defendants assert that the Class Complaint fails to state a plausible RICO claim under § 1962(c), and so, it also fails to state a plausible RICO conspiracy claim under § 1962(d). *See Tal v. Hogan*, 453 F.3d 1244, 1270 (10th Cir. 2006) (“If a plaintiff has no viable claim under § 1962(a), (b), or (c), then its subsection (d) conspiracy claim fails as a matter of law.”). For reasons already explained, the court rejects defendants’ arguments that the Class Complaint fails to state a RICO conspiracy claim under § 1962(c). Instead, the court

concludes that the class plaintiffs have alleged a plausible RICO claim under § 1962(c) sufficient to survive Rule 12(b)(6) dismissal. The class plaintiffs also allege that defendants violated § 1962(d) by conspiring to violate § 1962(c). Class Compl. ¶ 678. The class plaintiffs thus have stated a plausible claim for RICO conspiracy.

#### **8. CEO Heather Bresch is Named as a RICO conspirator**

Finally, the Mylan Defendants assert that it was malicious and improper for the class plaintiffs to name Mylan CEO Heather Bresch as one of the RICO Defendants. The Mylan Defendants argue that the Class Complaint attributes conduct to Ms. Bresch that she made on behalf of Mylan in her role as the company’s CEO. And they assert that these allegations are insufficient to state a RICO claim against Ms. Bresch in her personal capacity. *See, e.g., Ferrari v. Mercedes-Benz USA, LLC*, No. 15-cv-04379-YGR, 2016 WL 7188030, at \*3 (N.D. Cal. Dec. 12, 2016) (dismissing RICO claims against three named CEO defendants because the “allegations are insufficient to allege that [the CEOs] conducted or participated in the conduct of a racketeering enterprise, rather than just the business of [the company] separate and apart from any alleged racketeering acts”). The court disagrees.

The Class Complaint alleges that Ms. Bresch engaged in various fraudulent actions and personally conducted or participated in the RICO enterprise’s affairs. *See, e.g.,* Class Complaint ¶¶ 226–28, 380–84, 419–48, 613–22, 624–25. The Supreme Court has held that “an employee who conducts the affairs of a corporation through illegal acts comes within the terms of [the RICO] statute that forbids any ‘person’ unlawfully to conduct an ‘enterprise,’ particularly when the statute explicitly defines ‘person’ to include ‘any individual . . . capable of holding a legal or beneficial interest in property,’ and defines ‘enterprise’ to include a ‘corporation.’” *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001) (quoting 18 U.S.C. §§ 1961(3), (4)).

In *Cedric Kushner*, the Supreme Court held that an individual and his wholly owned corporation were sufficiently distinct for RICO purposes. *Id.* at 166. The Court found that “[t]he corporate owner/employee, a natural person, is distinct from the corporation itself, a legally different entity with different rights and responsibilities due to its different legal status.” *Id.* at 163. And “nothing in the [RICO] statute . . . requires more ‘separateness’ than that.” *Id.* The Court also observed, “[a]fter all, incorporation’s basic purpose is to create a distinct legal entity, with legal rights, obligations, powers, and privileges different from those of the natural individuals who created it, who own it, or whom it employs.” *Id.* Applying that principle here, the Class Complaint plausibly alleges that Ms. Bresch participated in the affairs of the RICO enterprise.

Finally, the Mylan Defendants also argue that the Class Complaint’s allegations against Ms. Bresch lack any factual support. The court cannot make that kind of decision on a motion to dismiss. Taking the Class Complaint’s allegations as true, the class plaintiffs have alleged that Ms. Bresch engaged in various false and fraudulent conduct sufficient to support the RICO claim. Naturally, to prevail on their claims against Ms. Bresch, the class plaintiff must come forward with admissible evidence to support their allegations. But that question is one for another day. At the pleading stage, the class plaintiffs sufficiently have alleged a plausible RICO claim against Ms. Bresch.

### **C. Timeliness of the Class Plaintiffs’ Antitrust and State Consumer Protection Claims.**

Defendants next assert that the class plaintiffs’ competitive delay claims are time-barred under federal antitrust law, the RICO statutes, and 30 of the 33 state law claims pleaded in the Class Complaint. Defendants explain that each of these laws impose a statute of limitations of four years or less. And, defendants contend, the class plaintiffs’ competitive delay claims accrued more than four years before they filed their lawsuit.

Indeed, the Class Complaint alleges that defendants entered the unlawful “pay-for-delay” agreements in 2011 and 2012. Class Complaint ¶¶ 270 (alleging that defendants settled the Teva Litigation on April 27, 2012), 298 (alleging that defendants announced the Intelliject settlement on February 16, 2012), 302–03 (alleging that defendants agreed to stay the Sandoz litigation indefinitely and that the stay was entered on May 10, 2011). But, defendants assert, the class plaintiffs didn’t file their competitive delay claims against Mylan until January 2017 and didn’t add Pfizer as a defendant until February 3, 2017. Defendants thus contend that the four-year (or shorter) statutes of limitations governing the class plaintiffs’ claims under the federal antitrust laws, the RICO statute, and 30 of the 33 state law claims bar the competitive delay claims. The class plaintiffs respond with two arguments why their competitive delay claims are not time-barred.

*First*, they argue that the continuing violation doctrine applies to make their competitive delay claims timely. The Supreme Court has described this doctrine in the antitrust context in this fashion:

Antitrust law provides that, in the case of a “continuing violation,” say, a price-fixing conspiracy that brings about a series of unlawfully high priced sales over a period of years, each overt act that is part of the violation and that injures the plaintiff, *e.g.*, each sale to the plaintiff, starts the statutory period running again, regardless of the plaintiff’s knowledge of the alleged illegality at much earlier times.

*Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997) (citations and internal quotation marks omitted).

Applying the continuing violation doctrine, the class plaintiffs contend that their claims accrued—not when defendants entered the alleged “pay-for-delay” settlement agreements—but instead each time they were overcharged for the EpiPen at artificially inflated prices. As the class plaintiffs recite, other courts have held that ongoing sales of a pharmaceutical product at a

supracompetitive price constitute a continuing violation that makes an action timely “so long as the last act evidencing the continuing practice falls within the limitations period.” *See, e.g., In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 746–47 (E.D. Pa. 2014) (citation and internal quotation marks omitted); *see also In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 400 (D. Mass. 2013) (recognizing that “[a]lthough the business of a monopolist’s rival may be injured at the time the anticompetitive conduct occurs, a *purchaser*, by contrast, is not harmed until the monopolist actually exercises its illicit power to extract an excessive price,” and so, “[i]ndulging all inferences in the Plaintiffs’ favor” on a motion to dismiss “it is reasonable to assume here that, every time the Direct Purchasers were overcharged for brand Nexium, they suffered a cognizable injury” (quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 295 (2d Cir. 1979))).

Indeed, *In re Niaspan Antitrust Litigation* recognized: “Every court to have considered this issue in the pay-for-delay context has held that a new cause of action accrues to purchasers upon each overpriced sale of the drug.” *Id.* at 746–47 (first citing *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 549 (D.N.J. 2004); then citing *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 378 (S.D.N.Y. 2002); then citing *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 12-md-2343, 2013 WL 2181185, at \*29 (E.D. Tenn. May 20, 2013)); *see also In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 248 (D. Conn. 2015) (holding that purchasers’ antitrust claims based on alleged unlawful reverse payment settlement agreements were timely because “a new claim accrues with each alleged overcharge. Claims are therefore not time-barred that stem from alleged overcharges incurred within the relevant statutory period, whatever that period may be for a particular statute, measured backward from the filing of the claims”).

Defendants respond that the above-cited cases applied a more “lenient continuing violations standard” than the one used by the Tenth Circuit. Doc. 216 at 18. The court disagrees. Although our Circuit has not considered the question in the pay-for-delay context, it has applied the continuing violation doctrine to antitrust claims. The Circuit recognized: “In the context of a continuing conspiracy to violate the antitrust laws, each time a plaintiff is injured by an act of the defendants a cause of action accrues to him to recover the damages caused by that act and as to those damages, the statute of limitations runs from the commission of the act.” *Auraria Student Hous. at the Regency, LLC v. Campus Vill. Apartments, LLC*, 843 F.3d 1225, 1247–48 (10th Cir. 2016) (quoting *Champagne Metals v. Ken-Mac Metals, Inc.*, 458 F.3d 1073, 1088 (10th Cir. 2006)). The Circuit has held that “an overt act will restart the statute of limitations under the continuing conspiracy exception when the act is (1) a new and independent act that is not merely a reaffirmation of a previous act; and (2) the act inflict[s] new and accumulating injury on the plaintiff.” *Id.* at 1248 (citation and internal quotation marks omitted).

*Auraria Student Housing* illustrates a proper use of the continuing violation doctrine. There, the Tenth Circuit affirmed the district court’s application of the doctrine to plaintiff’s claims that defendant had conspired with a university to exclude plaintiff from the freshmen student housing market. *Id.* at 1248. The Tenth Circuit recognized that the “initial conspiratorial decision”—enactment of a residency requirement that made defendant the sole provider of new student housing—was not the “final” act of the conspiracy. *Id.* Instead, defendants’ efforts to enforce the requirement each year made the injury to plaintiff “new and accumulating.” *Id.* The Circuit thus held that plaintiff timely asserted its claims under the continuing conspiracy exception.



Similarly, in *Champagne Metals*, the Tenth Circuit applied the continuing conspiracy exception to a horizontal group boycott. 458 F.3d at 1078. The Circuit held that the defendants' initial agreement to exclude a competitor was not "final" but, instead, required "further action" by the conspirators. *Id.* at 1089. The Circuit found that "[t]he subsequent actions (contacting and pressuring the mills when those mills were considering recognizing [the excluded competitor]) were both distinct from the act outside the limitations period (the agreement to effect a boycott) and a continuation of the same conspiracy." *Id.* (citation, internal quotation marks, and alternations omitted). Also, the Circuit observed that the alleged conspirators "did not simply sit back and watch as the unabated inertial consequences of their (alleged) anticompetitive agreement harmed [plaintiff]; rather, their actions within the limitations period manifested a commitment to renewing and enforcing that agreement." *Id.* (citation, internal quotation marks, and alternations omitted). Thus, the Circuit held, plaintiff asserted its claims timely under the continuing violation doctrine. *Id.* at 1089–90.

Likewise here, when the court reads the Class Complaint's allegations in class plaintiffs' favor, it finds allegations that defendants constructed "pay-for-delay" settlements as part of a scheme to maintain monopoly power and force consumers to pay inflated prices for the EpiPen. Construing the allegations in the light most favorable to class plaintiffs, the "pay-for-delay" settlements were not the "final" act of the conspiracy. Rather, defendants engaged in new and additional acts each time they charged the allegedly inflated prices for the EpiPen. And each of those acts inflicted a new and accumulating injury on the class plaintiffs because they had paid inflated prices for the EpiPen. The court concludes that the class plaintiffs asserted their claims timely under the continuing violation doctrine. It reaches this conclusion because the Class

Complaint alleges damages for overcharges paid in the four years before the filing of this lawsuit.

*Second*, the class plaintiffs contend that the doctrines of the discovery rule, fraudulent concealment, and equitable tolling apply to toll the statute of limitations. The class plaintiffs assert that the statute of limitations for their “pay-for-delay” claims did not commence when defendants entered the alleged reverse payment settlement in 2012. Instead, the class plaintiffs assert, these three doctrines toll the statute of limitations because defendants fraudulently concealed their actions and thus prevented the class plaintiffs from discovering their injuries and asserting their claims timely.

Indeed, the Class Complaint specifically alleges that the class plaintiffs “had no knowledge of the combination or conspiracy alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until on or about (at the earliest) August 22, 2016, the date [when] Congress publicly announced its investigation of EpiPen pricing.” Class Compl. ¶ 503. The class plaintiffs assert that they are “consumers and third-party payors who had no direct contact or interaction with Defendants and had no means from which they could have discovered the combination and conspiracy described in this Complaint before August 1, 2016.” *Id.* ¶ 504. They also assert that no information about the alleged unlawful activities was available in the public domain before August 1, 2016. *Id.* ¶ 505. Alternatively, the class plaintiffs allege, defendants actively concealed their anticompetitive conspiracy and also that defendants’ scheme was self-concealing. *Id.* ¶¶ 509–10. The Class Complaint thus asserts that “a reasonable person under the circumstances would not have been alerted to begin to investigate the legitimacy of the Defendants’ EpiPens prices before August 22, 2016.” *Id.* ¶ 510. And, the class plaintiffs contend, they “could not have discovered the alleged unlawful activity, including

the conspiracy or combination alleged herein, at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by the Defendants and their co-conspirators to avoid detection of, and fraudulently conceal, their unlawful conduct.” *Id.* ¶ 511.

These allegations “assert[ ] affirmative conduct to conceal the fraud” and “are sufficient to invoke the doctrine of equitable tolling at this stage in the proceeding.” *Aldrich v. McCulloch Props., Inc.*, 627 F.2d 1036, 1042 (10th Cir. 1980) (citations omitted) (reversing district court’s Rule 12(b)(6) dismissal of securities act violations on statute of limitations grounds because the Complaint sufficiently alleged fraudulent concealment to toll the statute of limitations and render the claims timely). Indeed, our Circuit has explained: “The question of whether a plaintiff should have discovered the basis of his suit under the doctrine of equitable tolling does not lend itself to determination as a matter of law.” *Id.* (citation omitted). Here, at the pleading stage, the class plaintiffs adequately have alleged facts capable of supporting the discovery rule, fraudulent concealment, and equitable tolling to avoid Rule 12(b)(6) dismissal on statute of limitations grounds.

#### **D. State Consumer Protection Claims**

The Class Complaint alleges that Mylan<sup>23</sup> has violated various state consumer protection laws. The Mylan Defendants argue that the Class Complaint fails to plead plausible claims under these state consumer protection laws. And they assert four arguments why the court should dismiss the claims. The court addresses each argument separately, below.

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<sup>23</sup> The Class Complaint asserts the state consumer protection law claims just against Mylan. Class Complaint ¶¶ 683–93.

## 1. Standing

First, the Mylan Defendants contend that the class plaintiffs lack standing to assert their state consumer protection claims. Article III of the United States Constitution limits federal courts' jurisdiction to "cases" and "controversies." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013). To present a case or controversy under Article III, a plaintiff must establish that he has standing to sue. *Id.* (citations omitted); *see also Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 133 (2011) (citing *Allen v. Wright*, 468 U.S. 737, 751 (1984)). Article III standing requires a plaintiff to establish (1) that he or she has "suffered an 'injury in fact'"; (2) that the injury is "'fairly . . . trace[able] to the challenged action of the defendant'"; and, (3) that it is "'likely'" that "the injury will be 'redressed by a favorable decision.'" *Ariz. Christian Sch. Tuition Org.*, 563 U.S. at 134 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)); *see also Awad v. Ziriya*, 670 F.3d 1111, 1120 (10th Cir. 2012). "At bottom, the gist of the question of standing is whether petitioners have such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination." *Massachusetts v. E.P.A.*, 549 U.S. 497, 517 (2007) (citation and internal quotation marks omitted).

The Mylan Defendants argue that the class plaintiffs lack standing to assert consumer protection claims because they neither plead (1) an injury-in-fact nor (2) that any injury is fairly traceable to defendants' conduct. Neither argument persuades the court.

*First*, an injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (citations and internal quotation marks omitted). The Supreme Court has explained the requirement of pleading injury in fact this way: "At the pleading stage, general factual

allegations of injury resulting from the defendant’s conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim.” *Id.* at 561 (citations, internal quotation marks, and alterations omitted).

Like the arguments addressed above, the Mylan Defendants assert that the class plaintiffs cannot establish standing based on their pleading’s allegations that they paid inflated prices for the EpiPen. The Mylan Defendants contend that the class plaintiffs received exactly what they purchased—an EpiPen device (or, in some contexts, two of them). And, according to the Mylan Defendants, absent allegations that the EpiPen was different than what they expected to purchase, the class plaintiffs have no standing to assert their consumer protection claims.

For support, the Mylan Defendants rely on two cases where courts held that the plaintiffs had failed to allege actual injuries. *See Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002) (holding that plaintiffs lacked standing to sue because they “concede they were not among the injured” by an allegedly defective drug but only claim economic injury without defining that injury); *see also Eike v. Allergan, Inc.*, 850 F.3d 315, 318 (7th Cir. 2017) (finding that class members lacked standing because “[o]ne cannot bring a suit in federal court without pleading that one has been injured in some way (physically, financially—whatever) by the defendant . . . [t]he fact that a seller does not sell the product that you want, or at the price you’d like to pay, is not an actionable injury; it is just a regret or disappointment—which is all we have here, the class having failed to allege ‘an invasion of a legally protected interest.’” (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016))). But these cases differ from the class plaintiffs’ allegations here. The Class Complaint in this case actually alleges injury in the form of economic loss. Specifically, the class plaintiffs allege that defendants engaged in unlawful conduct (including unfair methods of competition and unfair or deceptive acts or practices) and

that, but for the unlawful conduct, the class plaintiffs “would have paid less for both branded and generic versions of EpiPen by: (a) substituting their purchases of EpiPen with less-expensive generic versions of EpiPen; (b) purchasing generic EpiPen at lower prices sooner; (c) purchasing individual, rather than pairs, of EpiPen injectors; (d) buying spare auto-injectors that were generic or cheaper brands; and (e) purchasing branded EpiPen at a reduced price.” Class Compl. ¶ 492; *see also id.* ¶ 679 (“But for the Defendants’ fraudulent scheme and racketeering, Plaintiffs and the Class would not have accepted, acquired, and purchased the EpiPen 2-Pak.”). The class plaintiffs also allege that they—as a consequence of defendants’ conduct—“have sustained substantial losses and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.” *Id.* ¶ 492.

“Generally, economic injury is a paradigmatic form of injury in fact.” *Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233, 1240 (D. Kan. 2007) (citing *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (further citations omitted)). In *Gonzalez*, our court held that a plaintiff sufficiently alleged “economic damages resulting from the difference between the purchase price of the beverage products as warranted and their actual value considering the potential presence of benzene in those products.” *Id.* The court held that the “benefit of the bargain damages are sufficient to demonstrate an injury in fact.” *Id.*

Although the class plaintiffs here never allege that they purchased a defective product, the court finds that they adequately have alleged economic loss sufficient to discharge the standing requirement. The class plaintiffs allege that Mylan’s conduct caused them to pay inflated prices for the EpiPen, and—but for Mylan’s unlawful conduct—they would have purchased other versions of the EpiPen (both branded and generic) at lower cost. *See Maya v. Centex Corp.*, 658 F.3d 1060, 1069 (9th Cir. 2011) (holding plaintiffs’ allegations that they

“spent money that, absent defendants’ actions, they would not have spent” constituted a “quintessential injury-in-fact” (citing *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 286 (1997) (holding that consumers who paid more for gas than they should have as a result of discriminatory tax laws had Article III standing)); *see also Pirozzi v. Apple, Inc.*, 913 F. Supp. 2d 840, 846–47 (N.D. Cal. 2012) (“Overpaying for goods or purchasing goods a person otherwise would not have purchased based upon alleged misrepresentations by the manufacturer would satisfy the injury-in-fact and causation requirements for Article III standing.”). *Cf. Estrada v. Johnson & Johnson*, No. 2:14-cv-01051-TLN-EFB, 2015 WL 1440466, at \*5 (E.D. Cal. Mar. 27, 2015) (holding that plaintiff lacked standing because she never alleged that she would have purchased an alternative product but for defendant’s conduct). Accepting these allegations as true and in the class plaintiffs’ favor—as the court must for now—the court concludes the class plaintiffs have alleged an injury in fact.

*Second*, to satisfy the standing requirement of traceability, “the defendant[s]’ conduct must have caused the injury.” *Benham v. Ozark Materials River Rock, LLC*, 885 F.3d 1267, 1273 (10th Cir. 2018). “[T]he ‘traceability’ of a plaintiff’s harm to the defendant’s actions need not rise to the level of proximate causation.” *Habecker v. Town of Estes Park, Colo.*, 518 F.3d 1217, 1225 (10th Cir. 2008). But “Article III does ‘require proof of a substantial likelihood that the defendant’s conduct caused plaintiff’s injury in fact.’” *Id.* (quoting *Nova Health Sys. v. Gandy*, 416 F.3d 1149, 1156 (10th Cir. 2005)).

Here, the class plaintiffs allege that Mylan engaged in unlawful anticompetitive conduct and unfair or deceptive practices. The class plaintiffs allege that Mylan’s actions caused them to pay inflated prices for the EpiPen. And, the class plaintiffs allege, but for Mylan’s unlawful conduct, they would have paid less for the EpiPen (both branded and generic versions). The

court finds these alleged injuries are “fairly traceable” to Mylan’s alleged conduct, and they suffice to satisfy the standing requirement at the pleading stage.

## 2. Preemption

The Mylan Defendants next assert that federal patent law preempts the class plaintiffs’ state consumer protection law claims. In essence, the Mylan Defendants argue that the class plaintiffs are using state consumer protection laws to regulate the EpiPen’s price—a patented product. The Mylan Defendants contend that federal patent law preempts these claims because the patent holder maintains the exclusive right to make pricing decisions about its patented product. Doc. 95 at 85–87 (first citing *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (holding that federal patent law preempted the District of Columbia’s Prescription Drug Excessive Pricing Act of 2005 because the “underlying determination about the proper balance between innovators’ profit and consumer access to medication . . . is exclusively one for Congress to make,” and the local law stood “as an obstacle to the federal patent law’s balance of objectives”); then citing *Se. Pa. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) (holding that “[t]o the extent that plaintiffs seek to use state law to challenge [defendant’s] exercise of its exclusive patent rights to make pricing decisions, plaintiffs’ claims are preempted”)).

The class plaintiffs respond that their state consumer protection claims don’t challenge Mylan’s rights under the patent laws to make pricing decisions. Instead, the class plaintiffs explain, their state consumer protection law claims allege that Mylan engaged in unfair methods of competition, unfair or deceptive acts or practices, or unconscionable acts or practices that violated various state consumer protection laws. The class plaintiffs allege that these violations furthered defendants’ scheme to charge inflated prices for the EpiPen. According to the class



plaintiffs, Mylan did not confine its conduct to lawful use of its patent rights. Instead, the class plaintiffs allege, Mylan engaged in unlawful conduct that caused consumers to pay inflated prices for the EpiPen.

As the class plaintiffs point out, the Mylan Defendants cited no authority holding that federal patent law permits a patent holder to commit unfair and deceptive practices that violate state consumer protection laws—simply because it owns patent rights. Indeed, many courts have concluded just the opposite. These cases hold that federal patent law does not preempt state consumer protection claims when a state law claim “address[es] entirely different wrongs[,]’ ‘provide[s] different forms of relief,’ and ‘is not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law.’” *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 357 (D.R.I. 2017) (quoting *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1478 (Fed. Cir. 1998)). “For the claim to escape preemption, it must seek a remedy for ‘bad faith misconduct in the marketplace,’ rather than ‘bad faith misconduct in the PTO.’” *Id.* (citing *Dow Chem.*, 139 F.3d at 1476–78). This standard requires a plaintiff to “allege and ultimately prove, fraud on the PTO *or* bad faith in the marketplace, regardless of whether the underlying state claim demands proof of such conduct.” *Id.* (citation omitted) (emphasis added).

Applying that legal standard to the allegations here, the class plaintiffs have alleged that Mylan has committed a variety of misconduct in the marketplace and thus violated the state consumer protection laws. Class Complaint ¶¶ 684.a.–684.bb. Specifically, the Class Complaint alleges that Mylan violated state consumer protection laws by “engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse,

reverse ‘pay-for-delay’ settlements, and sham citizens’ petitions as described herein.” *Id.* ¶ 684.x.

Other courts have found allegations like this sufficient to state plausible consumer protection law claims not preempted by the federal patent laws. *See, e.g., Picone v. Shire PLC*, No. 16-cv-12396-ADB, 2017 WL 4873506, at \*14 (D. Mass. Oct. 20, 2017) (denying portion of Rule 12(b)(6) motion seeking dismissal of state consumer protection and antitrust law claims based on preemption because those claims “are based on tortious conduct in the marketplace—*i.e.*, the purportedly illegal settlement agreements—that require different elements than any arguably corresponding federal patent law claim (such as patent invalidity), and are therefore not protected or governed by federal patent law”); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d at 357 (holding on a Rule 12(b)(6) motion to dismiss that federal patent law did not preempt plaintiffs’ state consumer protection law claims because plaintiffs alleged that defendants enforced their patent in the marketplace with bad faith); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 224 (S.D.N.Y. 2012) (holding on a Rule 12(b)(6) motion that the patent laws didn’t preempt plaintiffs’ state consumer protection law claims because plaintiffs alleged other “wrongful conduct in the marketplace” to support the claims such as “an invalid Orange Book listing, sham patent infringement litigation, and a sham citizen petition”).

The court denies the Mylan Defendants’ motion to dismiss the class plaintiffs’ state consumer protection law claims based on a federal preemption defense.

### **3. Elements of the State Consumer Protection Law Claims**

The Mylan Defendants next contend that the class plaintiffs have failed to plead the elements of their state consumer protection law claims. Specifically, the Mylan Defendants argue that the Class Complaint never alleges: (1) deceptive or misleading conduct; (2) unfair or

unconscionable conduct; (3) actual loss; (4) reliance; (5) causation; or (5) the requisite particularity to support the claims. The court rejects each of these arguments.

*First*, the Mylan Defendants assert that the Class Complaint never pleads any deceptive or misleading conduct capable of supporting any of their state consumer protection law claims. As the class plaintiffs explain, the various state consumer protection laws pleaded in the Class Complaint differ in their language. But all of them prohibit deceptive or misleading acts or practices in trade or commerce.

Our court and many others have recognized that the question whether an act is deceptive is a factual one for the jury to decide. *Tufts v. Newmar Corp.*, 53 F. Supp. 2d 1171, 1177 (D. Kan. 1999) (citing *Farrell v. Gen. Motors Corp.*, 815 P.2d 538, 547 (Kan. 1991)); *see also Organic Consumers Assoc. v. Sanderson Farms, Inc.*, 284 F. Supp. 3d 1005, 1014 (N.D. Cal. 2018) (“Whether a business practice is deceptive [and thus violates the California consumer protection laws] is generally a question of fact that requires weighing of evidence from both sides.”); *Nature’s Prods., Inc. v. Natrol, Inc.*, 990 F. Supp. 2d 1307, 1322 (S.D. Fla. 2013) (holding that the jury must decide whether a seller’s representation (*i.e.*, that certain healthcare products were gluten free) constituted an unfair or deceptive trade practice under the Florida statute because it presented “a question of fact for the jury to determine”); *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 543 (S.D.N.Y. 2013) (“Under either [the New York or Connecticut consumer protection] statute, whether a particular act or practice is deceptive is usually a question of fact.”) (citations omitted)).

Here, the class plaintiffs assert that they have alleged various deceptive acts capable of supporting a finding or inference that Mylan violated state consumer protection laws. The court agrees. The Class Complaint alleges that Mylan made several misrepresentations as part of

defendants' scheme to monopolize the EAI market and charge consumers inflated prices for the EpiPen. These misrepresentations include: misinformation about Auvi-Q and its bioequivalence to the EpiPen (Class Complaint ¶¶ 229–31); misleading statements about EpiPen's status as the "preferred brand" and suggesting that Auvi-Q's exclusion from drug formularies was based on clinical recommendations and not Mylan's huge, conditional rebates (*id.* ¶¶ 232–34); false representations about the medical necessity of the EpiPen 2-Pak (*id.* ¶¶ 335–46); Ms. Bresch's false statement that Mylan had invested \$1 billion in developing the EpiPen to create "access and awareness and improv[e] the product" (*id.* ¶ 375); and falsely claiming that 80% of consumers with insurance pay nothing for EpiPen (*id.* ¶¶ 403–04).

The Mylan Defendants assert that these alleged misrepresentations cannot possibly support state law consumer protection claims because none amounted to material representations, *i.e.*, these statements did not affect consumers' purchasing decisions because no reasonable person would attach importance to them. The court cannot reach this conclusion as a matter of law based on the allegations pleaded by the class plaintiffs. Indeed, as the class plaintiffs argue, in the context of reviewing orders issued by the Federal Trade Commission, courts have recognized the FTC's presumption of materiality for matters "that significantly involve health, safety, or other areas with which the reasonable consumer would be concerned, including a claim that concerns the purpose, safety, efficacy, or *cost* of the product or service, its durability, performance, warranties or quality or a finding by another agency regarding the product." *Novartis Corp. v. FTC*, 223 F.3d 783, 786 (D.C. Cir. 2000) (citations and internal quotations marks omitted) (emphasis added); *see also Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992) (enforcing an FTC order finding that Kraft had misrepresented information about the amount of calcium contained in its cheese Singles relative to the calcium content in five ounces of milk and

concluding that the evidence supporting the presumption of materiality). It is plausible to infer from the class plaintiffs' allegations that a consumer would find the alleged misrepresentations about the EpiPen's cost material to consumers. The same is true for the medical necessity of the 2-Pak and Auvi-Q's bioequivalence to the EpiPen. The court thus finds that the class plaintiffs' allegations sufficiently allege material misrepresentations to support the state consumer protection law claims and survive dismissal at the pleading stage.

Also, the Mylan Defendants assert that none of the alleged misrepresentations about the EpiPen price could have misled consumers about the actual price or the nature of the product. The court disagrees. The class plaintiffs direct the court to at least two alleged misrepresentations that—when viewed in the class plaintiffs' favor—permit a plausible inference that these statements were deceptive. First, the Class Complaint alleges that Mylan stated publicly on its website and in the media that “80% of consumers with insurance pay nothing for the EpiPen.” Class Compl. ¶ 403. The Class Complaint alleges that this statement is a pernicious “half-truth” because, as one commentator has questioned, the EpiPen's retail price is over \$600 and many Americans have high-deductible health plans that require making payments out of pocket before insurance coverage applies. *Id.* Also, the class plaintiffs contend, this statement ignores the costs that insurance companies incur to pay for the EpiPen which, in turn, produces increased premiums and higher co-pays. *Id.* ¶ 404. Construing the allegations in the class plaintiffs' favor, it is plausible to infer that this statement misled consumers about the EpiPen's true price.

Next, the class plaintiffs assert that Ms. Bresch falsely stated during a *Forbes* Summit interview that “Mylan has invested \$1 billion in developing the EpiPen in creating access and awareness and improving the product.” *Id.* ¶ 375 (citation and internal quotation marks omitted).

The Class Complaint alleges that this statement was false because Mylan did not spend \$1 billion on actual product improvement but, instead, spent it on lobbying and paying its executives. *Id.* ¶ 385. Accepting these allegations as true—as the court must on a motion to dismiss—it is plausible to infer that these false statements misled consumers about the EpiPen and influenced their purchasing decisions.<sup>24</sup>

The Mylan Defendants also contend that Mylan’s statements about the medical necessity of the EpiPen 2-Pak are not deceptive. For support, the Mylan Defendants have submitted a chart comparing statements from an August 2011 press release about the 2-Pak with NIAID and WAO guidelines. Doc. 95-9. In doing so, the Mylan Defendants ask the court to construe the medical guidelines and find that they support Mylan’s statement in the press release that its decision to sell only the EpiPen 2-Pak “aligns” with medical guidelines. *Id.* at 3. The court cannot properly decide this factual dispute on a motion to dismiss. Also, the class plaintiffs assert that the press release is misleading because it omits material facts. These allegations suffice to allege that Mylan’s statements about the EpiPen 2-Pak were deceptive or misleading.

Finally, the Mylan Defendants argue that the alleged misleading statements about Auvi-Q cannot support the state consumer protection law claims. The Mylan Defendants contend that

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<sup>24</sup> The Mylan Defendants also assert that Ms. Bresch’s statements to *Forbes* are not actionable because she did not make them to consumers. For support, the Mylan Defendants cite *Group Health Plan, Inc. v. Philip Morris, Inc.*, 68 F. Supp. 2d 1064 (D. Minn. 1999). In that case, the Minnesota federal court dismissed plaintiffs’ claims asserted under the Minnesota consumer protection laws because the complaint “contain[ed] no allegations that Defendants were attempting to sell their products” when they made the alleged misrepresentations while testifying before Congress. *Id.* at 1069. Also, plaintiffs “[did] not allege that they purchased any products from Defendants.” *Id.* Those facts differ significantly from the ones here.

The class plaintiffs have alleged that they purchased the EpiPen. Also, the class plaintiffs allege that Ms. Bresch made the false statements to *Forbes* as part of defendants’ scheme to monopolize the market and inflate the EpiPen’s price. It is plausible to infer from the Class Complaint’s allegations that Ms. Bresch directed the statements to consumers—through an interview with a nationally circulated magazine—as part of defendants’ scheme to sell the EpiPen to consumers at inflated prices.

the statements could not have caused consumers to purchase EpiPen over Auvi-Q because the class plaintiffs never allege that Auvi-Q was a superior product or less expensive than EpiPen. The Mylan Defendants assert that the class plaintiffs could make no such allegations because, in October 2015, Sanofi recalled Auvi-Q from the market. As the class plaintiffs argue, however, the Mylan Defendants ignore the context of the alleged misrepresentations about Auvi-Q. The Class Complaint alleges that Mylan made the misrepresentations as part of defendants' scheme to restrain competition in the EAI market and, specifically, to block Auvi-Q from that market. *See* Class Compl. ¶ 235. On a motion to dismiss, the court cannot determine—as a matter of law—whether Auvi-Q left the market because of manufacturing issues or, as the class plaintiffs assert, Mylan's conduct prevented it from gaining traction in the market. The court thus finds that the allegedly deceptive and misleading statements about Auvi-Q suffice to support the state consumer protection law claims.

*Second*, the Mylan Defendants argue that the class plaintiffs never allege any unfair practices that violate state consumer protection laws. Largely, the Mylan Defendants premise this argument on ones that defendants asserted earlier in their briefs. The Mylan Defendants contend that the Class Complaint fails to allege that Mylan engaged in any anticompetitive or fraudulent conduct capable of supporting a finding or inference that it engaged in unfair practices violating state consumer protection laws. But the court already has determined that the Class Complaint plausibly alleges that defendants—including Mylan—violated the antitrust and RICO laws by implementing a fraudulent scheme to monopolize the market and force consumers to pay inflated prices for EpiPen. As explained in the next paragraph, these allegations also suffice to assert plausibly that Mylan engaged in unfair practices violating state consumer protection laws.

As both parties explain in their briefs, states apply different standards to determine what constitutes unfair or unconscionable conduct capable of violating state consumer protection laws. Some states employ the “cigarette test,” examining whether the alleged unfair practice: (1) offends established public policy; (2) is immoral, unethical, oppressive, unscrupulous; and (3) causes substantial injury to consumers. *See, e.g., Zito v. United Techs. Corp.*, No. 3:15-cv-744(AWT), 2016 WL 2946157, at \*6 (D. Conn. Mar. 11, 2016) (explaining that Connecticut has adopted the “cigarette” test for determining when a practice is unfair under the Connecticut Unfair Trade Practices Act); *see also Hucke v. Kubra Data Transfer Ltd., Corp.*, 160 F. Supp. 3d 1320, 1328 (S.D. Fla. 2015) (applying the “cigarette test” to a Florida Deceptive and Unfair Trade Practices Act claim); *Hanrahan v. Specialized Loan Servicing, LLC*, 54 F. Supp. 3d 149, 154 (D. Mass. 2014) (applying the “cigarette test” to the Massachusetts Consumer Protection Act); *Rodriguez v. Chase Home Fin., LLC*, No. 10 C 05876CH, 2011 WL 5076346, at \*3 (N.D. Ill. Oct. 25, 2011) (applying the “cigarette test” to an Illinois Consumer Fraud Act claim).

Other states apply a “substantial injury” test, considering whether the alleged unfair practice: (1) produces substantial injury to consumers; (2) is not the type of injury that a consumer reasonably could avoid; and (3) is not outweighed by countervailing benefits to consumers or competition. *See, e.g., Kautzman v. Carrington Mortg. Servs., LLC*, No. C16-1940-JCC, 2017 WL 8727860, at \*1 (W.D. Wash. Nov. 3, 2017) (applying the “substantial injury” test to a Washington Consumer Protection Act claim); *Sager v. Hous. Comm’n of Anne Arundel Cty.*, 957 F. Supp. 2d 627, 642 (D. Md. 2013) (applying the “substantial injury” test to a Maryland Consumer Protection Act claim); *Darling v. W. Thrift & Loan*, 600 F. Supp. 2d 189, 202 (D. Me. 2009) (applying the “substantial injury” test to a Maine Unfair Trade Practices Act claim).



The class plaintiffs have demonstrated that their allegations suffice to state a claim under either one of these tests. The Class Complaint adequately alleges the three elements of first test recited above—the “cigarette test.” First, the class plaintiffs allege that Mylan’s unfair acts offend public policy. Class Compl. ¶ 1012. Construing their allegations in the class plaintiffs’ favor, Mylan’s alleged unfair conduct offended the public policy against anticompetitive and fraudulent conduct and the public policy favoring consumer protection.<sup>25</sup> Second, the class plaintiffs allege that the conduct is “immoral, unethical, oppressive, [and] unscrupulous . . . .” *See, e.g., Votto v. Am. Car Rental, Inc.*, 871 A.2d 981, 985 (Conn. 2005). One court has defined the second prong of this test as including “[a] trade practice that is undertaken to maximize the defendant’s profit at the expense of the plaintiff’s rights . . . .” *Id.* (applying the cigarette test to a Connecticut Unfair Trade Practices Act claim). One reasonably can infer that Mylan’s alleged conduct satisfies that definition under the test’s second prong. Finally, the class plaintiffs allege that the unfair conduct substantially injured consumers. *Id.* Taking the allegations as true, the Class Complaint alleges that Mylan’s conduct substantially injured the class plaintiffs by forcing them to pay inflated prices for the EpiPen.

The Class Complaint also plausibly alleges the elements of the second test—the “substantial injury” test. Namely, it asserts that: (1) the class plaintiffs allege that Mylan’s unfair conduct substantially harmed consumers by requiring them to pay inflated prices for the EpiPen; (2) the class plaintiffs allege that they could not have avoided this injury because

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<sup>25</sup> The Mylan Defendants assert that public policy supports Mylan’s freedom to set prices for the EpiPen—as its patent holder—because the exclusivity granted by patent rights encourages innovation. Here, the class plaintiffs allege that Mylan did more than simply set prices as a patent holder. Instead, the Class Complaint alleges that Mylan engaged in various anticompetitive and fraudulent competition for the purpose of restraining competition. The court recognizes that these are just allegations in the Class Complaint, but the court must accept them as true facts on a motion to dismiss. Taking them as true, public policy does not favor this type of conduct.

Mylan—through its unfair conduct—restrained competition, limited consumer choice, and prevented consumers from accessing competing products, and (3) the class plaintiffs identify no countervailing benefits to consumers or competition that could outweigh Mylan’s unfair conduct.

In sum, the court concludes that the class plaintiffs’ allegations plausibly allege unfair practices sufficient to support their state consumer protection law claims.<sup>26</sup>

*Third*, the Mylan Defendants assert that the state consumer protection law claims fail as a matter of law because the class plaintiffs never allege that they sustained an actual injury or ascertainable loss. The Mylan Defendants’ arguments mirror the ones that they asserted to attack the class plaintiffs’ standing. For the same reasons already explained, the court rejects the Mylan Defendants’ arguments. The class plaintiffs have pleaded economic loss adequately to support state law consumer protection claims.

*Fourth*, the Mylan Defendants argue that the class plaintiffs have failed to plead reliance. But, when pleading their state consumer protection law claims, the Class Complaint explicitly alleges that the class plaintiffs relied on Mylan’s misrepresentations and omissions about the EpiPen. *See, e.g.*, Class Complaint ¶¶ 716, 729, 748, 789, 806, 820, 835, 848, 863, 878, 893, 910, 925, 941, 956, 971, 986, 1001, 1018, 1036, 1050, 1063, 1076, 1101, 1115, 1127, 1141, 1155, 1168, 1183, 1196, 1211, 1225, 1239, 1253, 1267, 1281, 1296, 1312, 1328, 1343, 1357, 1372, 1386, 1401, 1416.

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<sup>26</sup> The Mylan Defendants also assert that the class plaintiffs fail to allege a claim under California’s Unfair Competition Law (“UCL”). This law requires a plaintiff to allege that defendant violated some other law. *See Moran v. Prime Healthcare Mgmt., Inc.*, 208 Cal. Rptr. 3d 303, 311 (Cal. Ct. App. 2016) (explaining that “violation of another law is a predicate for stating a cause of action under the UCL’s unlawful prong” (citation and internal quotation marks omitted)). As the court already has concluded, the class plaintiffs plausibly have alleged that defendants (including Mylan) violated other laws—including the antitrust laws and RICO. These allegations suffice to support a plausible claims under the California UCL.

The Mylan Defendants contend that the class plaintiffs’ reliance allegations are just conclusory, and thus insufficient to support the state consumer protection law claims. In the context of a fraud claim, our court has held that a plaintiff—to satisfy Rule 9(b)’s heightened pleading standard—need only allege that it relied on an alleged misrepresentation. Such allegations need not assert “details concerning its reliance” because “the Tenth Circuit’s standard does not require more.” *In re Syngenta AG MIR 162 Corn Litig.*, 131 F. Supp. 3d 1177, 1228 (D. Kan. 2015) (first citing *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1236 (10th Cir. 2000)); then citing *Mattos v. Eli Lilly & Co.*, No. 12-1014-JWL, 2012 WL 1893551, at \*7 n.7 (D. Kan. May 23, 2012) (Lungstrum, J.)). In *Syngenta*, Judge Lungstrum held that a plaintiff’s allegation that it had relied on the alleged misrepresentations sufficed to state a fraud claim and that defendant was “free to ask about the details of [the plaintiff’s] reliance in discovery.” *Id.* Applying the same rationale here, the class plaintiffs’ allegations that they relied on Mylan’s misrepresentations adequately state a claim for relief. Like Judge Lungstrum explained in *Syngenta*, the Mylan Defendants can inquire during discovery about the details of that alleged reliance.

Also, as the class plaintiffs correctly assert, a majority of their state consumer protection law claims do not require them to plead reliance.<sup>27</sup> And, for other states, the class plaintiffs need

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<sup>27</sup> These state consumer protection laws include: **Arizona** (*Siemer v. Assocs. First Capital Corp.*, No. CV97-281TUCJMRJCC, 2001 WL 35948712, at \*4 (D. Ariz. Mar. 30, 2001) (holding that plaintiffs’ purchases of credit life insurance was “alone . . . sufficient to show reliance to the degree necessary” under the Arizona Consumer Fraud Act)); **Arkansas** (*Frelin v. Oakwood Homes Corp.*, No. CIV-2001-53-3, 2002 WL 31863487, at \*4 (Ark. Cir. Ct. Nov. 25, 2002)); **Colorado** (*Hall v. Walter*, 969 P.2d 224, 231 (Colo. 1998)); **Connecticut** (*Hinchliffe v. Am. Motors Corp.*, 440 A.2d 810, 815–16 (Conn. 1981)); **Delaware** (*Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983)); **Florida** (*Davis v. Powertel, Inc.*, 776 So. 2d 971, 974 (Fla. Dist. Ct. App. 2000)); **Hawaii** (*Courbat v. Dahana Ranch, Inc.*, 141 P.3d 427, 435 (Haw. 2006)); **Illinois** (*Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584, 593 (Ill. 1996)); **Kansas** (Kan. Stat. Ann. § 50-626(b)(1); *see also Midland Pizza, LLC v. Sw. Bell Tel. Co.*, No. 10-2219-CM-GLR, 2010 WL 4622191, at \*3 (D. Kan. Nov. 5, 2010) (citing Pattern Instructions Kansas, Civil 4th § 129.01-A)); **Kentucky** (*Telcom Directories, Inc. v. Commonwealth ex rel. Cowan*, 833 S.W.2d 848, 850 (Ky. Ct. App. 1991)); **Maine** (*Doll v. Ford Motor Co.*, 814 F. Supp. 2d 526, 549 (D.

not plead reliance when they allege misrepresentations by concealment or omission. *See In re Motor Fuel Temperature Sales Practices Litig.*, 292 F.R.D. 652, 663 & n.5 (D. Kan. 2013) (holding that plaintiffs need not prove actual reliance to support their California Unfair Competition Law claims because “actual reliance is presumed given [defendant’s] material misrepresentations and omissions”). *See also, e.g., Glenn v. Hyundai Motor Am.*, No. SA CV 15-2052-DOC, 2016 WL 3621280, at \*12–13 (C.D. Cal. June 24, 2016) (holding that plaintiff stated a claim under the Alabama Deceptive Trade Practices Act based on defendants’ alleged omissions that had plaintiff known the truth, he would not have made the purchase); *Wright v. Kia Motors Am., Inc.*, No. Civ. 06-6212-AA, 2007 WL 316351, at \*3 (D. Or. Jan. 29, 2007) (denying Rule 12(b)(6) motion to dismiss Oregon Unfair Trade Practices Act claim because plaintiff need not allege reliance when she alleged that defendant failed to disclose material facts). The Class Complaint here alleges various omissions of material fact that allow the court to presume reliance under these state consumer protection statutes. *See* Class Complaint ¶¶ 684.c., 684.e., 684.i., 684.j., 684.m., 684.n., 684.o.–684.t., 684.aa., 747–49.

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Md. 2001) (discussing the pleading requirements of a Maine Unfair Practices Act claim); *Tungate v. MacLean-Stevens Studios, Inc.*, 714 A.2d 792, 797 (Me. 1998)); **Maryland** (Md. Code Ann. Com. Law § 13-302); **Massachusetts** (*Heller Fin. v. INA*, 573 N.E.2d 8, 13 (Mass. 1991)); **Michigan** (*Evans v. Ameriquist Mortg. Co.*, No. 233115, 2003 WL 734169, at \*3 (Mich. Ct. App. Mar. 4, 2003)); **Minnesota** (*Wiegand v. Walser Auto. Grps., Inc.*, 683 N.W.2d 807, 811 (Minn. 2004)); **Missouri** (*Hess v. Chase Manhattan Bank, USA, N.A.*, 220 S.W.3d 758, 774 (Mo. 2007)); **New Hampshire** (*Mulligan v. Choice Mortg. Corp.*, No. CIV. 96-596-B, 1998 WL 544431, at \*11 (D.N.H. Aug. 11, 1998)); **New Jersey** (*Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 366 (N.J. 1997)); **New Mexico** (*Lohman v. Daimler-Chrysler Corp.*, 166 P.3d 1091, 1098 (N.M. Ct. App. 2007)); **New York** (*Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank*, 647 N.E.2d 741, 745 (N.Y. 1995)); **North Carolina** (*Pearce v. Am. Defender Life Ins. Co.*, 343 S.E.2d 174, 180 (N.C. 1986)); **Ohio** (*Delahunt v. Cytodyne Techs.*, 241 F. Supp. 2d 827, 835–36 (S.D. Ohio 2003)); **South Carolina** (*City of Charleston v. Hotels.com, LP*, 487 F. Supp. 2d 676, 680 (D.S.C. 2007)); **Tennessee** (*Fleming v. Murphy*, No. W2006-00701-COA-R3-CV, 2007 WL 2050930, at \*8 (Tenn. Ct. App. July 19, 2007)); **Utah** (*Andreason v. Felsted*, 137 P.3d 1, 4 (Utah Ct. App. 2006)); **Vermont** (Vt. Stat. Ann. tit. 9, § 2461(b)); **Washington** (*Indoor Billboard/Washington, Inc. v. Integra Telecom of Wash., Inc.*, 170 P.3d 10, 19–22 (Wash. 2007)); **West Virginia** (W. Va. Code Ann. § 46A-6-102(7)(M)).

The Mylan Defendants also allege that the class plaintiffs' consumer protection claims under six state laws fail as a matter of law because those state laws require continuing harm. *See* Doc. 95 at 49 n.45 (citing the Georgia, Illinois, Maine, Minnesota, New Mexico, and Ohio statutes). But the Class Complaint seeks injunctive relief "to stop Mylan's *continued deceptive and unconscionable practices* of selling the EpiPen 2-Pak at an inflated price." Class Compl. ¶ 692 (emphasis added). The court finds these allegations sufficient to assert continuing harm under the consumer protection laws of these six states.

In sum, the court declines to dismiss the class plaintiffs' state consumer protection law claims based on the Mylan Defendants' argument that the Class Complaint never pleads reliance.

*Fifth*, the Mylan Defendants contend that the state consumer protection law claims fail because the class plaintiffs never allege that Mylan's conduct caused their injuries. The Mylan Defendants rely again on their standing arguments. *See* Doc. 219 at 49. As the court concluded above, the Class Complaint adequately alleges that Mylan's unlawful conduct caused them to pay inflated prices for the EpiPen, and—but for Mylan's unlawful conduct—the class plaintiffs would have paid less for the EpiPen (both branded and generic versions). These allegations adequately allege causation sufficient to support the state consumer protection law claims.

*Finally*, the Mylan Defendants assert that the class plaintiffs have failed to plead the state consumer protection law claims with the particularity required by Fed. R. Civ. P. 9(b). The class plaintiffs respond, asserting that at least 15 state consumer protection statutes don't require a plaintiff to plead the claims with particularity. Doc. 123 at 143 & n.567. The class plaintiffs also assert that Rule 9(b)'s heightened pleading standards don't apply to their allegations of fraud by omission or concealment. *See, e.g., AKH Co. v. Universal Underwriters Ins. Co.*, No. 13-2003-JAR, 2015 WL 1809157, at \*13 (D. Kan. Apr. 21, 2015) (explaining that "allegations of

concealment, as opposed to an affirmative act, do not require the same level of specificity because often it is impossible to know of the exact ‘who, when, and where’ in relation to an omission” and finding that “[g]iven this relaxed standard” the alleged claims about concealment were sufficiently specific to state a fraud claim). And, the class plaintiffs contend, they need not plead their claims based on unconscionable or unfair practices with particularity. *See DuMont v. Litton Loan Servicing, LP*, No. 12 Civ. 2677(ER), 2015 WL 1061138, at \*13 (S.D.N.Y. Mar. 11, 2015) (explaining that “unconscionable commercial practices claims are distinct from [consumer protection] claims sounding in fraud,” and thus “the heightened pleading standard of Rule 9(b) does not apply” (citations and internal quotation marks omitted)).

The court concludes that the class plaintiffs have alleged their state consumer protection law claims with sufficient particularity. The Tenth Circuit “requires a complaint alleging fraud to set forth the time, place and contents of the false representation, the identity of the party making the false statements and the consequences thereof.” *See Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1236 (10th Cir. 2000) (internal quotation and citation omitted). The Class Complaint satisfies that standard here.

It alleges several misrepresentations or omissions identifying the time, place, and contents of the alleged misrepresentations, as well as the identity of the party making them. For example, the Class Complaint alleges that Mylan CEO Heather Bresch gave false and misleading statements about EpiPen’s profits and the reasons for raising the EpiPen’s profits in her September 21, 2016, Congressional testimony, a January 27, 2017, interview with CBS News, a June 9, 2017, interview with the *Los Angeles Times*, and a December 1, 2016, *Forbes* Summit interview. *See Class Complaint* ¶¶ 194–95, 375, 417–48. It also alleges that Mylan made misleading statements in an August 24, 2011, press release about its decision to sell the EpiPen

exclusively as a 2-Pak. *Id.* ¶¶ 336–39. It also alleges that Mylan made misleading statements in its marketing materials distributed during 2014. *Id.* 232–34. According to the Class Complaint, the marketing materials included misleading statements, touting EpiPen as the “preferred brand” and suggesting that Auvi-Q’s exclusion was based on clinical recommendations—not the large, conditional rebates that Mylan gave to formularies in exchange for offering EpiPen exclusively and excluding Auvi-Q. *Id.*

While it is true, the Class Complaint does not “provide[ ] details about how and when” the class plaintiffs learned about the misrepresentations, this is of no legal consequence at this stage. The “Tenth Circuit’s standard requires only particular information about the representation itself.” *In re Syngenta AG MIR 162 Corn Litig.*, 131 F. Supp. 3d at 1228 (citing *Near v. Crivello*, 673 F. Supp. 2d 1265, 1285 (D. Kan. 2009)). As Judge Lungstrum explained, “[a] plaintiff need not plead every fact that supports its claim of fraud, and such facts concerning [a plaintiff’s] receipt of the statements are readily obtained in discovery.” *Id.* Here, the Class Complaint’s allegations about Mylan’s purported misrepresentations satisfy the Tenth Circuit’s standard.

The Class Complaint also alleges the consequences of Mylan’s alleged misrepresentations. They caused the class plaintiffs to pay inflated prices for the EpiPen. *Id.* ¶¶ 492, 685–91. For all these reasons, the court finds that the class plaintiffs have alleged their state consumer protection law claims with sufficient particularity—to the extent the asserted state law claims even require such heightened pleading.

#### **4. Specific State Consumer Protection Laws**

Finally, the Mylan Defendants assert that the court must dismiss the class claims under certain state consumer protection laws because those statutes bar class actions. These statutes

include the state consumer protection laws of Alabama, Colorado, Georgia, Louisiana, Mississippi, South Carolina, and Tennessee.

The class plaintiffs respond, asserting that the Mylan Defendants' argument is premature and without merit. They contend that the court can address this issue at the class certification stage, and, even then, other courts have permitted putative class action claims for state consumer protection violations to proceed despite a statute's restrictions on class actions. *See Lisk v. Lumber One Wood Preserving, LLC*, 792 F.3d 1331, 1336 (11th Cir. 2015) (holding that the Alabama Deceptive Trade Practices Act "restricting class actions . . . does not apply in federal court. Rule 23 controls."); *Suchanek v. Sturm Foods, Inc.*, 311 F.R.D. 239, 264 (S.D. Ill. 2015) (holding that Rule 23 governed plaintiffs' consumer protection act claims under Alabama, South Carolina, and Tennessee law despite those statutes' restrictions on class actions); *In re Hydroxycut Mktg. & Sales Practices Litig.*, 299 F.R.D. 648, 654 (S.D. Cal. 2014) (explaining that "[w]hether the state statutory provisions that prohibit class actions for unfair or deceptive practices are 'procedural' or 'substantive,' is a difficult question with no clear answer" but concluding that "these limitations on class actions [are] procedural in nature" so "Rule 23 governs Plaintiffs' claims [under the consumer protection laws of Georgia, Louisiana, Montana, South Carolina, and Tennessee] and are not subject to dismissal based on the state statutes prohibiting class actions").

As the class plaintiffs recognize, the Tenth Circuit has not provided guidance on the question. *See Friedman v. Dollar Thrifty Auto. Grp., Inc.*, No. 12-cv-02432-WYD-KMT, 2015 WL 8479746, at \*5 (D. Colo. Dec. 10, 2015) (acknowledging "there is no definitive guidance from the Tenth Circuit or the Colorado Supreme Court" whether the Colorado Consumer Protection Act's class action restriction is substantive and thus controls over Rule 23). Although



our court has dismissed class claims asserted under the Colorado Consumer Protection Act at the pleading stage based on that statute’s restriction for class actions, *see In re Syngenta AG MIR 162 Corn Litig.*, 131 F. Supp. 3d at 1234–35, this ruling never addressed whether Colorado’s class action restriction is a substantive right or procedural rule, *see id.*<sup>28</sup>

Some courts have concluded that the Colorado class action restriction is substantive, thus controlling, and requires dismissal of class action claims asserted under the Act. *See, e.g., Davidson v. Apple, Inc.*, No. 16-CV-04942-LHK, 2018 WL 2325426, at \*11 (N.D. Cal. May 8, 2018) (holding that the Colorado Consumer Protection Act’s restriction on class actions was a substantive state right that barred plaintiffs’ class claims); *Friedman*, 2015 WL 8479746, at \*5 (holding that “the class action restriction in the [Colorado Consumer Protection Act] is substantive, not procedural . . . [a]ccordingly, the state statute controls rather than Fed. R. Civ. P. 23, and the class action restriction is enforceable”).

Other courts have reached the opposite conclusion. *See Andren v. Alere, Inc.*, No. 16cv1255-GPC(AGS), 2017 WL 6509550, at \*21–22 (S.D. Cal. Dec. 20, 2017) (holding that the class action restriction in the Colorado consumer protection statute was procedural and thus did not bar class action claims asserted under the statute); *In re Volkswagen Timing Chain Prod. Liab. Litig.*, No. 16-2765(JLL), 2017 WL 1902160, at \*24 (D.N.J. May 8, 2017) (holding that class action restrictions in the state consumer protection laws of Colorado, Georgia, and South

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<sup>28</sup> The class plaintiffs argue that *Syngenta* differs because that case involved only money damages—not claims for injunctive relief like the class plaintiffs seek here. The court is not persuaded by this argument. Indeed, one Colorado court recently has concluded that the Colorado Consumer Protection Act does not permit a plaintiff to seek injunctive relief “on behalf of either himself or a class.” *Carter v. Amica Mut. Ins. Co.*, No. 17-cv-02156-RM-MEH, 2018 WL 3093320, at \*9 (D. Colo. June 22, 2018) (citation omitted). The Mylan Defendants have not moved the court to dismiss the class plaintiffs’ claims for injunctive relief under the Colorado Consumer Protection Act for this reason. Their motion only seeks dismissal of the class claims generally. For reasons explained above, the court defers ruling this issue until later in the litigation.

Carolina did not bar plaintiffs' class action claims in federal court because Rule 23—not the state law restrictions—governed the claims).

While it is a close call, the court declines, for now, to dismiss these state law claims. This interim conclusion is driven by pragmatic factors. For one, leaving these claims in the case will not materially affect the discovery burden borne by the parties. Also, it may provide an opportunity for our Circuit to decide the question conclusively. This tack, as plaintiffs suggest, is one other courts have employed. *See, e.g., Falk v. Nissan N. Am., Inc.*, No. 17-cv-04871-HSG, 2018 WL 2234303, at \*7 (N.D. Cal. May 16, 2018) (denying defendant's motion to dismiss a plaintiff's Colorado Consumer Protection Act claim based on the statute's class action restriction because the issue was too "premature to decide at this early stage" and "can be addressed on a motion for class certification"); *In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160, at \*24 (denying motion to dismiss state consumer protection law claims based on the statutes' class action restrictions because the motion "does not attack the sufficiency of the class allegations in the Complaint, but rather directs its argument as to whether the action could proceed as a class action in general" and "any attacks as to whether class certification is appropriate can be raised at the class certification phase.").

Finding these cases persuasive and following their guidance, the court declines to dismiss the state consumer protection claims asserted under the laws of Alabama, Colorado, Georgia, Louisiana, Mississippi, South Carolina, and Tennessee on the Rule 12(b)(6) motion to dismiss. But class plaintiffs are on notice that real doubt exists about the substance of these claims. And, if the Mylan Defendants reassert these arguments at class certification or summary judgment, the court will decide them then.

The Mylan Defendants also argue that other state-specific grounds exist to dismiss the class plaintiffs' state consumer protection law claims. *See* Doc. 95 at 101 & n.78. But “[i]n the interest of judicial economy,” the Mylan Defendants assert that the court need not confront all these issues now. *Id.* And the Mylan Defendants reserve their right to address their additional defenses on a motion for judgment on the pleadings under Rule 12(c). The class plaintiffs don't respond to this request. The court thus permits the Mylan Defendants to raise such arguments later in the litigation, if they choose to do so.

In sum, the court finds that the class plaintiffs have stated plausible claims for relief under the various state consumer protection laws asserted in the Class Complaint. However, the court still dismisses the state consumer protection law claims asserted under the laws of ten states because the Class Complaint includes no named plaintiff who resides in those ten states. *See supra* Part III.A.8. Those states include: Arizona, Idaho,<sup>29</sup> Indiana,<sup>30</sup> Louisiana,<sup>31</sup> New Mexico, Oregon, Vermont, Washington,<sup>32</sup> Wisconsin, and Wyoming.<sup>33</sup> The court also dismisses

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<sup>29</sup> *See* Doc. 569. After the class plaintiffs filed a voluntary dismissal of the only class plaintiff residing in Idaho (Doc. 555), the Mylan Defendants filed a Notice asking the court to dismiss the Idaho consumer protection claim for the same reasons asserted in their previously filed Motion to Dismiss because a named plaintiff no longer exists in the Class Complaint.

<sup>30</sup> The Class Complaint names only one plaintiff who resides in Indiana—Alene McDaniel. Class Compl. ¶ 29. But Ms. McDaniel voluntarily dismissed her claims on July 31, 2018. Doc. 829. So the Class Complaint contains no named plaintiff residing in Indiana.

<sup>31</sup> *See* Doc. 569. The Notice described in note 29 *supra* also seeks dismissal of the Louisiana consumer protection claim because the class plaintiffs filed a voluntary dismissal of the only class plaintiff residing in Louisiana (Doc. 549).

<sup>32</sup> The Class Complaint names only one plaintiff who resides in Washington—Connie Stafford. Class Compl. ¶ 61. But Ms. Stafford voluntarily dismissed her claims on July 24, 2018. Doc. 811. So the Class Complaint contains no named plaintiff residing in Washington.

<sup>33</sup> The Class Complaint names only one plaintiff who resides in Wyoming—Curt Palmer. Class Compl. ¶ 64. But Mr. Palmer voluntarily dismissed his claims on February 7, 2018. Doc. 139. So the Class Complaint contains no named plaintiff residing in Wyoming.

the Class Complaint’s claim asserted under the Georgia Uniform Deceptive Trade Practices Act. Kimberly Dollander is the only plaintiff who asserts a claim under this statute on her own behalf and on behalf of other Georgia residents. Class Compl. ¶ 855. But Ms. Dollander voluntarily dismissed her claims on July 31, 2018. Doc. 829. The court does not dismiss the Georgia Fair Business Practice Act claim, however, because two plaintiffs—Ms. Dollander and Local 282—assert this claim on behalf of themselves and other Georgia residents. Class Compl. ¶ 841. Because Local 282 remains a plaintiff in the case, the court does not dismiss the Georgia Fair Business Practice Act claim.

### **E. Unjust Enrichment**

Leaving no stone unturned, the class plaintiffs bring an unjust enrichment claim “under the common law of all 50 states” and even one under the laws of unidentified “territories” of the United States. Class Compl. ¶ 60. Because the Class Complaint includes no named plaintiff who resides in Alaska, Arizona, the District of Columbia, Idaho, Indiana, Iowa, Louisiana, Montana, New Mexico, North and South Dakota, Oregon, Puerto Rico, Rhode Island, Vermont, Washington, Wisconsin, or Wyoming, the court dismisses the unjust enrichment claims asserted under those states’ laws. *See supra* Part III.A.8.

The Mylan Defendants<sup>34</sup> seek dismissal of the remaining unjust enrichment claims, arguing—similar to other arguments that the court has addressed above—that the class plaintiffs cannot assert unjust enrichment claims when they received exactly what they paid for—*i.e.*, the EpiPen. Other courts have refused to dismiss unjust enrichment claims for this reason at the motion to dismiss stage because, generally, the question whether a plaintiff received the benefit of the bargain is a factual one. *See, e.g., In re Auto. Parts Antitrust Litig.*, 29 F. Supp. 3d 982,

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<sup>34</sup> The Class Complaint asserts the unjust enrichment claim against just Mylan. Class Compl. ¶¶ 1421–28.

1015 (E.D. Mich. 2014) (denying motion to dismiss unjust enrichment claims because the court “disagree[d] with Defendants that the exchange of Fuel Senders for payment acts as a flat ban on [plaintiffs’] unjust enrichment claims,” instead, “[t]he issue is whether the transaction was unjust” and plaintiffs’ allegations that they “overpaid for Fuel Senders because Defendants fixed the prices of Fuel Senders and rigged the bidding process . . . [gave] rise to factual questions as to whether the consideration was reasonable, valuable or adequate”); *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, 687 F. Supp. 2d 897, 910 (W.D. Mo. 2009) (holding that defendants’ argument that “there can be no unjust enrichment because Plaintiffs received what they bargained for” involved “factual matters that the Court cannot resolve while ruling on a motion to dismiss”); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 545 (D.N.J. 2004) (denying a Rule 12(b)(6) motion to dismiss unjust enrichment claims because “[p]laintiffs’ receipt of valuable medicine for their payments does not, as Defendants contend, bar an unjust enrichment claim” and “[d]eterminations that depend on evaluating whether a benefit received approximates the value paid are primarily questions of fact, and as such, are not appropriately addressed on a motion to dismiss”). For the same reason, the court cannot conclude—as a matter of law—that the class plaintiffs’ unjust enrichment claims fail simply because they have alleged that they received the EpiPen in exchange for their payments.

Instead, the court finds that the class plaintiffs have alleged facts that plausibly state a claim for unjust enrichment. Although the elements of an unjust enrichment claim differ among various state laws, generally, an unjust enrichment claim requires a plaintiff to allege that: (1) he or she conferred a benefit on defendant, and (2) defendant’s retention of the benefit under the circumstances is unjust. *See* Doc. 95-3 (Mylan Defendants submitted a chart showing the pleading requirements for unjust enrichment claims under the various state laws asserted in the

Class Complaint);<sup>35</sup> *see also In re Estate of Sauder*, 156 P.3d 1204, 1220 (Kan. 2007) (“The theory of unjust enrichment rests upon three elements: (1) a benefit conferred; (2) an appreciation or knowledge of the benefit by the one receiving the benefit; and (3) the acceptance or retention of the benefit under such circumstances as to make it inequitable to retain the benefit without payment of its value.” (citations omitted)).

Here, the class plaintiffs have alleged facts sufficient to support the elements of an unjust enrichment claim. The Class Complaint alleges that the class plaintiffs conferred a benefit on the Mylan Defendants in the form of overpayments for the EpiPen. Class Compl. ¶ 1424. And, the class plaintiffs assert, the Mylan Defendants’ retention of those benefits is unjust because they procured the benefit through “price gouging, unconscionable sales, unlawful acts, and as set forth [in other parts of the Class Complaint].” *Id.* ¶ 1427. These allegations suffice to state plausible unjust enrichment claims under the remaining state laws asserted in the Class Complaint.

#### **IV. Conclusion**

For reasons explained, the court grants defendants’ Motions to Dismiss in part.

The court dismisses:

- (1) the class plaintiffs’ exclusive dealing claims against the Mylan Defendants based on discounts or rebates that Mylan offered to state or state agencies because the *Noerr-Pennington* doctrine immunizes them from liability;
- (2) the class plaintiffs’ antitrust claim based on deceptive speech asserted against the Mylan Defendants to the extent the class plaintiffs base their claim on Mylan’s

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<sup>35</sup> The class plaintiffs agree that the Mylan Defendants’ chart provides the elements of unjust enrichment claims under the various state laws asserted in the Class Complaint. *See* Doc. 123 at 147 n. 581.

alleged failure to disclose that it paid physicians for their statements supporting the EpiPen 2-Pak;

- (3) the class plaintiffs' state law antitrust claims asserted against both sets of defendants under the laws of Alaska, Arizona, the District of Columbia, Iowa, New Mexico, North and South Dakota, Oregon, Puerto Rico, Rhode Island, Vermont, and Wisconsin because the Class Complaint includes no named plaintiff who resides in any of these states;
- (4) the class plaintiffs' state law antitrust claims asserted under the laws of Arkansas, Massachusetts, and Missouri because indirect purchasers may not bring a cause of action under these state statutes;
- (5) the class plaintiffs' state law claims based on unilateral conduct and asserted in Counts IV, V, and VI (monopolization, attempted monopolization, and tying) under California's Cartwright Act (but not its the Unfair Competition Law) and under the laws of Kansas, New York, and Tennessee because these states do not recognize unilateral conduct claims;
- (6) the class plaintiffs' state law consumer protection claims asserted in Count VIII under the laws of Arizona, Idaho, Indiana, Louisiana, New Mexico, Oregon, Vermont, Washington, Wisconsin, and Wyoming and the Georgia Uniform Deceptive Trade Practices Act because the Class Complaint includes no named plaintiff who resides in any of these states; and
- (7) the class plaintiffs' unjust enrichment claims asserted in Count IX under the laws of Alaska, Arizona, the District of Columbia, Idaho, Indiana, Iowa, Louisiana, Montana, New Mexico, North and South Dakota, Oregon, Puerto Rico, Rhode

Island, Vermont, Washington, Wisconsin, and Wyoming because the Class Complaint includes no named plaintiff who resides in any of these states.

In all other respects, the court denies defendants' Motions to Dismiss.

**IT IS THEREFORE ORDERED BY THE COURT** that the Pfizer Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint (Doc. 92) is granted in part and denied in part as set forth in this Order.

**IT IS FURTHER ORDERED THAT** that the Mylan Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint (Doc. 94) is granted in part and denied in part as set forth in this Order.

**IT IS FURTHER ORDERED THAT** the Mylan Defendants' Request for Oral Argument (Doc. 220) is denied.

**IT IS SO ORDERED.**

**Dated this 20th day of August, 2018, at Kansas City, Kansas.**

**s/ Daniel D. Crabtree**  
**Daniel D. Crabtree**  
**United States District Judge**