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

The parties have filed motions asking the court to decide three threshold evidentiary issues in anticipation of the upcoming trial scheduled to begin on January 24, 2022. Doc. 2515 ("The Mylan Defendants' Brief on Three Threshold Issues for Trial"); Doc. 2525 ("Class Plaintiffs' Brief Regarding Certain Evidentiary Issues"). And, both parties have filed responses to the other side's opening briefs. Doc. 2517 ("Plaintiffs' Opposition to Mylan's Brief on Three Threshold Issues for Trial"); Doc. 2518 ("The Mylan Defendants' Response to Plaintiffs' Brief Regarding Certain Evidentiary Issues"). After considering the parties' arguments, the court rules the three threshold issues, below.

1. 2-Paks

The Mylan Defendants[1] ask the court to exclude evidence about Mylan's decision to sell EpiPens exclusively in a 2-Pak. Mylan argues that evidence about the 2-Pak switch doesn't qualify as relevant evidence under Federal Rule of Evidence 401 because this evidence is irrelevant to plaintiffs' generic delay antitrust claims at issue for trial. *See* Fed. R. Evid. 401

[1] The Mylan Defendants include Mylan N.V., Mylan Specialty L.P., Mylan Pharmaceuticals Inc., and Heather Bresch. Doc. 2169 at 1. This Order refers to these four defendants collectively as "the Mylan Defendants" or "Mylan."

("Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."). So, Mylan contends, evidence about the 2-Pak switch is inadmissible under Federal Rule of Evidence 402. *See* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible.").

Plaintiffs disagree. They argue that evidence of the 2-Pak switch is relevant to several issues of antitrust liability including: (a) market power, (b) willful maintenance of monopoly power, and (c) specific intent to monopolize. Doc. 2517 at 3. But plaintiffs fail to show how the 2-Pak evidence is relevant to any of these issues.

Plaintiffs rely heavily on a Mylan PowerPoint presentation about the 2-Pak switch. Doc. 2525 at 7–8. On page two of that presentation, Mylan noted two reasons for "[e]liminat[ing] the single EpiPen[.]" Doc. 2525 at 7; *see also* Doc. 2416-3 at 10. They were: (1) "[d]ouble the revenue per Rx of 2 pack vs single[,]" and (2) "[s]trong potential generic defense[.]" Doc. 2416-3 at 10. Plaintiffs argue that both of these statements about the 2-Pak switch are relevant to their generic delay claims.

For the first statement about "doubling the revenue," plaintiffs argue this comment involves a direct correlation to product price, and thus it is relevant to Mylan's monopoly power and abuse of that power. The court fails to see the connection. Mylan's statement about a desire to "double the revenue" by forcing consumers to buy two EpiPens may not place Mylan in the most flattering light. But, Mylan's desire to increase its revenue in this fashion isn't "of consequence" to deciding the lone antitrust theory remaining for trial—that is, nothing about this evidence is capable of supporting a finding or inference that Mylan maintained monopoly power by entering an unlawful reverse payment settlement to delay generic competition. Also, the statement about doubling the revenue doesn't show a specific intent to monopolize. It may show

an "intent to . . . protect and maximize profits, or 'do all the business if [Mylan] can,'" but that type of conduct "is neither actionable nor sanctioned by the antitrust laws." *SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 969 (10th Cir. 1994) (quoting *Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325, 1339 (7th Cir. 1986)); *see also FTC v. Qualcomm Inc.*, 969 F.3d 974, 994 n.15 (9th Cir. 2020) (explaining that "the goal of antitrust law is not to force businesses to forego profits" and concluding that defendant's "desire to maximize profits both in the short-term *and* the long-term undermines, rather than supports, the district court's finding of anticompetitive conduct"). Thus, an exhibit that merely discussed how the 2-Pak switch presented an opportunity to maximize profits isn't relevant to plaintiffs' antitrust claims premised on a generic delay theory.

For the second statement, plaintiffs argue that Mylan's mention of a "strong potential generic defense" is relevant to their generic delay theory. But again, plaintiffs fail to persuade the court of the requisite connection between this statement and their generic delay claims. They argue that this statement shows Mylan was growing the market to a size that created a barrier to entry, making it harder for generic competitors to enter the market and compete. But, as defendants correctly note, growing the market doesn't create a barrier to entry. Just the opposite, a growing market provides incentive for competitors to enter it.

Also, placed in its entire context, the PowerPoint's reference to a "strong generic defense" contemplates how EpiPen will compete with a generic competitor when it enters the market—not how to delay a generic competitor from launching its product. The fourth page of the PowerPoint is titled "Generic EpiPen Defense." Doc. 2190-14 at 7. It starts by predicting how pharmacy benefit managers (PBMs) will cover EpiPens when a generic product enters the market: "EpiPen will be delegated to tier 3 by most PBMs and Payers w/ generic in tier 1." *Id.*

Next, it pitches a "coupon program" designed to "maintain loyalty to brand EpiPen" by guaranteeing a low copay for the EpiPen when it is placed on 3rd tier coverage. *Id.* Mylan contends that this slide shows a "potential strategic reaction to the *launch* (not delay) of a generic." Doc. 2518 at 4. The plain language of the exhibit supports Mylan's characterization of the evidence. And, there's nothing unlawful or illegal about strategizing to compete against a generic. *SCFC ILC, Inc.*, 36 F.3d at 969 ("[I]ntent to harm a rival . . . is neither actionable nor sanctioned by the antitrust laws."). Indeed, competition is the very virtue the antitrust laws strive to protect.

Plaintiff's brief also argues that eliminating the sale of EpiPens in a single pack is relevant to damages because "the jury will need to understand how consumers were required to purchase the devices." Doc. 2525 at 9 n.1. Nothing other than plaintiffs' *ipse dixit* conclusion supports the idea that the jury needs to understand the quantity of EpiPens in a package to assess damages for a generic delay claim. Instead, to assess generic delay damages, the jury must evaluate evidence showing the quantities purchased and the prices paid for EpiPens compared what those quantities and prices would have been absent any generic delay. The 2-Pak switch simply isn't relevant to the generic delay damage calculation—and if it is, plaintiffs haven't shown it.[2]

Based on the current record, plaintiffs have failed to shoulder their burden to show that evidence about the 2-Pak switch is relevant to their generic delay claims. Like any in limine

[2] Plaintiffs also cite the deposition testimony of a class representative who testified that she would have bought the EpiPen in the single pack, but that wasn't an option, and, instead, she was "forced" to purchase the EpiPen in a 2-Pak. Doc. 2525 at 9 n.1. This testimony has nothing to do with generic delay. Instead, it contends Mylan violated the law by forcing consumers to purchase EpiPens in the 2-Pak. That may have been a theory plaintiffs used to support their RICO claim, but the court has dismissed that claim. And, Mylan's decision to stop selling EpiPens in the single pack isn't relevant to plaintiffs' antitrust claim premised on a generic delay theory.

ruling, the court can revisit the question if plaintiffs marshal evidence that the 2-Pak switch somehow is "of consequence" to market power, or that it shows an attempt by Mylan to delay generic competition. But, based on the current record and the clear and plain language of the PowerPoint exhibit, plaintiffs haven't shown that the 2-Pak evidence is relevant to their generic delay claims. Thus, the court grants Mylan's request to exclude evidence of the 2-Pak switch under Fed. R. Evid. 402 because it's "[i]rrelevant evidence" that "is not admissible." Fed. R. Evid. 402.

2. WAC Increase

Next, Mylan asks the court to exclude evidence suggesting that Mylan's increases to the EpiPen WAC price were improper. Mylan recognizes that the parties already have stipulated to the WAC figures. And, it doesn't object to plaintiffs introducing evidence of the *fact* of the WAC prices. But, it objects to plaintiffs inferring that Mylan somehow violated the law by increasing the WAC prices. Mylan argues that such an inference is irrelevant to plaintiff's antitrust generic delay claims.

Plaintiffs respond, arguing that the WAC price increases are directly relevant to antitrust impact, plaintiffs' injuries, overcharges, and damages. They explain that their expert will use evidence of the price increases to show that Mylan's ability to raise the WAC price—along with other market characteristics—shows Mylan possessed market power during the relevant time. The court agrees. Evidence about the WAC price increases is relevant to the antitrust claims at issue for trial. This case involves Mylan's pricing and alleged overcharging for the EpiPen while Mylan purportedly stifled generic competition by entering an unlawful reverse settlement payment to delay generic entry. Thus, evidence of WAC price increases qualifies as relevant, admissible evidence under Federal Rule of Evidence 401.

Mylan also argues that, even if evidence of WAC price increases qualifies as admissible evidence, the court should exclude it under Federal Rule of Evidence 403 because "its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [and] misleading the jury[.]" Fed. R. Evid. 403. For its unfair prejudice argument, Mylan asserts that plaintiffs intend to introduce evidence about the WAC price increases through inflammatory news articles that contain misleading or inaccurate information. *See, e.g.*, Doc. 2515 at 10 n.11 (citing Robert Pearl, *Mylan's Outrageous EpiPen Price Hikes: How Many Children Will Suffer?*, Forbes (Sept. 1, 2016) (according to Mylan, this article "describ[es] a fictional, hypothetical incident of a child dying at school because her parents could not afford an EpiPen")). Mylan argues that the court should exclude such evidence as prejudicial to Mylan. But, the court questions whether such news articles qualify as admissible evidence under other evidentiary rules, including the hearsay rules. *See* Fed. R. Evid 801–07. And, even if plaintiffs might overcome a hearsay objection to an offer of these news articles, Mylan still can raise other evidentiary objections to the exhibit, including one under Fed. R. Evid. 403. But, just because one form of inflammatory evidence is inadmissible doesn't mean that Rule 403 bars all evidence and argument about that same subject. In short, the current record doesn't warrant a blanket prohibition against all evidence and argument about Mylan's WAC price increases.

Mylan's confusion argument contends that evidence about WAC price increases will mislead and confuse the jury whether plaintiffs are trying to recover for WAC price increases themselves. Mylan asserts that scenario poses a particular problem here where few class members actually paid the WAC price—or any price close to it—for an EpiPen. The court has more faith in jurors than this argument does. And, likewise, the court predicts that its instructions to the jury—with substantial input from counsel—will explain the claims

adequately. A blanket exclusion of all arguments based on evidence about WAC price increases isn't warranted. Short of exclusion, other tools will suffice to prevent juror confusion about the evidence, including careful and cautionary instructions to the jurors about the evidence. And, Mylan will have an opportunity to reassert its Rule 403 objections at trial to specific evidence about the WAC price increases if Mylan believes that some actual argument poses a danger of misleading the jury. The court overrules Mylan's Rule 403 objection to all arguments based on evidence about WAC price increases.

3. Provigil

Last, Mylan asks the court to exclude evidence about the settlement of a patent lawsuit between Mylan and Cephalon involving the drug Provigil. Cephalon (a pharmaceutical company who Teva later acquired) sued Mylan and other generic competitors for patent infringement of Cephalon's product, Provigil. In 2005 and 2006, Cephalon entered agreements with Mylan and other generic competitors which, plaintiffs contend, amounted to unlawful pay-for-delay settlements—*i.e.*, plaintiffs allege Cephalon paid Mylan and the generic competitors some $300 million to delay launching their generics. According to plaintiffs, both the FTC and civil plaintiffs filed lawsuits over the alleged pay-for-delay settlement agreements. In 2015, Teva settled the FTC's lawsuit for $1.2 billion. And, in 2017, Mylan settled a lawsuit with civil plaintiffs for $96.5 million. Mylan asserts that it never admitted any liability for the Provigil settlement and no court ever made any finding against Mylan about the Provigil settlement.

Mylan argues that the Provigil evidence isn't relevant to the antitrust generic delay theory at issue for trial because it involves the settlement of an unrelated drug product. Thus, Mylan argues, the evidence is inadmissible under Federal Rule of Evidence 402. But, even if the

evidence is admissible, Mylan asks the court to exclude it under Federal Rule of Evidence 403 because it is unfairly prejudicial.

Plaintiffs argue that evidence about the Provigil settlement is relevant to the antitrust generic delay theory involving the Teva (Nuvigil)/Mylan (EpiPen) settlement at issue here because it shows "Mylan entered a similar pay-for-delay scheme with the same counterparty Cephalon (the entity that sued Mylan over Nuvigil and later was acquired by Teva), concerning the drug Provigil." Doc. 2517 at 4. Plaintiffs contend that the evidence is admissible under Federal Rule of Evidence 404(b) because it's evidence of another "crime, wrong, or act" committed by Mylan that is admissible to prove "motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed. R. Evid. 404(b). Rule 404(b) evidence "is admissible if four factors are satisfied: (1) the evidence is offered for a proper purpose; (2) the evidence is relevant; (3) the probative value of the evidence is not substantially outweighed by its potential for unfair prejudice; and (4) the district court provides an appropriate limiting instruction upon request." *Chavez v. City of Albuquerque*, 402 F.3d 1039, 1046 (10th Cir. 2005) (citations omitted). Plaintiffs argue that all four factors are satisfied here, and thus, the court should allow plaintiffs to introduce evidence about the Provigil settlement. The court disagrees.

The Provigil evidence at best has limited utility in determining whether the EpiPen/Nuvigil settlement was an unlawful reverse payment settlement contrived to forestall a generic epinephrine auto-injector from competing with EpiPen. Although Teva and Mylan paid significant sums to settle litigation accusing them of entering unlawful reverse settlement payments involving Provigil, none of the litigation produced an admission or finding of liability.

Thus, none of the Provigil evidence proves that Mylan previously had entered an unlawful reverse settlement payment.

Instead, admitting the evidence would mean that the jury also must decide whether Mylan had engaged in a prior bad act with the Provigil settlement. To make that decision, the parties would have to introduce a significant amount of evidence about the Provigil litigation—evidence spanning more than 10 years and involving many documents and a number of witnesses that have nothing to do with plaintiffs' theory about the EpiPen/Nuvigil settlement. The court then would have to instruct the jury about that side issue, giving legal direction to evaluate that distinct set of evidence. This scenario would produce a trial-within-a-trial about the Provigil settlement, causing undue delay that far outweighs any probative value. In similar circumstances, our Circuit has affirmed a trial court's decision to exclude Rule 404(b) evidence because it fails the Rule 403 balancing test. *See United States v. Talamante*, 981 F.2d 1153, 1156 n.5 (10th Cir. 1992) (affirming trial court's decision to exclude evidence of other wrongs and noting that admitting the evidence under Rule 404(b) "could have led to collateral mini trials" (citing *United States v. Waloke*, 962 F.2d 824, 830 (8th Cir. 1992) (district court may exclude evidence under Rule 403 if it would cause undue delay or lead to collateral mini trials))); *see also Schneider v. City & Cnty. of Denver*, 47 F. App'x 517, 530 (10th Cir. 2002) (affirming trial court's decision to exclude certain testimony because, among other things, the trial court did so "to thwart a mini-trial and to avoid unfair prejudice under Rule 403"); *Beck's Off. Furniture & Supplies, Inc. v. Haworth, Inc.*, Nos. 95-4018, 95-4029, 1996 WL 466673, at *11 (10th Cir. Aug. 16, 1996) (affirming trial court's exclusion of Rule 404(b) evidence because trial court "found the risk of prejudice to [defendant] substantially outweighed its probative value to" plaintiff and admitting the evidence "would require a mini-trial to allow [defendant] the

opportunity to explain" why its prior conduct wasn't evidence of other wrongs). The court reaches the same conclusion here. The limited probative value of the Provigil evidence "is substantially outweighed by the danger of . . . confusing the issues, misleading the jury, [and] undue delay[.]" Fed. R. Evid. 403. Thus, the court excludes the Provigil evidence under Federal Rule of Evidence 403.

4. Conclusion

In sum, the court grants Mylan's request the exclude evidence about (1) the 2-Pak switch, and (2) the Provigil settlement. But, the court denies Mylan's request to exclude evidence about and all argument based on Mylan's increases to the EpiPen's WAC price.

IT IS THEREFORE ORDERED BY THE COURT THAT the Mylan Defendants' Brief on Three Threshold Issues for Trial (Doc. 2515) is granted in part and denied in part, as explained by this Order.

IT IS FURTHER ORDERED THAT the Class Plaintiffs' Brief Regarding Certain Evidentiary Issues (Doc. 2525) is granted in part and denied in part, as explained by this Order.

IT IS SO ORDERED.

Dated this 23rd day of December, 2021, at Kansas City, Kansas.

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