IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litigation	Master Docket No. 20-1076-CFC
This Document Relates to:	
All Actions	

MEMORANDUM ORDER

Pending before me is Plaintiffs' *Daubert* Motion No. 2 to Exclude Certain Opinions of Dr. Maria Garibotti. D.I. 654. I write for the parties and incorporate by reference the background and applicable legal standards set forth in my Memorandum Order issued on March 20, 2025 (D.I. 837).

I.

Plaintiffs first seek to preclude Dr. Garibotti from offering at trial her opinion that the alleged reverse payment was not large compared to AstraZeneca's Seroquel XR revenues. D.I. 655 at 5; *see* D.I. 656-1 at 32–33. Plaintiffs say that

this comparison "is directly contrary to *Actavis*," D.I. 655 at 5, and that therefore it does not satisfy Rule 702's reliability[1] and fit requirements. *See* D.I. 655 at 1.

According to Plaintiffs, *Actavis* "requires the size of a reverse payment to be assessed in terms of the litigation expenses the brand company avoided by settling." D.I. 655 at 5. The Supreme Court, however, made clear in *Actavis* that "the size" of the payment is *not* to be assessed in terms of avoided litigation expenses. The Court held in *Actavis* that whether a reverse payment "brings about anticompetitive effects" in violation of federal antitrust law "depends upon [1] *its size*, [2] its scale in relation to the payor's anticipated future litigation costs, [3] its independence from other services for which it might represent payment, and [4] the lack of any other convincing justification." *FTC v. Actavis, Inc.*, 570 U.S. 136, 159 (2013) (emphasis added). Thus, under *Actavis*, the payment's size is a consideration separate and distinct from the payment's scale in relation to avoided litigation expenses; and both factors—along with two other factors—are to be weighed in determining the lawfulness of the challenged payment.

Third Circuit law also makes clear that *Actavis* does not require the size of a reverse payment to be assessed solely in terms of avoided litigation expenses. In

[1] Opinions that are wrong as a matter of law are unreliable and thus inadmissible under Rule 702. *VLSI Tech. LLC v. Intel Corp.*, 2022 WL 2304112, at *3 (D. Del. 2022).

In re Lipitor Antitrust Litig., 868 F.3d 231 (3d Cir. 2017), for example, the court held that the challenged reverse payment was plausibly unlawful in part because it "far exceeded" "any services provided by" the generic manufacturer. *Id.* at 253–54. And in *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020), the court held that the challenged reverse payment was plausibly large in part because it "exceeded what [the generic manufacturer] had projected it was likely to earn by winning the infringement suit and marketing its generic[.]" *Id.* at 357.

Plaintiffs insist that "[t]he Supreme Court [in *Actavis*] expressly rejected Dr. Garibotti's comparison of the reverse payment's size to the value of brand sales." D.I. 655 at 6. Their failure to provide a citation in support of this assertion is not surprising, as the Court in *Actavis* neither expressly nor impliedly rejected the challenged comparison. Rather, the Court rejected in *Actavis* the so-called "scope-of-the-patent" test—under which settlement agreements were "immune from antitrust attack" if the generic's licensed entry occurred before the patent expired—and held that reverse-payment settlements of patent cases could be subject to antitrust liability under the so-called "rule of reason." *See Actavis*, 570 U.S. at 141, 159. The Court did not address whether it is appropriate to compare the revenues generated from sales of the brand drug to the amount of the reverse payment in assessing the lawfulness of the payment. The Court certainly

did not "expressly reject[] Dr. Garibotti's comparison of the reverse payment's size to the value of brand sales," as Plaintiffs contend.

Finally, Plaintiffs argue in their Reply Brief that "Dr. Garibotti's view that the brand's monopoly profits are a benchmark for what is 'large' is inconsistent with *Actavis*" because "*Actavis*'[] concern was with brand manufacturers using 'monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.'" D.I. 782 at 2–3 (quoting *Actavis*, 570 U.S. at 156). Plaintiffs say that "[a]llowing an argument that a reverse payment is not large compared to brand profits would allow the brand to argue that it *can* use monopoly profits to avoid [the risk of patent invalidation or a finding of noninfringement] since those profits always dwarf the generic's competitive earnings (and the payments required to induce the generic to postpone such earnings)." D.I. 782 at 3 (emphasis in the original). Putting aside whether Plaintiffs waived this argument,[2] the argument fails on the merits because it "put[s] the cart before the horse—*i.e.*, [it] essentially assumes that [AstraZeneca]'s monopoly profits were not based on a lawful monopoly arising from the patent but rather based on an unlawful monopoly because the patent is either invalid or not infringed." *In re HIV Antitrust Litig.*, 2023 WL 5670808, at *8 (N.D. Cal. Mar. 19, 2023).

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[2] *See Lampkins v. Mitra QSR, LLC*, 2018 WL 6188779, at *3 n.2 (D. Del. Nov. 28, 2018) (deeming argument raised for first time in a reply brief as waived).

In short, Dr. Garibotti's use of AstraZeneca's profits from Seroquel XR sales as a benchmark for assessing whether the challenged reverse payment was unlawful under *Actavis* is neither explicitly nor implicitly barred by *Actavis* or Third Circuit case law. Accordingly, I will not exclude her comparison of those profits with the size of the challenged reverse payment as unreliable or unfit under Rule 702.

II.

Plaintiffs next seek to preclude Dr. Garibotti from offering at trial her opinions that AstraZeneca derived significant value from the challenged settlement in reducing the costs of uncertainty about when generic competition would occur and that this value bears on whether the challenged reverse payment was large. Dr. Garibotti referred to this uncertainty in her report as "business uncertainty." D.I. 656-1 at 30. According to Dr. Garibotti, this uncertainty carried financial consequences for AstraZeneca because, while the underlying patent litigation was pending, "AstraZeneca executives would have needed to decide how much to invest in marketing for Seroquel XR not knowing the precise date of Handa's entry and generic competition." D.I. 656-1 at 30. In Dr. Garibotti's opinion, if the executives guessed wrong about the level of generic competition, the cost of over-investment or underinvestment "could reach into the tens of millions of dollars in lost sales." D.I. 656-1 at 31.

Here again, Plaintiffs argue that Dr. Garibotti's consideration of the costs of business uncertainty "is directly contrary to *Actavis*," D.I. 655 at 9, and therefore is unreliable and unfit for admission under Rule 702, D.I. 655 at 1. And, here again, Plaintiffs read into *Actavis* a holding that does not exist. The word "uncertainty" does not appear in the majority opinion in *Actavis*, and nowhere in that opinion did the Court preclude a judge or jury from considering the costs of business uncertainty in determining whether a challenged reverse payment was large or unlawful.

Plaintiffs seem to suggest that *Actavis* precludes consideration of the costs of business uncertainty because "[u]nder *Actavis*, anticompetitive harm arises from a payment that 'likely seeks to prevent the risk of competition.'" D.I. 655 at 9 (quoting *Actavis*, 570 U.S. at 157). If this is in fact Plaintiffs' argument, it fails for two reasons. First, "preven[ting] the risk of competition" is not the same thing as mitigating business uncertainty. Second, Plaintiffs omitted three key words—"if otherwise unexplained"—from the sentence they quote from *Actavis*. The "relevant anticompetitive harm" recognized in the sentence Plaintiffs quote from *Actavis* arises from a "payment [that] (*if otherwise unexplained*) likely seeks to prevent the risk of competition." 570 U.S. at 157 (emphasis added). As the Court went on to note:

> Although the parties may have reasons to prefer settlements that include reverse payments, the relevant

> antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.

Id. at 158. The Court did not say in *Actavis* that "some other justification" cannot include mitigating the costs of business uncertainty.

Plaintiffs also point to the Third Circuit's holding in *AbbVie* that *Actavis* made it unlawful for a patentee to use its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. *See* D.I. 655 at 9; 976 F.3d at 352. Avoiding the risk of a litigation outcome, however, is not the same thing as avoiding the business costs associated with not knowing the outcome of the underlying patent litigation. As Defendants state in their briefing: "Dr. Garibotti made clear that, from an economic perspective, the uncertainty she considers a patentee to face is not simply *whether* it will win or lose, but rather, not knowing the final answer to that question." D.I. 708 at 7 (emphasis in the original).

In sum, then, Dr. Garibotti's consideration of the costs of business uncertainty is not contrary to the law and is neither unreliable nor unfit under Rule 702.

III.

Plaintiffs next argue that Dr. Garibotti's method of identifying offsetting or redeeming virtues is contrary to law and therefore unreliable and unfit for

admission as evidence under Rule 702. D.I. 655 at 1, 10. In *Actavis*, the Court stated that "offsetting or redeeming virtues are sometimes present" in reverse-payment settlement agreements and held that a defendant can defeat an antitrust claim by presenting at trial such "legitimate justifications" that "explain[ ] the presence of the challenged [reverse-payment] term and show[ ] the lawfulness of that term under the rule of reason." 570 U.S. at 156. In this case, Dr. Garibotti has identified the alleged reverse payment's "offsetting or redeeming virtues" by "comparing the actual world outcome—the Settlement Agreement as it was agreed and the resulting timing and effect of generic entry—to what would have occurred had the parties chosen to continue with litigation." D.I. 656-1 at 35. Dr. Garibotti thus quantified the settlement's procompetitive benefits by calculating the difference between what Plaintiffs paid for Seroquel XR in the actual world and what they would have paid had generic entry not occurred until December 1, 2017, after the expiration of AstraZeneca's patent. D.I. 656-1 at 36. Plaintiffs say this analysis is contrary to law in three ways.

First, Plaintiffs argue that an assumption underlying Dr. Garibotti's procompetitive benefits calculation—i.e., that AstraZeneca's patent would have prevented generic entry prior to its expiration because it was valid and infringed—is "the 'scope-of-the-patent' test that *Actavis* rejected." D.I. 655 at 11. The "scope-of-the-patent" test immunized settlement agreements "from antitrust

attack" if the generic's licensed entry occurred before the patent expired. *Actavis*, 570 U.S. at 141. Plaintiffs are correct that the Court in *Actavis* rejected that test and held that such agreements could trigger antitrust liability under the rule of reason. But the Court did not hold or suggest in any way that an antitrust defendant could not argue as part of the rule of reason analysis that a settlement that licenses generic entry before the patent's expiration is procompetitive compared to a scenario in which the brand prevails in the underlying patent litigation and prevents generic entry until the patent's expiration date.

Second, Plaintiffs argue that Dr. Garibotti's method of identifying the settlement's procompetitive justifications must be excluded as contrary to law because "it violates fundamental antitrust law that the competitive effects of an agreement must be determined as of the time of the agreement." D.I. 655 at 10–11. Defendants concede that Dr. Garibotti "considered later arising facts" when identifying the settlement's procompetitive benefits, but they argue that her analysis is nonetheless admissible. D.I. 708 at 12, 13. Defendants also make the point that my answer to the question of whether the jury should be allowed to consider events that occurred after the negotiation of the challenged reverse payment will affect other significant legal matters in the case, including causation. D.I. 708 at 15. And they say it would be inappropriate to resolve this larger issue in the context of this *Daubert* motion. D.I. 708 at 15. Defendants ask in their

response brief for an opportunity to provide supplemental briefing to the extent I would be inclined to rule on the issue, D.I. 708 at 15 n.5, and Plaintiffs say that they "welcome" that request, D.I. 782 at 8. Since I agree that supplemental briefing would be helpful, I will defer ruling on this issue until I have the benefit of that briefing.

Third, Plaintiffs argue that Dr. Garibotti's method of identifying procompetitive justifications is contrary to law because "it assesses the competitive effects of the settlement rather than the reverse payment [(i.e., AstraZeneca's no-AG promise and its 4-million-dollar cash payment)]." D.I. 655 at 11. Plaintiffs insist that "Third Circuit law is unambiguous that it is the defendants' burden to justify the reverse payment, not the settlement as a whole" and thus, Dr. Garibotti's discussion of the settlement's unchallenged provisions "does not fit this case challenging the use of a reverse payment." D.I. 655 at 16–17; *see also* D.I. 782 at 9. In support of this proposition, Plaintiffs cite the Third Circuit's decision in *In re Lipitor*, in which the Third Circuit stated that "defendants have the burden of justifying the rather large reverse payment." 868 F.3d at 256; D.I. 655 at 16.

But, as Defendants point out, *Lipitor* is not an unambiguous command to ignore unchallenged provisions of the settlement agreement when conducting a rule of reason analysis. *See* D.I. 708 at 17. In *Lipitor*, the Third Circuit held merely that the defendants, at the motion-to-dismiss stage, had not explained why

"other elements of the settlement" justified the at-issue payment. 868 F.3d. at 256. That holding, in my view, implies that other provisions of the settlement agreement *should be* considered when evaluating whether the reverse payment was justified.

Defendants also cite *Actavis* and *Ohio v. Am. Express Co.*, 585 U.S. 529 (2018) for the proposition that "[u]nder the rule of reason, it is Defendants' burden to offer procompetitive justifications for the challenged restraint, not the agreement as a whole." D.I. 655 at 16. But those cases in no way suggest that the factfinder must ignore unchallenged provisions of the settlement agreement when evaluating the procompetitive justifications of the challenged payment.

Other courts that have considered this very question have rejected Plaintiffs' position—and for good reason. Taking such a narrow view divorces the alleged reverse payment from the business context in which it was negotiated. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 734655, at *4 (D. Mass. Feb. 6, 2018). The settlement should be evaluated "as a whole, and not in a piecemeal, provision-by-provision approach" because, after all, settlements are "negotiated as a whole, agreed to as a whole, and [go] into effect as a whole." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 753–54 (E.D. Pa. 2015). "[F]ailing to evaluate the agreement as a whole would overlook context essential to determining any possible [pro]competitive effects." *Id.* at 754. Thus, the fact that

Dr. Garibotti evaluated the procompetitive justifications of the settlement as a whole and not just the alleged reverse payment does not render her opinions inadmissible under Rule 702.

In sum, then, I reject Plaintiffs' first and third arguments that Dr. Garibotti's method of identifying offsetting or redeeming virtues is contrary to law, and I will defer ruling on Plaintiffs' second argument until I receive the parties' supplemental briefing on that issue.

IV.

Finally, Plaintiffs seek to preclude Dr. Garibotti from offering at trial her opinion that the model used by Plaintiffs' causation expert, Dr. Keith Leffler, is unreliable because it cannot "predict with any certainty what two competing parties would have negotiated." D.I. 655 at 18 (quoting paragraph 187 of Dr. Garibotti's expert report). Plaintiffs argue that Dr. Garibotti's critique of Dr. Leffler's model is "contrary to law" and therefore inadmissible under Rule 702 because "[c]ausation need not be proven with certainty." D.I. 655 at 18.

Plaintiffs do not cite any case that states literally that "causation need not be proven with certainty," and in any event, consistent with Dr. Garibotti's deposition testimony—"I don't think I'm offering the opinion that you need absolute certainty," D.I. 709-1 at 105 (Tr. 281:15–16)—I do not infer from her phraseology

that she understood or meant to convey that Plaintiffs must establish causation "with certainty."

More to the point, Plaintiffs' argument is premature, as I have yet to finalize jury instructions. Accordingly, I will deny the motion to the extent it seeks a ruling at this juncture that would prohibit Dr. Garibotti from using the words "predict with any certainty" at trial. Plaintiffs conclude their argument with these two sentences: "The Court will instruct the jury on Plaintiffs' burden to prove causation. It should not permit Dr. Garibotti to offer a conflicting opinion on the level of certainty required." D.I. 655 at 19. That sounds right to me. I will instruct the jury on causation, and I will not permit any expert to offer an opinion that conflicts with an instruction. (Of course, to the extent an expert offered at trial an opinion that conflicted with the jury instructions, opposing counsel would be able to use that conflicting testimony to undermine the expert's credibility.) Defendants do not dispute these points. As Defendants' counsel stated at the February 6 oral argument, he intends to be "mindful of" the jury instructions at trial when he questions Dr. Garibotti on direct examination precisely to avoid her using "a word on direct examination that is going to get instructed out[.]" 2.6.25 Tr. 222:14–16 (docketed as D.I. 825).

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NOW THEREFORE, at Wilmington on this Thirty-first day of March in 2025, it is HEREBY ORDERED that Plaintiffs' *Daubert* Motion No. 2 to Exclude

Certain Opinions of Dr. Maria Garibotti (D.I. 654) is DENIED IN PART and DEFERRED IN PART. It is FURTHER ORDERED that the parties shall meet and confer and propose no later than April 4, 2025 a schedule for additional briefing with respect to the issue of whether, and if so, to what extent, events that occurred after the date of the challenged settlement agreement may be considered at trial.

CHIEF JUDGE