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

Plaintiffs in these consolidated class actions have accused Defendants of violating sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2. Pending before me is Defendants' motion for summary judgment on all Plaintiffs' claims. D.I. 625.

I.

These class actions arise out of a 2011 agreement to settle a patent lawsuit relating to extended-release quetiapine fumarate, an anti-psychotic drug sold by Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively, AstraZeneca) under the brand-name Seroquel XR® (Seroquel). AstraZeneca had alleged in the underlying lawsuit that generic versions of Seroquel made by Defendant Handa Pharmaceuticals LLC and other generic manufacturers were covered by the so-called #437 patent owned by AstraZeneca and that abbreviated

new drug applications (ANDAs) filed by Handa and the other manufacturers with the Food and Drug Administration (FDA) to market their respective generic versions of Seroquel constituted patent infringement under the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(2)(A) (making the submission of an ANDA "an act of infringement . . . for a [generic] drug claimed in a patent or the use of which is claimed in a patent" for the brand drug).

Although the #437 patent's expiration date was May 28, 2017, AstraZeneca was entitled to an additional six-month period of the patent's exclusivity under 21 U.S.C. § 355 because of AstraZeneca's participation in pediatric studies of Seroquel. D.I. 627 ¶ 4; D.I. 718 ¶ 4. Thus, as long as the #437 patent remained valid, it effectively precluded a manufacturer from marketing before November 28, 2017 a generic version of Seroquel that infringed the #437 patent unless that manufacturer had a license from AstraZeneca.

As part of an agreement to settle its case against Handa, AstraZeneca paid Handa $4 million in cash, licensed the #437 patent exclusively to Handa as of November 2016 (i.e., a year before the patent's pediatric exclusivity period ended), and agreed not to launch its own generic version of Seroquel during the 180-day period in which only Handa and AstraZeneca had FDA approval to lawfully market generic versions of Seroquel—thus ensuring that the only generic versions of Seroquel on the market during that period would be sold by Handa, which

enjoyed a 180-day period of exclusivity as the first generic manufacturer to file a Seroquel ANDA. D.I. 718 ¶ 59; D.I. 627 ¶¶ 16–17; *see also FTC v. Actavis, Inc.*, 570 U.S. 136, 143–44 (2013) (explaining that the first generic manufacturer to file with the FDA an ANDA to market a generic drug "will enjoy a period of 180 days of exclusivity" and that "[d]uring that period of exclusivity[,] no other generic can compete with the brand-name drug"); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 393 (3d Cir. 2015) (holding that "[t]he relevant statute permits the brand to produce an 'authorized generic' during the [first generic filer's] exclusivity period") (citations omitted).

Plaintiffs allege that these settlement terms constituted an unlawful "reverse payment"—i.e., a payment made *by the plaintiff* (AstraZeneca) *to the defendant* (Handa) to settle claims *brought by the plaintiff*—that delayed and suppressed competition among sellers of generic versions of Seroquel in violation of the Sherman Act, as interpreted in *Actavis*. Plaintiffs allege that as a result of this delay and suppressed competition, they paid more than they should have for branded and/or generic versions of Seroquel. *See, e.g.*, D.I. 135 ¶ 25. And they say that the settlement agreement's reverse payment caused them this antitrust injury because, but for that payment, AstraZeneca and Handa would have entered into an alternative settlement agreement that would have allowed Handa to launch generic versions of Seroquel in July 2015. *See* D.I. 635-1 at 22.

The settlement agreement between AstraZeneca and Handa contained another provision—the so-called Supply Option—that is relevant to the pending motion. Under the Supply Option, AstraZeneca agreed to supply Handa with Seroquel tablets for Handa to sell as Handa's authorized generic versions of Seroquel. D.I. 627 ¶ 18; D.I. 718 ¶ 18. Handa exercised that option in August 2012, D.I. 627 ¶ 20; D.I. 718 ¶ 20,[1] and sold the tablets it purchased from AstraZeneca pursuant to the Supply Option when it entered the market in November 2016, D.I. 718 ¶ 69. As it turned out, Handa never manufactured its own generic versions of Seroquel. D.I. 627 ¶ 24; D.I. 718 ¶ 24.

II.

A court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of any genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A factual dispute is genuine where "the evidence is such that a reasonable jury could return a verdict for the nonmoving

[1] To be more precise, Par Pharmaceutical Inc. "acquired Handa's Seroquel XR ANDA, and Handa assigned to Par its rights under the Settlement Agreement." D.I. 627 ¶ 19; *see also* D.I. 718 ¶ 19. And then Par, as the assignee of Handa's rights under the settlement, invoked the Supply Option in August 2012. D.I. 627 ¶ 20; *see also* D.I. 718 ¶ 20.

party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining if there is a genuine dispute of fact, the court must view the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007).

III.

Defendants say they are entitled to summary judgment "because Plaintiffs' evidence fails to raise a genuine issue of material fact as to lack of causation." D.I. 625 at 1. Plaintiffs do not dispute that they must prove causation at trial to establish their antitrust claims. And indeed, the law is clear: To prevail on their claims, Plaintiffs "must show that the harm they say they experienced—increased drug prices for [Seroquel] (and its generic equivalents)—was caused by the settlement they are complaining about." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164–65 (3d Cir. 2017). To make that showing, Plaintiffs "must point to," among other things, "evidence affirmatively showing that [Handa] could have launched" its generic versions of Seroquel before November 2016. *Id.* at 166.

Plaintiffs have stipulated that in attempting to prove at trial that the alleged reverse payment caused them injury, "they will rely solely on what Plaintiffs characterize as the causation opinion offered by their expert, Dr. Keith Leffler, regarding an alternative licensed generic entry date that would have been

economically acceptable to AstraZeneca and to Handa had they settled without the alleged payment for delay, but otherwise agreed to all other terms in their actual settlement agreement, under which AstraZeneca would have supplied generic extended release quetiapine fumarate to Handa, manufactured by AstraZeneca under NDA 22-047." D.I. 591 at 2 (footnote omitted). As a result of this stipulation, Plaintiffs cannot prevail at trial if Dr. Leffler is not permitted to offer his causation opinion. Nor can Plaintiffs meet their burden to prove causation if they cannot prove to the jury's satisfaction that AstraZeneca and Handa would have included the Supply Option in an alternative settlement agreement.

Plaintiffs vigorously dispute this latter point. They insist that because they "do not challenge the Supply Option, it must remain in the but-for world" "as a [m]atter of [l]aw" and that they therefore have no burden to prove that an alternative settlement agreement would have contained the Supply Option. D.I. 716 at 9. The only Third Circuit case Plaintiffs cite in support of this assertion is *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003). But in *LePage's Inc.*, the court merely stated that the defendant in that case "d[id] not challenge [the plaintiff's damages expert]'s basic approach to calculating damages, conceding that 'an expert may construct a reasonable offense-free world as a yardstick for measuring what, hypothetically, would have happened "but for" the defendant's unlawful activities.'" *Id.* at 165. Thus, even assuming for argument's sake that the

court endorsed the defendant's concession in *LePage's Inc.*, that concession was only that "an expert *may* construct a reasonable offense-free world as a yardstick for measuring what, hypothetically, would have happened 'but for' the defendant's unlawful activities" to calculate damages. Nothing in *LePage's Inc.* suggests that Plaintiffs in this case are relieved of their burden to prove as a necessary predicate of causation that Handa was ready, willing, and able to launch its generic versions of Seroquel before November 2016. But in any event, the Third Circuit made clear in *Wellbutrin* that "[i]n order to withstand summary judgment, [Plaintiffs] must point to evidence affirmatively showing that [Handa] could have launched" its generic versions of Seroquel before that time. *Wellbutrin*, 868 F.3d at 166.

According to Defendants, Plaintiffs cannot make that showing for three reasons.

A.

Defendants argue first that Plaintiffs have adduced no evidence that AstraZeneca would have agreed to include the Supply Option in an alternative settlement agreement. *See* D.I. 626 at 7; *see also* 2.6.25 Tr. 20:21–21:1 (docketed as D.I. 825). Plaintiffs counter that the fact that AstraZeneca agreed to include the Supply Option in the 2011 settlement agreement is sufficient evidence for a rational juror to conclude that AstraZeneca would have agreed to include the Supply Option in an alternative settlement agreement. D.I. 716 at 12. I agree with

Plaintiffs. In an antitrust case, a party's conduct in the real world constitutes evidence from which the jury can infer that the party would have engaged in the same conduct in the but-for world. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 222 (3d Cir. 2012) (agreeing with special master's conclusion that "[e]vidence that all (or virtually all) class members substituted a lower priced generic for some of their K–Dur 20 purchases gives rise to the inference that they would have similarly done [that] in the but-for world"), *vacated on other grounds*, 570 U.S. 913 (2013), *relevant class ruling reinstated,* 2013 WL 5180857 (3d Cir. Sept. 9, 2013) (alterations in the original). Defendants, of course, are free at trial to point to differences between Dr. Leffler's alternative settlement agreement and the actual September 2011 settlement agreement and between the but-for hypothetical world posited by Dr. Leffler and the real world that existed in September 2011, and to argue that those differences show that it is unlikely or less likely that AstraZeneca would have agreed to the Supply Option in a hypothetical alternative settlement. But under *K-Dur*, the existence of the Supply Option in the real world provides a sufficient evidentiary basis for Plaintiffs to meet their burden to show that AstraZeneca would have agreed to include the Supply Option in an alternative settlement agreement.

Defendants did not respond in their Reply Brief to Plaintiffs' argument that the Supply Option constitutes evidence that AstraZeneca would have agreed to the

Supply Option in the but-for world. *See generally* D.I. 779. Instead, they faulted Plaintiffs (as I did above) for "insist[ing] [that] the factfinder can simply assume" that the alternative settlement would have included the Supply Option. D.I. 779 at 2. But the fact that Dr. Leffler "assumed" the existence of the Supply Option in his model is of no moment. The dispositive question for the pending motion is whether a reasonable juror could conclude from the existence of the Supply Option in the 2011 settlement agreement that it is more likely than not that AstraZeneca would have agreed to the Supply Option in an alternative settlement agreement. *Wellbutrin*, 868 F.3d at 167.

In response to questioning at oral argument, Defendants stated that the real-world Supply Option did not constitute sufficient evidence because "[i]t's a different settlement," and it would be "totally speculative" to infer from it that AstraZeneca would agree to that same Supply Option in the but-for world scenario. 2.6 Tr. 18:24–25. I cannot, however, square that argument with *K-Dur*. Defendants point to the fact that *K-Dur* was not a summary judgment ruling but instead was "a class-certification ruling inferring that purchasers who switched to a generic [in the real-world] would have switched [in the but-for world] had the generic been available earlier." D.I. 779 at 3 n.1. But Defendants do not suggest, and I cannot think of, a reason why the "different context" of a class certification ruling matters. Defendants also argue that the "court [in *K-Dur*] had *evidence* to

support the inference—it did not simply assume it." D.I. 779 at 3 n.1 (emphasis in the original). But "the evidence" the court cited was simply the fact that the purchasers had switched to a generic drug in the real world. *K-Dur*, 686 F.3d at 222. In other words, it is the exact same type of evidence that the Supply Option constitutes—i.e., evidence of the conduct of a party in the real world.

Defendants argue that *Wellbutrin* is "instructive," D.I. 626 at 11, but *Wellbutrin* does not save their motion. Like Plaintiffs, the plaintiffs in *Wellbutrin* alleged that they were injured by an unlawful reverse payment provision in an agreement that settled a Hatch-Waxman case. Also, like Plaintiffs, to prove causation, the plaintiffs in *Wellbutrin* argued that in the absence of the challenged settlement agreement one of the defendants—in that case, Anchen—would have launched a generic version of Wellbutrin before the launch date agreed to in the challenged settlement agreement. As the Third Circuit noted, "[t]he problem with the argument" was that it "d[id] not take into account" a patent owned by another manufacturer, Andrx, that would have blocked Anchen from lawfully launching its generic version of Wellbutrin. 868 F.3d at 165.

The plaintiffs in *Wellbutrin* tried to overcome that problem with evidence that Anchen and Andrx had been negotiating a licensing agreement "in the days preceding the [challenged settlement agreement] and had agreed on all but one term." *Id.* at 167. The plaintiffs argued that "[b]ased on those negotiations, . . . a

reasonable jury could infer that the two companies would have reached an agreement." *Id.* The Third Circuit rejected this argument as "completely speculative." In the court's words:

> It is certainly possible that Anchen and Andrx would have reached an agreement, but it is also certainly possible that the negotiations would have stalled and failed. Many a contract has foundered on a single deal-breaker point. Without more specific or concrete evidence, the jury in this case would be left with nothing on which it could rely to reach a conclusion one way or the other. Summary judgment [i]s thus appropriate.

Id.

Defendants say that the problem that undid the plaintiffs' causation theory in *Wellbutrin* is "[t]he same problem [that] pervades Plaintiffs' alternative settlement theory here." D.I. 626 at 12. But unlike Anchen and Andrx in *Wellbutrin*, AstraZeneca and Handa *did* reach an agreement here—i.e., the Supply Option. The negotiations between AstraZeneca and Handa did *not* "stall and fail" or "founder[] on a single deal-breaker point." And the jury in this case will *not* "be left with nothing on which it could rely to reach a conclusion one way or another."

To sum up, then, the Supply Option in the real world constitutes sufficient evidence from which a rational juror could conclude that AstraZeneca would have agreed to the Supply Option in an alternative settlement agreement.

B.

Defendants next argue that Plaintiffs cannot prove causation as a matter of law because "[t]here is no record evidence of AstraZeneca offering or agreeing to license Handa [ ] the [#]437 patent beginning earlier than November 2016." D.I. 626 at 13. Defendants are in effect arguing that Plaintiffs must prove that the but-for hypothetical alternative settlement posited by Dr. Leffler actually occurred. That cannot be the law. As Judge Alsup has noted, that "argument rests upon the befuddling notion that [Defendants] must have contemplated what they would have done in a but-for world which, due to [D]efendants' antitrust violation, *never happened*." *In re Glumetza Antitrust Litig.*, 2021 WL 1817092, at *15 (N.D. Cal. May 6, 2021) (emphasis in the original); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018) (holding that requiring direct evidence that defendants negotiated a different date of entry than the date agreed to in the challenged settlement agreement "would be an almost impossible standard to require of Plaintiffs, given that this is a but-for scenario"); *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *17 (N.D. Ga. June 14, 2018) (same).

To be clear, Dr. Leffler's model is based on the unchallenged economic theory that a party will settle when its expected value of settlement equals or exceeds the expected value of continuing the litigation. He based his opinion that

AstraZeneca would have agreed as part of an alternative settlement to grant Handa a license to practice the #437 patent before November 2016 on that theory and on record evidence that included Handa and AstraZeneca forecasts regarding the number of generic entrants in the market and sales and cost estimates for brand and generic sales of Seroquel. *See* D.I. 720-1 at 198, 201, 244. That opinion and record evidence provide a sufficient basis for a reasonable juror to find that AstraZeneca would have agreed in an alternative settlement agreement to grant Handa a license to the #437 patent beginning earlier than November 2016.

C.

Finally, Defendants argue that "[e]ven if Dr. Leffler's model could otherwise create a dispute of material fact, his application of that model to the facts of this case suffers from a fatal error that independently compels summary judgment." D.I. 626 at 15–16. The fatal error, Defendants say, was Dr. Leffler's failure to account in his model for Handa's different expectations of success with respect to its noninfringement and invalidity defenses in the underlying suit in which AstraZeneca accused Handa of infringing the #437 patent. *See generally* D.I. 634; D.I. 769; *see also* 2.6 Tr. 116:12–15 (explaining that the core of Defendants' "*Daubert* motion and the third summary judgment argument" are that Handa's "entry date and number of generics are linked"). Defendants made this identical argument in their *Daubert* motion to preclude Dr. Leffler from offering at

trial any opinion based on his model. For the reasons set forth in my Memorandum Order issued on March 31, 2025 (D.I. 855), which I incorporate by reference, I rejected that argument and denied Defendants' *Daubert* motion. For those same reasons, I reject the argument here as a basis for summary judgment in Defendants' favor.

* * * *

NOW THEREFORE, at Wilmington on this Second day of April in 2025, it is HEREBY ORDERED that Defendants' Motion for Summary Judgment (D.I. 625) is DENIED.

CHIEF JUDGE