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 Defendants' motion pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) to preclude Plaintiffs' economics expert Dr. Keith Leffler from offering at trial the modeling opinions set forth in ¶¶ 13(E)–(F), 92–108 of Dr. Leffler's Opening Expert Report and ¶¶ 2, 66–79 of his Rebuttal Expert Report. D.I. 633.

I held oral argument on the motion on February 6, 2025. *See generally* D.I. 825. In a Memorandum Order issued on February 19, 2025 (D.I. 828), I required Dr. Leffler to testify at a hearing on March 11, 2025 about two "dispositive questions that govern this motion": "(1) whether it was reasonable for Dr. Leffler to use in his model the same number of generic entrants regardless of whether Handa won on validity or non-infringement and (2) whether it was reasonable for him to have found that the number of expected generic entrants does

not materially change the alternative settlement entry date." D.I. 828 at 9 (internal quotation marks omitted).

Although the parties agreed at the outset of the March 11 hearing that I had correctly deemed both questions to be dispositive for purposes of deciding Defendants' motion, 3.11.25 Tr. 9:8–19 (docketed as D.I. 834), I realize now, after further reflection, that the second question has no bearing on the admissibility of Dr. Leffler's opinions under Rule 702(d). Dr. Leffler's finding that the number of expected generic entrants does not materially change the alternative settlement entry date is a conclusion or product of his economic model, not a principle or method applied by his model. Accordingly, the sole question that governs the pending motion is the first question I posed in the February 19 Memorandum Order.

I have considered carefully Dr. Leffler's March 11 testimony, counsel's arguments at the February 6 and March 11 hearings, and the parties' extensive briefing (D.I. 634, D.I. 714, D.I. 769, D.I. 838, D.I. 839). The relevant factual background and legal standards are set forth in my February 19 Memorandum Order (D.I. 828), which I incorporate by reference.

I.

I find that the AstraZeneca forecasts identified in footnote 146 of Dr. Leffler's Opening Report and the Handa forecasts in PTX 1178 (D.I. 835-9) and

PTX 1180 (D.I. 835-10) provided a reasonable basis for Dr. Leffler to have used in his model the same number of generic entrants—i.e., at least five entrants—regardless of whether the parties expected Handa to prevail on noninfringement, invalidity, or both defenses in the underlying patent case.

Defendants do not dispute that the AstraZeneca forecasts cited in footnote 146 of Dr. Leffler's Opening Report support his assertion in that footnote that those forecasts "impl[y] that [AstraZeneca] expected 5 or more generics to be competing after Handa's exclusivity." D.I. 835-2 ¶ 103 n.146. Rather, they argue that Handa would have expected the number of generic entrants to vary depending on Handa's expectations about the likelihoods of success of its noninfringement and invalidity defenses in the underlying patent litigation. Defendants' logic makes perfect sense in the abstract. As I noted in my February 19 Memorandum Order, "[a] verdict in favor of Handa only on infringement would have allowed Handa—but not other generic manufacturers—to enter the market" whereas "[a] verdict in Handa's favor on either of its invalidity defenses . . . would have opened the door for other generics to enter the market once Handa's 180-day FDA exclusivity period had run." D.I. 828 at 6.

But in the real world, Handa was free to reject, ignore, or simply fail to appreciate that logic. And the forecasts in PTX 1178 and PTX 1180 appear on their face to show that on September 5 and 7, 2011—that is, only weeks before the

challenged September 29, 2011 settlement—Handa expected that regardless of *how* it prevailed in the underlying patent case at least five generic manufacturers would enter the market following Handa's exclusivity period. Of the Handa forecasts in the record that were made before the September 29, 2011 settlement,[1] the forecasts in PTX 1178 and PTX 1180 are closest in time to that date. Accordingly, it was reasonable for Dr. Leffler to assume for purposes of his economic model that, like AstraZeneca, Handa expected the same number of generic entrants—i.e., at least five—regardless of whether Handa prevailed on its noninfringement or invalidity defenses in the underlying patent case.

Defendants concede that PTX 1178 and PTX 1180 are "simplified assessments of both a settlement (Case 1) and litigation (Case 2) outcome." D.I. 838 at 7. They fault the forecasts, however, for "not even includ[ing] a Handa settlement scenario addressing the outcome of other generics' ongoing litigations" and not "contemplat[ing] a noninfringed-but-valid outcome for Handa, despite [Dr.] Leffler's assumption (based on Belvis) that this was the *most* likely scenario." D.I. 838 at 8 (emphasis in the original). But Handa's actual expectations about the likelihood and economic effects of the various potential outcomes of the underlying patent case did not have to be reasonable. And, in any event, alleged shortcomings in these actual (as opposed to hypothetical) forecasts

[1] *See* PTX 1165 (835-8), PTX 1178, and PTX 1180.

are appropriate material for cross examination, not grounds for excluding Dr. Leffler's opinions at trial. The forecasts' lack of "contemplat[ion of] a noninfringed-but-valid outcome for Handa" arguably confirms—not undermines—the reasonableness of Dr. Leffler's decision to use five or more generic entrants in his model regardless of expected litigation outcomes.

II.

My finding that the AstraZeneca forecasts identified in Dr. Leffler's Opening Report and the Handa forecasts in PTX 1178 and PTX 1180 provided a reasonable basis for Dr. Leffler to hold constant the number of generic entrants (i.e., at five or more) in the application of his model resolves the pending motion. But it does not resolve whether and, if so, the extent to which, I will allow Dr. Leffler to refer to PTX 1178 and PTX 1180 at trial. Defendants argued in their post-hearing briefing that PTX 1178 and PTX 1180 "and any corresponding testimony" should be "stricken for non-disclosure." D.I. 838 at 22. I have effectively denied that request, as I considered PTX 1178 and PTX 1180 in ruling today on Defendants' *Daubert* motion. I decided it was appropriate to consider PTX 1178 and PTX 1180 for purposes of the motion because (1) they were identified in footnote 76 of Dr. Leffler's Opening Report (albeit not for anything related to the number of generic entrants in Dr. Leffler's model), D.I. 835-2 ¶ 54 n.76; (2) Defendants asked Handa employees questions about them in depositions

taken months before Dr. Leffler issued his Opening Report, D.I. 840-1, D.I. 840-2; and (3) they were apparently referred to in a document linked to an Excel version of Dr. Leffler's model used by Defendants during Dr. Leffler's deposition, D.I. 840-4.

I am, however, troubled by the fact that Dr. Leffler made no reference to PTX 1178 or PTX 1180 in paragraph 71 or footnote 139 of his Rebuttal Report. Dr. Leffler purported to address in paragraph 71 Defendants' criticism that he "oversimplified [his] model by using a single value for the likelihood of Handa winning the litigation," D.I. 835-3 ¶ 71—that is, the exact same criticism that is the basis for Defendants' *Daubert* motion. He responded as follows:

> The alternative settlement model is quite detailed as presented in my initial report. Using the single probability of Handa winning offered by Mr. Belvis of about 80% was reasonable. The only way that separately modeling the impact of non-infringement versus invalidity impacts my model is if a different number of generics were expected depending upon whether Handa won on validity or non-infringement. In my initial report, I used the same number of generic entrants regardless of whether Handa won on validity or non-infringement.[138] This is consistent with the forecasts of AstraZeneca and Handa,[139] which are the proper evidence for modeling an alternative no-payment settlement agreement reached in September 2011.

D.I. 835-3 ¶ 71. In footnote 139, Dr. Leffler identified three documents as the AstraZeneca and Handa forecasts that constituted "the proper evidence for modeling an alternative no-payment settlement agreement." He did not identify

PTX 1178 or PTX 1180. Moreover, in paragraph 72 of his Rebuttal Report, Dr. Leffler wrote that his "[r]eliance on Handa and AstraZeneca's forecasts *of four or more* [(*not* five or more)] generics expected in the market after 180 days regardless of a Handa win on invalidity or non-infringement [wa]s appropriate based on the parties' expectations at the time of settlement." D.I. 835-3 ¶ 72 (emphasis added).

To make matters worse, Plaintiffs made no mention of PTX 1178 or PTX 1180 in their brief filed in opposition to Defendants' *Daubert* motion or during the lengthy oral argument I held on the motion. Instead, Plaintiffs argued that Defendants were "wrong" to fault Dr. Leffler for not separately considering the chances of Handa winning on noninfringement and invalidity "[b]ecause the number of expected generic entrants affects *both* the expected values of litigation and of settlement" and thus according to Plaintiffs, "any modification of Dr. Leffler's model to separately consider the chances of winning on invalidity and noninfringement must be made to *both* the expected values of settlement and continued litigation." D.I. 714 at 6 (emphasis in the original). As I said in my February 19 Memorandum Order, that explanation makes no sense to me. D.I. 828 at 7. There is no logical reason I can think of (and neither Dr. Leffler nor Plaintiffs' counsel has ever explained) why both AstraZeneca and Handa in a hypothetical but-for world would necessarily have had the same expectations about

the number of generic entrants in a settlement scenario that they would have had in a continuing litigation scenario. And, as noted above, in the abstract, the parties' expectations in a continuing litigation scenario would have varied depending on how the parties expected Handa to prevail on its noninfringement and invalidity defenses.

I am equally troubled that Dr. Leffler appears to have offered at the March 11 hearing opinions and explanations he purports to have based on PTX 1178 and PTX 1180 that were not previously disclosed to Defendants. For example, when asked at the hearing why he used the same number of generic entrants in his model regardless of whether Handa expected to win on invalidity or noninfringement, Dr. Leffler testified: "Because, in reviewing all these forecasts, some of which clearly included the litigation scenario, they think they -- they are telling me *they think there will be five or more*." 3.11 Tr. 122:3–6 (emphasis added). In his Rebuttal Report and deposition, Dr. Leffler offered a different answer to the question—namely that he used the "same number" of generic entrants—not necessarily five or more generic entrants—regardless of litigation outcome. *See* D.I. 835-3 ¶ 71 (Rebuttal Report); D.I. 835-4 at 205:6–207:6 (deposition).[2] Dr. Leffler also disclosed at the hearing—apparently for the first

[2] To be clear, I am not exactly sure what Dr. Leffler was saying in the cited deposition lines, but Plaintiffs stated in their briefing, and I will accept, that Dr. Leffler intended to communicate in those lines of testimony that "[b]ecause the

time—that he relied on and accorded weight to PTX 1178 and PTX 1180 because those forecasts were "relatively contemporaneous" with the date of the challenged settlement. *See, e.g.*, 3.11 Tr. 106:2–4; 113:9–18.

Plaintiffs insist that "Dr. Leffler disclosed all his opinions in his reports and backup." D.I. 839 at 18. In support of this assertion, they point first to paragraph 103 of Dr. Leffler's Opening Report for the proposition that Dr. Leffler "used 5+ generic entrants to calculate the expected value of settlement and continued litigation regardless of the patent defense." D.I. 839 at 18. Paragraph 103, however, addresses AstraZeneca's expectations, not Handa's expectations. D.I. 835-2 ¶ 103. There is no dispute about the disclosure of AstraZeneca's forecasts as a basis for Dr. Leffler's decision to hold constant the number of generic entrants. The only issue is whether Plaintiffs sufficiently disclosed to Defendants Dr. Leffler's reliance on Handa's forecasts in PTX 1178 and PTX 1180 to set the number of generic entrants in his model. Plaintiffs also argue that the number of expected generic entrants and Defendants' assumptions about that number do not materially change the alternative settlement entry date. D.I. 839 at 19. But whether the number of expected generic entrants does or does

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number of expected generic entrants affects *both* the expected values of litigation and of settlement, any modification of Dr. Leffler's model to separately consider the chances of winning on invalidity and noninfringement must be made to *both* the expected values of settlement and continued litigation." D.I. 714 at 6 (emphasis in the original) (citing lines 205:6–207:6 of Dr. Leffler's testimony).

not materially change the alternative settlement entry date has no bearing on whether Dr. Leffler or Plaintiffs disclosed Dr. Leffler's reliance on PTX 1178 and PTX 1180 in deciding the number of generic entrants to use in his model. Finally, Plaintiffs point to a reference to PTX 1178 and a reference to PTX 1180 in a document linked to the backup Excel files Dr. Leffler produced with his Opening Report. D.I. 839 at 10–11, 19. Whether those references constitute a sufficient disclosure of PTX 1178 and PTX 1180, however, is far from obvious. Neither my clerks nor I were able to access the linked document from the Excel files in the USB drive filed with the Court by Plaintiffs.

I need not decide today the permissible scope of Dr. Leffler's testimony at trial. But given the questions raised by the absence of any reference to PTX 1178 and PTX 1180 in paragraph 71 and footnote 139 of Dr. Leffler's Rebuttal Report and deposition and in Plaintiffs' brief filed in opposition to the pending motion, I will allow Defendants to file a stand-alone motion *in limine* separate and apart from (and not subject to the normal page limitations for their inclusion in) the Pretrial Order to address Defendants' request to strike PTX 1178, PTX 1180, and "any corresponding testimony." If Defendants elect to file that motion, they must identify with specificity the "corresponding testimony" they seek to preclude, and they must provide sufficient briefing and case law citations to enable me to address

whether, and if so how, I should apply Federal Rule of Civil Procedure 37(c) and/or the *Pennypack* factors in resolving the motion.

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NOW THEREFORE, at Wilmington on this Thirty-first day of March in 2025, it is HEREBY ORDERED that Defendants' Motion to Exclude the Opinions of Dr. Keith Leffler (*Daubert* Motion No. 1) (D.I. 633) is DENIED. It is FURTHER ORDERED that if Defendants intend to file a motion *in limine* to preclude and/or limit Plaintiffs from adducing at trial evidence of PTX 1178 and PTX 1180, they shall do so no later than April 7, 2025. Any response to such motion shall be filed no later than April 15, 2025, and any reply shall be filed no later than April 22, 2025. Finally, it is FURTHER ORDERED that if such a motion is filed, Plaintiffs shall make Dr. Leffler available at the Pretrial Conference for questioning about the motion.

CHIEF JUDGE