

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

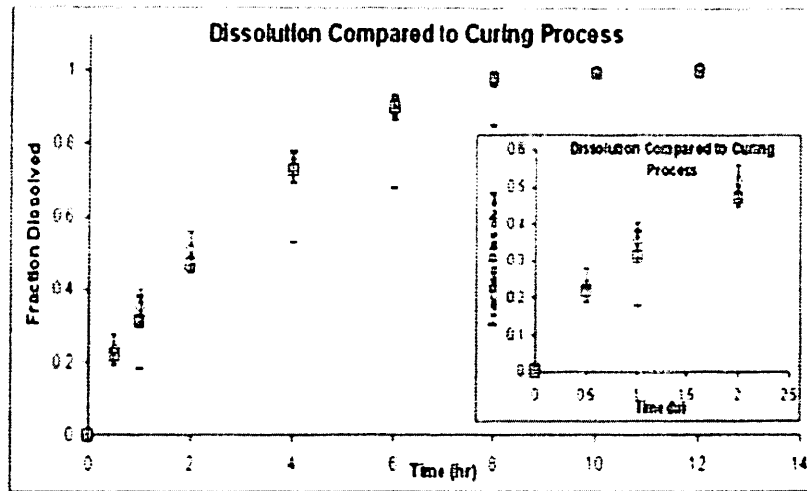
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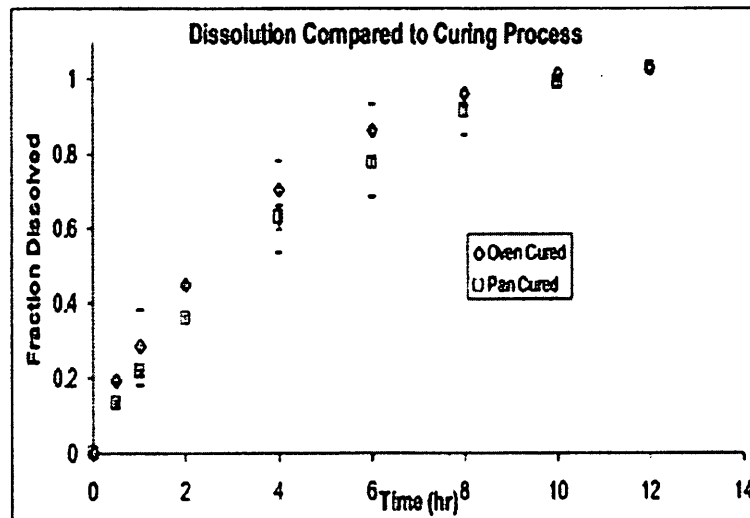
MEMORANDUM ORDER

Defendants have moved pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) to preclude Plaintiffs' expert Dr. Joseph Fix from offering at trial the opinions he set forth in two sentences in paragraph 164 of his Reply Report. D.I. 643; *see also* D.I. 772 at 1 (confirming that the motion is "limited to the two sentences"). Dr. Fix discusses in the two sentences the following two graphs, each of which depict the dissolution profiles of two tablets:

50mg Dissolutions: Oven-cured vs Pan-cured



300mg Dissolutions: Oven-cured vs Pan-cured



D.I. 719-7 at 7-8.

The two sentences in paragraph 164 of Dr. Fix's report read as follows:

Although numerical data are not provided [in the charts], the graphic representation of dissolution profiles for oven-cured and pan-cured tablets exhibit average drug release

percentages extremely close to each other and the clear overlap of standard deviation of the averages of individual time points strongly suggest that there was no statistical difference between the dissolution profiles. These results indicated the success of the alternative curing process and indicated that it should be applicable to other tablet strengths.

D.I. 719-2 ¶ 164. Defendants argue that the opinions set forth in these two sentences are inadmissible under Rule 702(b) and (c) because they are neither the product of reliable principles and methods nor based on sufficient facts or data.

D.I. 644 at 3.

Defendants say that the opinions in paragraph 164 are not the product of reliable principles and methods because Dr. Fix did not have access to the “raw data” on which the graphs were based and therefore Dr. Fix has no reliable basis to offer an opinion about whether the graphs depict any “statistical” differences or similarities between the two drugs profiled in the graphs. D.I. 644 at 3. Plaintiffs counter that “as a matter of law, the unavailability of raw data underlying these graphs does not make Dr. Fix’s analysis unreliable.” D.I. 717 at 14. But Plaintiffs do not cite any binding case law in support of that proposition; and the cases they do cite were decided before Rule 702 was amended effectively to preclude the admission of proffered expert testimony unless the proponent of the testimony demonstrates by a preponderance of the evidence that the proffered expert opinions are based on sufficient facts and data and are the product of reliable principles and

methods. Fed. R. Evid. 702 advisory committee’s note to 2023 amendment. Plaintiffs also insist that “experts in the field routinely rely on these kinds of dissolution profiles to assess dissolution results and develop generic drug products.” D.I. 717 at 14. But the only support they offer for this assertion is Dr. Fix’s expert reports.

Defendants say that the challenged opinions in paragraph 164 are not based on sufficient facts or data because there are no “clear overlaps” of standard deviations in the 300 mg tablet chart and, to the extent there are clear overlaps in the 50 mg tablet chart, that single chart provides an insufficient basis for Dr. Fix to conclude anything about other tablet strengths. D.I. 644 at 3–5. Plaintiffs counter, again relying on Dr. Fix’s expert reports, that “[i]t is routine within the industry, and reliable, to conduct a ‘bracketing study’ . . . on higher and lower dosage strengths, and then infer results in strengths in between.” D.I. 717 at 17.

Suffice it to say, I have no expertise in the pharmaceutical industry, drug dissolution rates, or statistics. For that reason, I am not in a position to assess the merits of the factual assertions made by the attorneys in the parties’ briefing and at the February 6 oral argument that underly, and must be resolved to decide, the pending motion.

Accordingly, I will have Dr. Fix testify about his relevant experience and expertise at trial before making a determination about whether he will be permitted

to offer testimony about the opinions in paragraph 164 of his Reply Report. *See* 29 Fed. Prac. & Proc. Evid. § 6264.3 (2d ed.) (explaining that a court may “hear qualification evidence before permitting the witness to give opinion testimony” and that such a hearing “may take place either in the presence or absence of the jury, at the discretion of the court”). The parties shall be prepared to address at the Pretrial Conference whether that testimony should be in the presence or absence of the jury.

NOW THEREFORE, at Wilmington on this Thirty-first day of March in 2025, it is HEREBY ORDERED that Defendants’ Motion to Exclude Dr. Fix’s Analysis of Certain Dissolution Data (*Daubert* Motion No. 3) (D.I. 643) is DEFERRED until trial.



CHIEF JUDGE