

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTELLAS PHARMA INC., <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 16-905-JFB-CJB
)	Consolidated
ACTAVIS ELIZABETH LLC, <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM ORDER

At Wilmington this **30th day of April, 2019.**

WHEREAS, on April 2, 2019, the parties in these consolidated Hatch-Waxman actions filed a “Motion for Teleconference to Resolve Discovery Dispute” (“Motion”) regarding their various requests that: (1) certain material be stricken from the parties’ expert reports; and (2) the parties be precluded from raising the stricken subject matter at trial.¹ (D.I. 391) In this Memorandum Order, the Court considers the portion of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.’s (collectively, “Astellas” or “Plaintiffs”) Motion relating to their assertion that Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA Inc.’s (“collectively, “Sawai”) expert, Michael J. Cima, Ph.D., improperly relies on: (1) Appendix C, which constitutes a summary of Sawai’s formulation development experiments with references to the underlying analytical data; and (2) the .RAW PXRD data files generated by testing done by Plaintiffs’ expert, Jerry L. Atwood, Ph.D.² (D.I. 393 at 6; D.I. 408

¹ Although the parties characterized their requests as “discovery disputes[,]” (D.I. 384 at 1), they are actually motions to strike. Despite this, the Court noted that it would, as a procedural matter, treat the disputes as if they were discovery disputes. (D.I. 389) That is, the Court permitted the parties to file letter briefs regarding the disputes and thereafter held a teleconference to allow for oral argument.

² The Court will resolve the parties’ remaining issues in forthcoming Order(s).

at 4) With respect to these issues, the Court has considered the parties' letter briefs, (D.I. 393, 398, 408, 421), and the parties' arguments made during the April 17, 2019 telephonic argument, (D.I. 420 (hereinafter, "Tr.));

NOW, THEREFORE, IT IS HEREBY ORDERED as follows:

1. Federal Rule of Civil Procedure 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26[](e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." In considering whether to exclude evidence relating to an untimely or otherwise improper disclosure, the United States Court of Appeals for the Third Circuit has directed district courts to weigh certain factors, known as "the *Pennypack* factors": (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply; and (5) the importance of the testimony sought to be excluded. *See Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel Co.*, 777 F.2d 113 (3d Cir. 1985); *see also Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997). Because "[t]he exclusion of critical evidence is an extreme sanction," the Third Circuit has explained that it should be reserved for circumstances amounting to "willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks and citations omitted).

2. Plaintiffs first request that the Court: (1) strike Appendix C in Professor Cima's February 22, 2019 Rebuttal Expert Report on Sawai's Non-Infringement of United States Patent Nos. 7,342,117 and 7,982,049 (the "Rebuttal Report"), which constitutes a summary of the

prototype formulations discussed in Sawai's Abbreviated New Drug Application ("ANDA") Pharmaceutical Development Report ("PDR"), as well as certain related portions of his Rebuttal Report, (*see* D.I. 393, ex. 1 at ¶ 4(a)); and (2) preclude Sawai from relying on this subject matter at trial, (D.I. 393 at 6). During discovery, Plaintiffs served Sawai with an Interrogatory that sought the underlying data for these formulations. (*Id.*, ex. 10 at 15) Following a meet-and-confer process, Astellas requested that Sawai provide an explanation of the underlying data for just two of the multiple tables included in the PDR: Tables 40 and 42. (D.I. 398, ex. 26 at 1; D.I. 393 at 6) Sawai complied with this request. (D.I. 398, ex. 24 at 25-26) However, because Professor Cima's Rebuttal Report summarizes each formulation at issue in the PDR, and because Plaintiffs did not have such underlying data for formulations beyond Tables 40 and 42 when their expert, Allan S. Myerson, Ph.D., prepared his opening report, Plaintiffs assert that Appendix C should be stricken in its entirety. (D.I. 393 at 6; D.I. 408 at 4; Tr. at 40-41) In response, Sawai argues that Professor Cima's Appendix C and related portions of his Rebuttal Report are proper rebuttal because Professor Myerson's opening report "made extensive arguments about how these prototype formulations . . . somehow showed that Sawai's ANDA product infringed." (D.I. 398 at 5; *see also* D.I. 421 at 1)

3. The Court does not find Appendix C and related portions of Professor Cima's Rebuttal Report to be an untimely or improper disclosure. Professor Myerson opines in his opening report that, for example, "[t]he PDR and testimony of Sawai's witnesses admit that [REDACTED] (D.I. 393, ex. 15 at ¶ 20; *see also, e.g., id.* at ¶ 18 ("These experiments . . . support the argument that . . . in the majority of these prototype formulations, [REDACTED] [REDACTED]"); *id.* at ¶ 56 ("[M]any of Sawai's prototype formulations, which initially appeared as

[REDACTED]

[REDACTED]’)) In response, it is appropriate for Professor Cima to rebut these opinions relating to prototypes. *See, e.g., Withrow v. Spears*, 967 F. Supp. 2d 982, 1001-02 (D. Del. 2013) (noting that rebuttal is proper if the intent is to rebut evidence on the same subject matter identified by the opposing party’s expert report, and that such rebuttal “may cite new evidence and data so long as the new evidence and data is offered to directly contradict or rebut the opposing party’s expert”) (internal quotation marks and citation omitted). The Court therefore DENIES Plaintiffs’ request to strike Appendix C and related content.³ However, the Court also believes that Professor Myerson should be given the opportunity to reply to Professor Cima’s Appendix C and related content, (*see* D.I. 393 at 6; D.I. 408 at 4), since Professor Myerson did not have the benefit of all of this data when he prepared his opening report. Accordingly, the Court GRANTS Plaintiffs’ request for leave to allow Professor Myerson to file a short reply expert report in response.

4. Plaintiffs next request that the Court: (1) strike Professor Cima’s analysis of Professor Atwood’s .RAW PXRD data files and require Professor Cima to rely on the PXRD printouts only; and (2) preclude Sawai from relying on the .RAW PXRD data files at trial. (D.I. 393 at 6; D.I. 408 at 4; *see also* D.I. 393, ex. 1 at ¶ 4(b)) Plaintiffs explain that Professor Atwood’s testing of Sawai’s ANDA product generated .RAW PXRD data files. (D.I. 393 at 6) Sawai requested that these .RAW data files be produced, and Plaintiffs produced them. (*Id.*; D.I.

³ The Court notes, however, that Professor Cima’s reference to Appendix C in Paragraph 463 of his Rebuttal Report seems a bit unfair under these circumstances—specifically, where Professor Cima asserts that Professor Myerson “did not consider all of the evidence available to him about these various prototypes[,]” citing in part to Appendix C. (D.I. 393, ex. 16 at ¶ 463) How could Professor Myerson consider all of the data in Appendix C when Sawai did not produce all of this data to Plaintiffs?

398 at 4-5) Sawai, however, did not provide Plaintiffs with .RAW PXRD data files during discovery for its own samples, (D.I. 393 at 6), and Plaintiffs ultimately did not pursue these files from Sawai, (D.I. 398 at 5; Tr. at 39). Accordingly, Plaintiffs simply relied on printouts of Sawai's PXRD data for their own infringement analysis. (D.I. 393 at 6) Yet Sawai's expert Professor Cima criticizes Plaintiffs' infringement analysis by focusing on Professor Atwood's .RAW data files (i.e., not on printouts like Plaintiffs utilized). (*See id.*) According to Plaintiffs, since printouts were the only data source provided to Plaintiffs, Dr. Cima "should not be allowed to rely on [] raw data and should be limited to visual analysis of the data in printouts[.]" (D.I. 408 at 4; *see also* D.I. 393 at 6)

5. The Court does not find Professor Cima's reliance on Professor Atwood's .RAW PXRD data files to be an untimely or improper disclosure. Sawai pursued these files during discovery, (D.I. 393 at 6),⁴ and received them from Plaintiffs; the Court therefore does not discern anything wrong or surprising about Professor Cima relying on them in his Rebuttal Report.⁵ Accordingly, the Court DENIES this portion of Plaintiffs' Motion.

6. Because this Memorandum Order may contain confidential information, it has

⁴ Though Plaintiffs' counsel indicated during telephonic argument on the Motion that "we provided [Sawai] the raw files as part of the expert discovery without them even asking[.]" (Tr. at 39), their letter indicated that "Sawai demanded access to the .RAW data files generated during PXRD measurements[.]" (D.I. 393 at 6).

⁵ Plaintiffs assert that because Sawai "with[e]ld" its own raw data files during discovery, Plaintiffs cannot now confront Professor Cima with the fact that such data files "would have provided the same results as Prof. Atwood's." (D.I. 408 at 4) Had Plaintiffs pursued such files during discovery (like Sawai apparently did), then Plaintiffs could have confronted Professor Cima with those files. But Plaintiffs did not. The Court does not understand how Plaintiffs' failure to follow up on this evidence somehow makes Professor Cima's reliance on Professor Atwood's raw data files untimely or otherwise improper.

been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Memorandum Order. Any such redacted version shall be submitted no later than **May 3, 2019**, for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE