

**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 **15th day of May, 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 Defendants Sawai Pharmaceutical Co., Ltd., Sawai USA Inc. (together with Sawai Pharmaceutical Co. Ltd., “Sawai”), Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.’s (together with Zydus Pharmaceuticals (USA) Inc., “Zydus” and collectively with Sawai, “Defendants”) Motion relating to their requests to strike Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.’s (collectively, “Astellas” or “Plaintiffs”) expert opinions and new documents regarding two validity-related topics: (1) the need for the “selection” of mirabegron for further development from the prior art (the “selection theory”); and (2) the inventorship story

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.

relating to United States Patent Nos. 7,342,117 and 7,982,049 (collectively, the “polymorph patents”).² (D.I. 392 at 3-6; D.I. 409 at 3-4) With respect to these issues, the Court has considered the parties’ letter briefs, (D.I. 392, 399, 409), and the parties’ arguments made during the April 17, 2019 telephonic argument, (D.I. 420 (hereinafter, “Tr.”));³

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

² Plaintiffs presently assert four patents in this case. The polymorph patents recite mirabegron crystals (or “polymorphs”). (*See* D.I. 392 at 1 n.2) The other two patents recite methods of treating overactive bladder with mirabegron. (*Id.*)

³ The Court will resolve the other issues raised by Defendants’ Motion in separate Order(s).

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. With respect to Plaintiffs’ selection theory, the Court DENIES Defendants’ request to strike this material (and any new supporting documents) from Plaintiffs’ experts’ Rebuttal Reports. Defendants assert that they served initial invalidity contentions with respect to, *inter alia*, the polymorph patents over 18 months ago, and subsequently sought Plaintiffs’ rebuttal validity contentions through Interrogatories served in September 2017 and during Rule 30(b)(6) depositions in the summer of 2018. (D.I. 392 at 3-4 & nn. 19, 20)⁴ Defendants complain that Plaintiffs were unhelpful in that regard, “provid[ing] bare-bones responses[,], refus[ing] to substantially supplement despite [] repeated requests[, and] inadequately prepar[ing] and/or improperly limit[ing] its corporate witnesses on related topics.” (*Id.* at 3-4 & nn. 21-23) As an example, Defendants point to Plaintiffs’ response to Defendants’ Interrogatory No. 15, which requested a “detailed explanation” and “claim by claim analysis” in support of Plaintiffs’ disagreement with Defendants’ Joint Invalidity Contentions. (D.I. 394, ex. K at 26) Plaintiffs responded, *inter alia*, that:

Defendants have not identified any prior art reference that anticipates any claim of the [asserted] patents. Defendants have not identified any prior art reference or combination of references that renders any claim of any of the aforesaid patents obvious. Defendants’ Joint Invalidity Contentions, served on August 25, 2017, are erroneous in their entirety; and Astellas disagrees with Defendants’ Joint Invalidity Contentions in their entirety.

⁴ Fact discovery in this case closed on July 13, 2018. (*See* D.I. 275)

(*Id.* at 27) Accordingly, Defendants assert that they were “surprised” to see Plaintiffs’ “new theory” in all four of their rebuttal expert reports regarding the “need for the ‘selection’ of mirabegron for further development from the prior art as part of the analysis of Defendants’ obviousness defenses.” (D.I. 392 at 4-5; Tr. at 63 (Sawai’s counsel asserting that Plaintiffs’ Response to Defendants’ Interrogatory No. 15 amounted to “nothing, essentially saying that our invalidity contentions were just wrong and with no reasoning whatsoever. So we had no idea that they were going to argue that . . . you would select something else besides [m]irabegron”)) Defendants argue that this disclosure was untimely and that the *Pennypack* factors weigh in favor of striking Plaintiffs’ selection theory. (D.I. 392 at 5)

3. For their part, Plaintiffs contend that their selection theory directly rebuts Defendants’ experts’ invalidity opinions and therefore is permissible in their experts’ rebuttal reports. (D.I. 399 at 4) For instance, one of Defendants’ experts, Michael B. Chancellor, M.D., opines in his opening report on invalidity that certain of the asserted claims are invalid over, *inter alia*, United States Patent No. 6,346,532 (the “532 patent”). In support, Dr. Chancellor asserts that “[a] [person of ordinary skill in the art, or POSA] would have been motivated to select mirabegron as a β_3 -adrenoceptor agonist” and “would have had a reasonable expectation of success in treating overactive bladder [‘OAB’] with mirabegron because it was known to be a selective β_3 -AR agonist[.]” (D.I. 394, ex. F at ¶¶ 117, 150-53, 169) In Plaintiffs’ expert Martin C. Michel, M.D.’s Rebuttal Report, in a section entitled “Astellas’s ‘532 Patent Concerns the Potential Treatment of Obesity/Diabetes—There was No Motivation for a POSA to Select Astellas’s ‘532 Patent When Looking For an OAB Treatment[.]” Dr. Michel opines that the ‘532 patent does not allow for the selection of any compound with the reasonable expectation of success for treating OAB, and furthermore, that there was no motivation for a POSA to select

any of one of the more than 100 compounds disclosed in that patent for OAB treatment, including the Example 41 compound (i.e., mirabegron). (*Id.*, ex. C at ¶¶ 217-20, 225-26, 228) These are among the paragraphs that Defendants seek to strike.⁵

4. The material relating to Plaintiffs' selection theory does not amount to an untimely or otherwise improper disclosure. Rather, the Court finds that this theory is proper rebuttal to Defendants' experts' invalidity assertions. *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); *see also* (D.I. 409 at 3 (Defendants acknowledging that "Astellas relies heavily on the 'selection' theory . . . as part of its rebuttal to Defendants' invalidity defenses")) While it may be true that Defendants sought information from Plaintiffs regarding their validity contentions during the discovery period, to the extent that Defendants were unsatisfied with Plaintiffs' responses, they could have filed a motion to compel a more complete or narrow response. (Had they, they almost certainly would have obtained relief, at least with regard to Plaintiffs' response to Defendants' Interrogatory No. 15, which said little but basically left open the possibility that Plaintiffs might argue *anything* in later rebutting Defendants' invalidity positions.). But

⁵ As another example, Defendants seek to strike portions of the Rebuttal Expert Report of Plaintiffs' expert Allan S. Myerson, Ph.D. wherein Professor Myerson opines that Defendants' experts Michael J. Cima, Ph.D. and Craig Eckhardt, Ph.D. fail to consider, in their invalidity analysis, the full scope and content of the '532 patent because the person of ordinary skill would have been looking at hundreds (if not thousands) of possible candidate compounds, not just mirabegron, and the experts provide no basis for motivation to focus on mirabegron. (*See, e.g.,* D.I. 394, ex. A at ¶¶ 150-51, 154-56)

Defendants did not. And, having failed to do so, Defendants had to have anticipated that Plaintiffs' Rebuttal Expert Reports regarding invalidity would say more than simply "Defendants' experts are wrong."⁶ Cf. *San Disk Corp. v. Round Rock Research LLC*, No. C 11-5243 RS, 2014 WL 2700853, at *3 (N.D. Cal. June 13, 2014) (denying plaintiff's motion to strike expert's descriptions of new indirect infringement theories not sufficiently set out in infringement contentions on that topic, and agreeing that "if [plaintiff] believed the infringement contentions were inadequate, it should have moved to compel amended contentions during discovery[;]" but granting the motion to strike as to additional accused products other than those that were "expressly" identified in infringement contentions because "[u]ntil the expert reports were served that identified [new] product lines [plaintiff] had not understood to be part of the case, [plaintiff] had no reason to know of any inadequacies in [defendant's] infringement contentions"). The Court therefore DENIES Defendants' Motion as it relates to Plaintiffs' selection theory.

5. With regard to Plaintiffs' inventorship story, the Court reaches the same conclusion. While Defendants suggested during the discovery period (i.e., by way of deposition questioning) that they would assert, *inter alia*, that Mr. Susumu Igarashi should have been a named inventor of the polymorph patents, (*see, e.g.*, D.I. 394, ex. R at Awamura Dep. Tr. at 244-45, 255-68; *see also* D.I. 409, ex. HH at 2), Plaintiffs first learned all of the details of Defendants' improper inventorship claim only when Defendants served their Final Invalidity

⁶ Defendants further assert that they were surprised by Plaintiffs' selection theory because it "has been rejected by the Federal Circuit." (D.I. 392 at 5 & n.26; Tr. at 62-63 ("The selection theory was surprising in that the [F]ederal [C]ircuit has rejected it before, so we were . . . surprised that they went that way.")) The issue of whether the selection theory is legally sound, however, is not presently before the Court. (Tr. at 63)

Contentions in October 2018, (D.I. 394, ex. V at 204-06), with the claim being further discussed in Professor Cima’s November 2018 opening report, (*id.*, ex. E at ¶¶ 198-206; *see also, e.g.*, D.I. 392 at 5 n.28 (“Defendants’ Final [Infringement Contentions] and Cima Opening [Report] summarize our understanding of the . . . invention story [relating to the polymorph patents] after fact discovery.”)) To the extent that Defendants were unsatisfied during the discovery period with Plaintiffs’ “minimal additional information [beyond largely “rehashed information” from the publicly available polymorph patents] about when each of the asserted claims was invented and by whom[,]” (D.I. 392 at 5-6), Defendants could have moved for relief from the Court, but they did not. The portions of Professor Myerson’s Rebuttal Report that Defendants seek to strike regarding the inventorship story of the polymorph patents directly rebut Professor Cima’s inventorship analysis. (*See* D.I. 394, ex. A at Section IX.F; D.I. 392 at 5 n.27; D.I. 399 at 5; D.I. 409 at 3 (Defendants acknowledging that “Astellas relies heavily on the . . . new PM ‘inventorship’ story as part of its rebuttal to Defendants’ invalidity defenses”)) Under these circumstances, the Court concludes that this disclosure is not untimely or otherwise improper. Defendants’ Motion as it relates to the inventorship story is DENIED.

6. Because this Memorandum Order may contain confidential information, it has 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 20, 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.

Handwritten signature of Christopher J. Burke in cursive script.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE