IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM ORDER

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") (collectively, Defendants") Motion relating to their request to strike Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.'s (collectively, "Astellas" or "Plaintiffs") expert opinions on secondary considerations of non-

[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.

obviousness ("SC").[2] (D.I. 392 at 1-3; D.I. 409 at 1-3) With respect to this issue,[3] 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.")).[4]

I. LEGAL STANDARD

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).

---

[2] Secondary considerations of non-obviousness are often also referred to as "objective indicia of non-obviousness."

[3] The Court has resolved the parties' other issues implicated by the Motion in prior Memorandum Orders. (D.I. 426; D.I. 436; D.I. 437; D.I. 438)

[4] Plaintiffs presently assert four patents in this case. Two of them, United States Patent Nos. 7,342,117 (the "'117 patent") and 7,982,049 (the "'049 patent"), recite mirabegron crystals (or "polymorphs"). (*See* D.I. 392 at 1 n.2) The other two patents, United States Patent Nos. 8,835,474 (the "'474 patent") and RE44,872 (the "'872 patent") recite methods of treating overactive bladder ("OAB") with mirabegron. (*Id.*)

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).

II. DISCUSSION

The present dispute relating to SC is a "continuation" of a previous discovery dispute addressed by the Court in October 2018. (D.I. 392 at 1) In connection with that previous discovery dispute, Sawai sought to strike Plaintiffs' Second Supplemental Response to Defendants' Interrogatory No. 14, in which Plaintiffs had belatedly provided, for the first time, meaningful articulations of their contentions regarding SC. (*See* D.I. 346 at 1-3)[5] In an October 24, 2018 Memorandum Order (the "October 2018 Order"), the Court ruled on the dispute as follows:

> Plaintiffs' [Third] Supplement[6] is not stricken from the case, and in making its secondary considerations case at trial, Plaintiffs and their experts may rely on any evidence/argument fairly raised in the [Third] Supplement. However, absent further order of the Court, Plaintiffs' reliance on secondary considerations is limited to the content of the [Third] Supplement.

(*Id.* at 5) The Court further permitted Sawai to take "targeted discovery relating to secondary considerations." (*Id.*)

---

[5] Plaintiffs served this response approximately two months after fact discovery had closed. (D.I. 346 at 3)

[6] While the October 2018 Order limited Plaintiffs to their Second Supplemental Response, Sawai subsequently agreed to allow Plaintiffs to rely on their Third Supplement, in which Plaintiffs clarified language and added a few of Sawai's own documents to one contention. (D.I. 392 at 1 n.4) Thus, the Court will hereafter refer to the "Third Supplement" as the document at issue.

Now, Defendants assert that Plaintiffs have violated the October 2018 Order by including "new details, evidence, and theories" relating to SC (i.e., beyond the content found in Plaintiffs' Third Supplement) in four rebuttal expert reports served in February 2019.[7] (D.I. 392 at 1) Accordingly, Defendants argue that "the entire issue of SC" should be excluded from this case. (*Id.* at 3 (emphasis omitted)) Alternatively, if the Court finds that SC in its entirety should not be excluded, Defendants seek to strike the portions of the rebuttal expert reports that raise new SC theories, arguments and evidence beyond the Third Supplement. (*Id.* at 3 n.15) Specifically, Defendants list out six SC[8] for which Plaintiffs' experts purportedly included new details, evidence and theories beyond that set out in the Third Supplement. (*Id.* at 1-2) For each of these, Defendants also cite to the relevant page number(s) of the Third Supplement and the paragraphs of the various expert rebuttal reports purportedly containing new content beyond that found in the Third Supplement. (*Id.* at 1-2 & nn. 5-10)

Plaintiffs, for their part, respond that their experts offered opinions on SC "consistent with what was fairly raised" in the Third Supplement. (D.I. 399 at 2) Beyond that, they contend that many of the objected-to paragraphs of their experts' reports were not limited to SC, but were "in direct response to Defendants' experts' alleged *prima facie* obviousness or nonenablement analyses[.]" (*Id.* at 3) The October 2018 Order did not preclude Plaintiffs' experts from

---

[7] These reports of Allan S. Myerson, Ph.D., Victor W. Nitti, M.D., Martin C. Michel, M.D. and Christopher A. Vellturo, Ph.D., (D.I. 394, exs. A-D), were provided in response to Defendants' opening invalidity expert reports prepared by Michael J. Cima, Ph.D., Michael B. Chancellor, M.D. and Craig Eckhardt, Ph.D., (*id.*, exs. E-G).

[8] These consist of teaching away, failure of others, praise by others, commercial success, long-felt need and unexpected results.

rebutting Defendants' experts' invalidity opinions set out in their opening reports, and Plaintiffs therefore assert that such rebuttal opinions and evidence are proper. (*Id.*)

The Court will take up each of the six SC highlighted by Defendants in turn.[9]

A. Teaching Away

Defendants first assert that Plaintiffs violated the October 2018 Order by including new content in their experts' reports relating to the "supposed 'teaching away' of references other than [Plaintiffs' United States Patent No. 6,346,532 B1 (the "'532 patent")] mentioned in the [Third] Supplement[.]" (D.I. 392 at 1 & n.5)[10] The Court does not agree.

In the Third Supplement, Plaintiffs first take up teaching away with respect to the '117 and '049 patents. For those patents, Plaintiffs assert that had a person of ordinary skill in the art ("POSA") been motivated to develop a mirabegron drug product, the POSA would have been motivated to use the dihydrochloride crystal form of mirabegron disclosed in the '532 patent, not the crystalline free base form of mirabegron recited in the '117 and '049 patents. (D.I. 394, ex. H (hereinafter, "Third Supp.") at 30) In the next paragraph, Plaintiffs argue that:

> As to the '474 and '872 Patents, beta-adrenergic receptors were known, for example, to be present in, *inter alia*, the heart, and stimulation of these receptors in the heart was known to, *inter alia*, increase heart rate and cardiac contractility; and were known to be present in, *inter alia*, the smooth muscle of blood vessels and the trachea, and stimulation of these receptors was known to, *inter alia*, lead to muscle tremors and tachycardia.

---

[9] At the outset, the Court DENIES Defendants' request to strike SC in its entirety. As discussed below, the Court finds that a good portion of the objected-to content was fairly raised in the Third Supplement. Accordingly, the Court will proceed by comparing the objected-to paragraphs with the content of the Third Supplement, assessing whether in any instance, certain material should be stricken because it does not comply with the Court's October 2018 Order.

[10] The '532 patent is another Astellas patent, which is not being asserted in this case. (*See, e.g.*, D.I. 394, ex. C at ¶ 4)

(*Id.*) Plaintiffs do not cite to any materials in support of this statement.

Turning to the four paragraphs of Dr. Michel's report called out by Defendants, (D.I. 392 at 1 n.5 (citing D.I. 394, ex. C at ¶¶ 190-94)), they discuss how the prior art taught away from the potential use of β_3 AR agonists to treat OAB. Dr. Michel contends that a key concern "would have been cardiovascular side effects, most importantly an increased heart rate" as well as muscular tremors, and he cites to various references in support. (D.I. 394, ex. C at ¶¶ 191-94)

The Court finds that such content was "fairly raised" in the Third Supplement. (*See* D.I. 399 at 2) When pressed during telephonic argument as to why the objected-to paragraphs of Dr. Michel's report go beyond the content of the Third Supplement, Sawai's counsel noted that Dr. Michel "relies on a bunch of new evidence that was not cited to us." (Tr. at 59) Defendants' understanding of the Third Supplement had been that Plaintiffs were relying therein only on the '532 patent as support for the teaching away argument relating to the '474 and '872 patents. Defendants thus say they were surprised to see the "many articles" referenced in the relevant paragraphs of Dr. Michel's report. (*Id.* at 61-62) In the Court's view, however, this was not a particularly reasonable assumption. Plaintiffs reference the '532 patent with regard to teaching away in the Third Supplement with respect to different patents (the '117 and '049 patents), and a different issue. Defendants should therefore not have been very surprised to see other references cited in Plaintiffs' experts' reports to support their opinions for teaching away with respect to the '474 and '872 patents.[11] And with respect to the substance of Dr. Michel's report, it does not

[11] As noted above, the October 2018 Order permitted Sawai to "take targeted discovery relating to secondary considerations." (D.I. 346 at 5) While it is not clear on this record what supplemental, targeted discovery actually occurred as a result, Sawai obviously could have pressed for additional information regarding the content of the Third Supplement

seem to be asserting new *theories or arguments* as to why the prior art taught away from the inventions disclosed in the '474 and '872 patents.

B. Failure of Others

Next, Defendants assert that Plaintiffs violated the October 2018 Order by including new content in their experts' reports relating to "drugs other than Detrol® to show supposed 'failure of others[.]'" (D.I. 392 at 1 & n.6) In the Third Supplement, Plaintiffs first generally note that others tried and failed to develop therapies for the treatment of OAB that avoided the side effects of dry mouth, headache, dyspepsia and constipation. (Third Supp. at 29) Plaintiffs next note that Myrbetriq is a "first-in-class drug" and to date the only beta-3 adrenergic agonist that is FDA-approved for the treatment of OAB. Finally, Plaintiffs state that "[f]or example, the anticholinergic drug Detrol (tolterodine tartrate) was FDA approved prior to the priority date of the '474 and '872 [p]atents for the treatment of patients with the symptoms of urinary frequency, urgency or urge incontinence, but the use of [Detrol] resulted in the aforesaid side effects." (*Id.* at 29-30)

Turning to the objected-to paragraphs of Plaintiffs' experts' reports, many of them relate to how mirabegron is a first-in-class drug, (D.I. 394, ex. B at ¶¶ 8, 62, 118, 123, 129; *id.*, ex. C at ¶¶ 12-15, 21, 23, 96-99, 195-201, 231, 333 (citing ¶ 231)), or to Detrol (tolterodine tartrate), (*id.*, ex. B at ¶ 128), which is "argument fairly raised" in the Third Supplement. Aside from those paragraphs, with respect to Dr. Nitti's report, Paragraph 83 seems to reference both Detrol (tolterodine) and another drug, oxybutynin. (*See id.*, ex. B at ¶ 83; *see also, e.g.*, *id.* at ¶ 65 (noting that the two most widely used drugs for OAB in 2002 "were the antimuscarinics

---

through this process (including what articles, if any, Plaintiffs would be relying on to support the statements made in the Third Supplement).

oxybutynin (brand name DITROPAN®) and tolterodine (brand name DETROL®)")) Because Plaintiffs did not reference oxybutynin in their Third Supplement, they may not rely on those portions of paragraph 83 in support of their failure of others argument.[12] Paragraph 84 relates to antimuscarinics generally, of which Detrol is one, and thus Plaintiffs may rely on such content in support of SC. Paragraph 127 generally notes that others tried and failed to develop a treatment for OAB that minimized side effects, and cites in support to two prior sections of the report, which relates to content fairly raised in the Third Supplement.[13] With respect to Dr. Michel's report, the highlighted portions of paragraphs 66 and 71 reference drugs other than Detrol, and Plaintiffs therefore may not rely on this content in support of failure of others. (*Id.*, ex. C at ¶¶ 66, 71)

C. Praise by Others

---

[12] With respect to this content and other content of Plaintiffs' experts' reports that the Court finds below as going beyond the Third Supplement (such that they may not be utilized for SC), Plaintiffs are *not* precluded from relying on such content as rebuttal to Defendants' *prima facie* obviousness case, if identified as such in their responsive letter. (D.I. 399 at 3; *see also* Tr. at 69-70) Although Defendants assert that such content relates to Astellas' untimely "selection" theory and is not proper rebuttal for that reason, (D.I. 409 at 2 & n.4), the Court has recently rejected that argument, (D.I. 438 at 3-6).

[13] The two prior sections of the report referenced here are Sections X.A and IX.E. Defendants did not specifically argue that these paragraphs cited in paragraph 127 should also be stricken, as it did elsewhere, (*see, e.g.*, D.I. 392 at 2 n.9), so it is unclear to the Court whether Defendants are really asking the Court to strike these paragraphs with respect to failure of others. Defendants highlighted in blue the content that they seek to strike with respect to SC. (Tr. at 57-58) Section X.A is not highlighted in blue, so the Court assumes that Sawai does not take issue with it with respect to SC. Section IX.E. does have certain portions highlighted in blue. (*See* D.I. 394, ex. B at ¶¶ 63-66, 68-69) The content of paragraphs 63 and 64 do not relate to "drugs" other than Detrol, (D.I. 392 at 1), and therefore the Court will not strike such content. Portions of paragraphs 66, 68 and 69 do relate to drugs other than Detrol, and Plaintiffs therefore may not rely on the highlighted content in support of failure of others.

Third, Defendants assert that Plaintiffs violated the October 2018 Order by including new content in their experts' reports relating to "supposed 'praise by others' beyond the three awards explicitly cited in the [Third] Supplement[.]" (D.I. 392 at 1-2 & n.7) In the Third Supplement, Plaintiffs generally asserted that "Myrbetriq® (mirabegron) has received industry recognition and praise because of, *inter alia*, the properties of the crystalline form of mirabegron claimed in [certain asserted claims] and "because of the approval and use of Myrbetriq® for the methods of treatment claimed in [certain asserted claims]." (Third Supp. at 28) Plaintiffs then list three awards that Myrbetriq has received, "[f]or example[:]" (1) the Okochi Memorial Technology Award from the Okochi Memorial Foundation; (2) the Pharmaceutical Society of Japan Award for Drug Research and Development from the Pharmaceutical Society of Japan; and (3) the Japan Institute of Invention and Innovation Tokyo Excellence Award from the Japan Institute of Invention and Innovation. (*Id.*)

The paragraph called out by Defendants in Dr. Nitti's report regarding praise by others asserts that the launch of Plaintiffs' Myrbetriq in 2012 received praise by others, including: (1) certain statements previously discussed in Dr. Nitti's report; and (2) certain awards discussed previously in the report. (D.I. 394, ex. B at ¶ 134) The "awards" that Dr. Nitti references here are the same three awards discussed in the Third Supplement. (*Id.* at ¶¶ 93-96)[14] However, the "statements" referenced in this paragraph were those made in conjunction with clinical studies on Myrbetriq, such as investigators' conclusions regarding the low level of side effects, as well as statements in journal articles praising the drug. (*Id.* at ¶¶ 79-92) Because such statements do

[14] Defendants do not appear to seek to strike these paragraphs, as they are not highlighted in blue.

not constitute "evidence/argument fairly raised" in the "praise by others" section of Plaintiffs' Third Supplement, as even Plaintiffs acknowledge, (*see* Tr. at 71),[15] Plaintiffs may not rely on these paragraphs in support of their arguments regarding praise by others.[16]

D. Commercial Success

Fourth, Defendants assert that Plaintiffs violated the October 2018 Order by including new content in their experts' reports relating to "different bases for the supposed 'commercial success' of Myrbetriq®[.]" (D.I. 392 at 2 & n.8) In the Third Supplement, Plaintiffs asserted that Myrbetriq is commercially successful because of the claimed properties of the crystalline form of mirabegron recited in the asserted claims of the '117 and '049 patents, and because mirabegron is approved, sold and used for the methods of treatment claimed in the asserted claims of the '474 and '872 patents. (Third Supp. at 26-27) Plaintiffs then cited to illustrative documents produced demonstrating the commercial success of their drug, and noted that "[f]or

---

[15] In asserting that their experts offered opinions on SC consistent with what was fairly raised in the Third Supplement, with respect to industry praise, Plaintiffs' letter noted that both their expert and the Third Supplement discussed "awards" received for mirabegron, but they left unaddressed these other statements relied upon by Dr. Nitti. (D.I. 399 at 2)

[16] Normally, expert reports may provide more detail than that disclosed in a party's contentions. *See, e.g.*, *Largan Precision Co. v. Genius Elec. Optical Co.*, Case No. 13-cv-02502-JD, 2014 WL 6882275, at *7 (N.D. Cal. Dec. 5, 2014) ("[E]xpert reports are meant to provide more detail than contentions."); *Dig. Reg of Texas, LLC v. Adobe Sys. Inc.*, No. CV 12-01971-CW (KAW), 2014 WL 1653131, at *5 (N.D. Cal. Apr. 24, 2014) ("[E]xpert reports may include information obtained during discovery[.]"); *Apple Inc. v. Samsung Elecs. Co.*, Case No.: 5:12-cv-0630-LHK-PSG, 2014 WL 173409, at *1 (N.D. Cal. Jan. 9, 2014) ("Expert reports may not introduce theories not set forth in contentions.[] The scope of contentions and expert reports are not, however, coextensive.[] Contentions need not disclose specific evidence, whereas expert reports must include a complete statement of the expert's opinions, the basis and reasons for them, and any data or other information considered when forming them."). Here, however, where Plaintiffs clearly violated their discovery obligations relating to SC, (*see, e.g.*, D.I. 346 at 2-3), the import of the Court's October 2018 Order was to rule that Plaintiffs will be held to a tougher standard—i.e., they may not rely on new arguments or evidence in support of their SC case not fairly raised in the Third Supplement.

example," certain documents show an increase in net sales and the total number of prescriptions recorded per month for Myrbetriq in the United States from October 2012 through June 2018. (*Id.* at 27)

Turning first to the objected-to paragraphs of Plaintiffs' expert Dr. Vellturo's report, certain of them reflect argument that was fairly raised in the Third Supplement, including the increase in prescriptions for Myrbetriq, (D.I. 394, ex. D at ¶ 39), and the assertion that Myrbetriq is a first-class drug and that it is the commercial embodiment of the '474 and '872 patents, (*id.* at ¶¶ 8, 45-50). Certain other of the objected-to paragraphs of Dr. Vellturo's report appear to rebut opinions raised in Defendants' opening expert reports on invalidity regarding the '532 patent, (*id.* at ¶¶ 61-62), which is proper content in Plaintiffs' experts' reports, (D.I. 399 at 3 (Plaintiffs noting that while the Court ordered that Plaintiffs could not rely on evidence/argument that were not "'fairly raised'" in their Third Supplement for SC, the Court "did *not* preclude Astellas' experts from *rebutting* opinions and evidence raised in [D]efendants' opening invalidity expert reports") (certain emphasis in original)). And yet others simply seem to be providing background information with regard to OAB and the treatment of OAB; these need not be stricken. (D.I. 394, ex. D at ¶¶ 15-23, 25, 27, 30) The remaining objected-to paragraphs of Dr. Vellturo's report, (*id.* at ¶¶ 9-10, 36, 52-55 and 60), do not discuss content fairly raised by Plaintiffs' Third Supplement. Therefore, Plaintiffs may not rely on these paragraphs for the SC of commercial success.

Defendants next object to several paragraphs found in Dr. Nitti's report. (D.I. 392 at 2 n.8 (citing D.I. 394, ex. B at ¶¶ 56-87, 124-25)) Yet most of these paragraphs do not seem

directly related to commercial success[17] and it is not clear to the Court that Plaintiffs intend to rely on them with respect to this SC. Indeed, many of these paragraphs are not highlighted in blue, which leads the Court to wonder if Defendants inadvertently cited to them in their letter with respect to commercial success. Paragraphs 56-57 seem to just provide background regarding the economic burden of OAB as of November 7, 2002. Paragraph 58 discusses the cause of OAB as of November 7, 2002. Paragraph 59 generally notes how it was difficult to develop new treatments for OAB, an assertion fairly raised in the Third Supplement's discussion of failure of others. Paragraphs 60-62, 75-78 and 85-87 relate to how Myrbetriq was a first-in-class drug with low side effects, points that are addressed in the Third Supplement's discussion of other SC. Paragraphs 63-74 and 83-84 relate to other treatments for OAB. Paragraphs 79-82 relate to clinical studies regarding Myrbetriq. In light of the uncertainty with respect to these paragraphs, the Court declines to strike them on these grounds.[18]

With respect to the two objected-to paragraphs of Dr. Michel's report, they too do not violate the Court's October 2018 Order. Paragraph 234 states that Myrbetriq has been a "very significant commercial success" because of the unexpected attributes of improved safety and efficacy. (D.I. 394, ex. C at ¶ 234) This content is fairly raised by the Third Supplement, which asserts that Myrbetriq is commercially successful because of the properties of the crystalline

---

[17] Dr. Nitti never uses the term "commercial success" in his report. He does include a section entitled "[t]he [d]iscovery [o]f [m]irabegron [a]nd [i]ts [s]uccessful [t]reatment [o]f OAB [h]as [b]een [p]raised [b]y [o]thers," but this paragraph relates to the SC of praise by others. (D.I. 394, ex. B at ¶ 134)

[18] Paragraphs 124 and 125, as Plaintiffs indicate, relate to the assertion that Myrbetriq is the commercial embodiment of the asserted patents claiming mirabegron for treating OAB, (D.I. 394, ex. B at ¶¶ 124-25), content that was fairly raised in Plaintiffs' Third Supplement with respect to commercial success, (D.I. 399 at 2).

form of mirabegron claimed in the patents. Paragraph 333 is a general paragraph referencing prior discussion of various SC, including paragraph 234, and stating that such SC support the opinion that the inventions set out in the asserted claims would not have been obvious to a POSA. (*Id.* at ¶ 333)

E. Long-felt Need

Fifth, Defendants assert that Plaintiffs violated the October 2018 Order by including new content in their experts' reports regarding the '474 and '872 patents relating to "post-patent filing data (e.g., clinical trials) to show mirabegron met a supposed 'long-felt but unmet need[.]'" (D.I. 392 at 2 & n.9)[19] In Plaintiffs' Third Supplement with respect to long-felt need, Plaintiffs assert that Myrbetriq is "the only FDA-approved mirabegron product" and "[t]o date, no other crystalline or non-crystalline form of mirabegron has been FDA-approved." (Third Supp. at 28) Plaintiffs note that Myrbetriq is FDA-approved for the treatment of OAB with particular symptoms and administered by physicians and patients for such treatment. (*Id.* at 28-29) Plaintiffs also reiterate that Myrbetriq is the only FDA-approved beta-3-adrenergic agonist for the treatment of OAB, and prior to the priority date of the '474 and '872 patents, the available FDA-approved oral pharmaceutical treatments for OAB had significant side effects. (*Id.* at 29)

Turning to the objected-to paragraphs of Dr. Nitti's report, Defendants object to paragraph 133 of Dr. Nitti's report, which references three prior sections as supporting his

---

[19] Defendants further assert that Plaintiffs never disclosed their opinion that the '117 patent and the '049 patent met a long-felt, but unmet need in the Third Supplement, yet Dr. Myerson's rebuttal report includes this new theory. (D.I. 392 at 2 & n.11 (citing D.I. 394, ex. A at ¶ 215)) Plaintiffs have agreed to withdraw this paragraph of Dr. Myerson's report, and they represent that they will not rely on this opinion at trial. (D.I. 399 at 2 n.2) Thus, this argument is moot.

opinion that mirabegron satisfied a long-felt unmet need. (D.I. 394, ex. B at ¶ 133) Of the paragraphs in those three sections, paragraphs 79-92 are the ones relating to post-patent filing data (e.g., clinical trials), which subject matter Defendants particularly call out as going beyond the Third Supplement's discussion of long-felt need. (D.I. 392 at 2) Upon review, the Court finds that these paragraphs relate to content fairly raised in the Third Supplement. Dr. Nitti's discussion of clinical trials and studies in these paragraphs relate to: (1) Myrbetriq's FDA-approval for OAB; and (2) how prior to Myrbetriq's entrance on the market, the available FDA-approved treatments for OAB had certain significant side effects which adversely impacted their use and patient compliance. (D.I. 394, ex. B at ¶¶ 79-92)[20]

As for Dr. Michel's report, certain of the objected-to paragraphs contain content "fairly raised" in the Third Supplement. Paragraph 64 generally summarizes how OAB and its symptoms had been difficult to satisfactorily treat by November 7, 2002, a point that is asserted in the Third Supplement. (*Id.*, ex. C at ¶ 64) Paragraphs 67-69 discuss how available FDA-approved oral treatments for OAB had significant side effects that meant that patient compliance when taking such treatments was poor. (*Id.* at ¶¶ 67-69) Paragraph 86 relates to how Myrbetriq is the only FDA-approved beta-3-adrenergic agonist for the treatment of OAB. (*Id.* at ¶ 86) Paragraph 333 is a general paragraph referencing prior discussion of various SC, including paragraph 233 which relates to long-felt need. (*Id.* at ¶ 333)

The remaining objected-to paragraphs, (*id.* at ¶¶ 65-66, 70-85), however, do seem to stretch beyond the content fairly raised in the Third Supplement in addressing potential drug

---

[20] The other paragraphs relate to OAB management and treatment as of November 7, 2002, (*id.* at ¶¶ 63-69), and the Court finds that the portions of such paragraphs highlighted in blue go beyond the content discussed in the Third Supplement's discussion of long-felt need, (Third Supp. at 28-29), and therefore may not be relied upon for the SC of long-felt need.

targets and treatments beyond those that were FDA-approved prior to the priority date of the '474 and '872 patents. Plaintiffs may not rely on these paragraphs in support of the SC of long-felt need.

F. Unexpected Results

Finally, Defendants assert that Plaintiffs violated the October 2018 Order by including new content in their experts' reports relating to "any previously undisclosed 'unexpected results[.]'" (D.I. 392 at 2 & n.10) In the Third Supplement, Plaintiffs state that the crystalline form of mirabegron claimed in certain claims of the '117 and '049 patents demonstrated unexpected results to a POSA, such as, "[f]or example," unexpected stability, bioavailability, and exhibition of "a lack of hygroscopicity as compared to other solid state forms of mirabegron, including the dihydrochloride salt of mirabegron and the ß-form crystalline form of mirabegron free base." (Third Supp. at 31) With respect to the claimed methods in the asserted claims of the '474 and '872 patents, they were said to have also demonstrated unexpected results such as, "[f]or example[:]" (1) particular action strengths as compared to the control compounds in certain isolated rat bladder smooth muscle relaxation tests; (2) mirabegron is exceptionally selective for beta-3-adrenergic receptors in human bladder tissue; (3) mirabegron is unexpectedly safe and effective in treating OAB, including the symptoms of urgency, urge urinary incontinence and urinary frequency; and (4) mirabegron has a low incidence and severity of side effects at therapeutically effective doses.

Upon review of the objected-to paragraphs of Plaintiffs' experts' reports, they seem to either be mistakenly cited to by Defendants, or they do not contain content beyond that fairly raised by the Third Supplement. Defendants cite first to paragraphs 67-71 of Dr. Michel's report. These paragraphs discuss how other treatments for OAB had frequent adverse side

effects. (D.I. 394, ex. C at ¶¶ 67-71) They are not referenced in the specific paragraph of the report discussing unexpected results, (*id.* at ¶ 232), nor expressly cited therein. This paragraph, paragraph 232, explains that the fact that mirabegron had desirable properties among the entire class of disclosed $ß_3$ AR agonists could not have been predicted, since mirabegron was the first and only drug approved by the FDA as safe and effective, and no other drug from this class has been approved since. If paragraphs 67-71 relate to this class of drugs, then the content therein is fairly raised by the Third Supplement, since the Third Supplement discusses how it was unexpected that mirabegron would be safe and effective and have low incidence and severity of side effects. If they do not, then the Court is unsure how they relate to unexpected results and whether Plaintiffs are even relying on them for this SC. (*See, e.g.*, D.I. 399 at 2 (Plaintiffs' letter not citing these paragraphs in reference to unexpected results)) Defendants next object to paragraph 232 of Dr. Michel's report, though the discussion in this paragraph contains argument "fairly raised" in the Third Supplement as it discusses mirabegron's unexpected desirable properties, including how it was found to be a safe and effective treatment for OAB. (D.I. 394, ex. C at ¶ 232) Objected-to paragraph 333 is a paragraph in which Dr. Michel cites back to the paragraphs in which he discussed SC, including paragraph 232, which support his opinion that the inventions were not obvious. Finally, Defendants object to paragraph 130 of Dr. Nitti's report. This paragraph cites to other sections of the report which demonstrate how Plaintiffs' discovery that mirabegron would usefully treat OAB with a low incidence and severity of side effects was an unexpected result, (*id.*, ex. B at ¶ 130), a result referenced in the Third Supplement.[21]

---

[21] Defendants also object to Dr. Vellturo's and Dr. Nitti's reliance on "Astellas documents whose Bates Numbers were not specifically cited or discussed in the [Third]

III. CONCLUSION

For the foregoing reasons, Defendants' Motion is GRANTED-IN-PART and DENIED-IN-PART. Plaintiffs may not rely on the paragraphs identified above as going beyond the content of the Third Supplement in support of their particular SC arguments.

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 31, 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.

Dated: May 28, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

Supplement, but were arguably 'disclosed' by their inclusion in either a 4,000- or 500,000-page citation as part of string cites under 'Rule 33(d).'" (D.I. 392 at 2 n.13) The Court is not persuaded by this objection. In the prior discovery dispute regarding SC, Sawai did not specifically raise an issue with the documentation cited in the Third Supplement. (*See* D.I. 342) Sawai had the ability to take supplemental discovery on SC and could have pressed for more information regarding the specific portions of documents being relied upon. In light of this, the Court will not find that reliance on these documents is wrongful or that reference to the documents should be stricken.