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. (D.I. 391)[1] 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. ("collectively, "Sawai") intentionally withheld samples of Sawai's [redacted] used to make Sawai's proposed Abbreviated New Drug Application ("ANDA") product.[2] With respect to this issue, the Court has considered the parties' letter briefs, (D.I. 393, 398, 408), and the parties' arguments made during the April 17, 2019 teleconference, (D.I. 420 (hereinafter, "Tr.")).

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[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).

I. BACKGROUND

The Court first provides a high-level overview of the infringement issues regarding Sawai's proposed ANDA product that are relevant to this dispute. Then, the Court will describe the relevant factual background.

A. Infringement Issues

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 recite methods of treating overactive bladder with mirabegron. (*Id.*)

According to Plaintiffs, there is no dispute that [redacted]. (D.I. 393 at 3 n.7; *see also, e.g.*, D.I. 211, ex. 4 at SAW-MIR 0000043) Sawai's ANDA describes a manufacturing process that [redacted]. (*See* D.I. 211, ex. 4 at SAW-MIR 0000043; D.I. 393 at 3 n.7; D.I. 393, ex. 16 at ¶ 241) [redacted] (*See* D.I. 209 at 1; D.I. 393, ex. 16 at ¶¶ 243, 246) Plaintiffs, for their part, assert that [redacted] (*See, e.g.*, D.I. 393 at 3; D.I. 398, ex. 25 at 18)

B. Factual Background

During fact discovery,[3] on May 23, 2017, Plaintiffs served Sawai with, *inter alia*, Request for Production of Documents and Things No. 26 ("RFP No. 26"), which requested production of:

> 26. At least: (a) fifty (50) grams of Sawai's ANDA Product, (b) fifty (50) grams of any [redacted] for use in Sawai's ANDA Product, (c) fifty (50) grams of Mirabegron API for use in Sawai's ANDA Product, (d) fifty (50) uncoated tablets of Sawai's ANDA Product, and (e) fifty (50) coated tablets of Sawai's ANDA Product, each being representative of Sawai's ANDA Product and that have not passed their respective expiration dates (to the extent the requested amount of an unexpired sample(s) is not available, then in addition to the requested sample(s), the requested amount of the sample(s) that is representative of, or meets the specifications for use in, Sawai's ANDA Product).

(D.I. 393, ex. 2 at 15) On July 6, 2017, Sawai objected to RFP No. 26 for a number of reasons, including "to the extent that [the request] seeks samples in amounts larger than Sawai Defendants currently have in their possession, custody, or control and/or that would leave Sawai Defendants with insufficient amounts of samples for regulatory purposes in connection with Sawai's ANDA product." (*Id.*, ex. 3 at 51) Sawai also objected to the Request "to the extent it seeks production of things outside [Sawai's] possession, custody, or control." (*Id.*)

Next, in response to an August 29, 2017 correspondence from Plaintiffs seeking production of "certain unexpired representative samples[,]"[4] Sawai disputed the relevance of such samples, and further noted that the "requested samples are not in Sawai's possession, but may be in the possession of the [contract manufacturing organization] Strides Shasun

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

[4] Plaintiffs' correspondence is not in the record, and thus it is unclear whether [redacted] was among the samples explicitly requested.

[hereinafter, 'Strides']." (*Id.*, ex. 4; *see also* Tr. at 18)[5] The parties continued to meet and confer, and on September 15, 2017, Plaintiffs agreed to accept samples of the final tablets and the API, with the understanding that, *inter alia*, "Plaintiffs may seek additional samples, including, e.g., uncoated tablets [redacted] up to the amounts requested in RFP No. 26 should the amounts being produced be insufficient to conduct polymorph testing[.]" (D.I. 393, ex. 5 at 3 (emphasis added)) Sawai responded on September 22, 2017 that "by providing [samples of the final tablets and the API], Sawai and/or Strides are not waiving nor intending to waive [] the ability to object to any Astellas' request(s) for additional samples for the reasons stated in Sawai's response to" RFP No. 26. (*Id.* at 2)

On January 22, 2018, Plaintiffs renewed their request that "Sawai produce fifty (50) grams of [redacted] that is unexpired and representative of [redacted] described in Sawai's ANDA[.]" (*Id.* at 1-2) The next day, Sawai's counsel responded that he had "confirmed that Sawai does not have these samples in its possession. Previously, Strides [] indicated to us that they *did not have any* of these samples either. However, we are working to confirm with Strides *whether they currently have* [redacted] (*Id.* at 1 (emphasis added)) On January 29, 2018, Sawai's counsel e-mailed Plaintiffs' counsel to say that Sawai had "heard from Strides today and *they do not have any* [redacted] . . . you requested." (*Id.*, ex. 6 at 1 (emphasis added))[6] At that point, "Plaintiffs did not further pursue samples that Sawai represented no longer existed." (D.I. 393 at 3)

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[5] Sawai's letter does not make any mention of having to withhold any samples for regulatory purposes.

[6] The Court will herein refer to the two January 2018 e-mails from Sawai's counsel that are referenced in this paragraph as the "January 2018 e-mails."

As it turns out, however, Strides *did* still have [redacted] as of January 2018. More specifically, it still had samples that it had stored in a sealed container back in [redacted] Strides thereafter periodically tested these samples both before and after January 2018 "as part of an ongoing stability program for Sawai." (*Id.*; *see also* D.I. 408 at 1; Tr. at 22-23) Plaintiffs assert that they first learned that Strides still had such [redacted] on September 14, 2018 (the same day as the Rule 30(b)(6) deposition of Strides' witness), when Sawai produced a "Long Term Stability – Summary Report" that summarized stability testing done by Strides on [redacted] on dates both before and after January 2018. (D.I. 393 at 3; *id.*, ex. 7; *see also* D.I. 408 at 1; Tr. at 12)

Such stability testing is also referenced in Sawai's ANDA. Sawai's [redacted] ANDA, produced to Plaintiffs in April 2017, proposes "[redacted]"[7] for Sawai's ANDA product, while noting that "[redacted]." (D.I. 398, ex. 21 at SAW-MIR 0005120) This ANDA document, entitled "Stability Summary and Conclusions[,]" references [redacted] (*Id.* at SAW-MIR0005117-18 & SAW-MIR 0005123; *see also* D.I. 398 at 3 & n.10; Tr. at 22-23) According to Plaintiffs, "Sawai now represents that [redacted] [that Strides had] [redacted]" (D.I. 393 at 3)

In his April 2, 2019 Rebuttal Expert Report (the "report") on Sawai's non-infringement of the '117 patent and the '049 patent, Sawai's expert, Michael J. Cima, Ph.D., relies on Strides'

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[7] [redacted] from the date of the ANDA document occurred in March 2017. (*See* D.I. 408 at 1)

testing of [redacted]. (*See, e.g.*, *id.*, ex. 16 at ¶ 456) Plaintiffs now assert that they were surprised by Professor Cima's reliance on Strides' testing of [redacted] to support Sawai's non-infringement argument, and that "Sawai intentionally withheld [redacted] to gain an advantage in this litigation." (D.I. 408 at 1; D.I. 393 at 4; *see also* Tr. at 6 ("Sawai . . . not only withheld these samples but intentionally lied regarding whether they existed or not repeatedly."))

II. LEGAL STANDARDS

A. Motion to Strike

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).

B Spoliation

"Spoliation occurs where: the evidence was in the party's control; the evidence is relevant to the claims or defenses in the case; there has been actual suppression or withholding of evidence; and, the duty to preserve the evidence was reasonably foreseeable to the party." *Bull v. United Parcel Serv. Inc.*, 665 F.3d 68, 73 (3d Cir. 2012). "[A] finding of bad faith is pivotal to a spoliation determination. . . . [w]ithholding [evidence] requires intent." *Id.* at 79 ("As a result, we must be convinced that . . . [the non-movant] intended to actually withhold the [evidence] from [the movant] before we can conclude that sanctionable spoliation occurred.").[8]

III. DISCUSSION

With their Motion, Plaintiffs seek two forms of relief. First, Plaintiffs argue that because Sawai failed to provide samples of [redacted] to Plaintiffs, Professor Cima's reliance on Strides' testing of those samples should be stricken from his rebuttal report. (D.I. 393 at 4) Second, Plaintiffs argue that, because Sawai "let the samples expire," the Court should find such conduct amounts to spoliation of evidence. (*Id.*) As a sanction for spoliation, Plaintiffs further request

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[8] If a court finds that spoliation has occurred, it must determine an appropriate sanction for the suppression or withholding of evidence. This analysis considers: "(1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future." *Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 79 (3d Cir. 1994). Possible sanctions for spoliation include "dismissal of a claim or granting judgment in favor of a prejudiced party;[] suppression of evidence;[] an adverse inference . . .;[] fines;[] and attorneys' fees and costs." *Mosaid Techs. Inc. v. Samsung Elecs. Co.*, 348 F. Supp. 2d 332, 335 (D.N.J. 2004) (citations omitted).

that the Court enter an adverse inference for Plaintiffs' use at trial. (*Id.* at 4-5) The Court will consider these requests in turn.[9]

A. Whether Reference to Testing of [redacted] Should be Stricken

With respect to Plaintiffs' request that Professor Cima's reliance on Strides' testing of the [redacted] be stricken from his report (and that Sawai be precluded from reliance on such testing during trial), the Court must first determine whether Sawai has made an untimely or improper disclosure. If the Court makes such a finding, it must then weigh the *Pennypack* factors to determine whether all or part of the referenced evidence should be excluded.

1. Sawai's Conduct Constitutes an Improper Disclosure

After considering the record, the Court concludes that Sawai's conduct regarding the [redacted] does amount to an untimely or improper disclosure. This is because, in the Court's view, the substance of Sawai's discovery-related responses could have and did reasonably lead Plaintiffs to believe that Strides had no further [redacted] available in January 2018—when in fact, Strides did possess some such samples.

In arguing for a contrary finding, Sawai's counsel has explained that when he wrote the January 2018 e-mails referenced above—e-mails indicating that Strides did not have "any" [redacted]—what he meant was that Strides did not have any [redacted] other than those samples that Strides had stored in a sealed container in 2015 and planned to use for stability

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[9] In their Motion, Plaintiffs had further requested that Sawai be compelled to turn over "any work-product testing it may have conducted on the [redacted] as there is a substantial need to provide all testing of the now-expired [redacted] to Plaintiffs." (D.I. 393 at 4) During the teleconference, however, Plaintiffs represented that they were seeking only that Professor Cima's reliance on the [redacted] testing be stricken, and/or that an adverse inference be entered with regard to the [redacted] (Tr. at 14) The Court thus will focus solely herein on those forms of requested relief.

testing ("samples on stability" or "stability samples"). In Sawai's counsel's view, everyone in the case (including Plaintiffs and their counsel) knew in January 2018 that Strides actually did possess [redacted] (Tr. at 20, 22-23) Thus, according to Sawai's counsel, his statement in a January 2018 e-mail that Strides "did not have any" [redacted] was simply "a short form answer in light of the objections and meet-and-confers [that meant] that Strides did not have any available [redacted] beyond the stability samples[.]" (D.I. 398 at 3) There are, however, at least two problems with this argument.

The first relates to the actual words that Sawai's counsel used in the January 2018 e-mails. Those words, as even Sawai acknowledges, were not as carefully chosen as they should have been. (Tr. at 27 (Sawai's counsel acknowledging that "in hindsight" he should have expressly stated that there were no samples available because the [redacted] that Strides did have were required for stability testing, and that his e-mail response was "perhaps a sloppy shorthand")) The e-mails did not sufficiently explain that Strides "does not have any [redacted] *except for that on stability*" (or use other words to that effect). Instead, the actual text of the e-mails conveyed that Strides does not have "any [redacted]" Lawyers know that words matter. As to a key disputed issue in a case, if a discovery-related response is nuanced, then counsel is responsible for conveying that nuance clearly. Here, Sawai's counsel did not do so.

The second problem is that the record does not clearly establish that Plaintiffs understood what Sawai *says* Plaintiffs understood as of January 2018, i.e., that: (1) Strides did have [redacted], but only those on stability; (2) the samples on stability were off limits to Plaintiffs, and

so (3) any future reference made by Sawai to [redacted] could only be a reference to the existence of [redacted] *other than those on stability*. Recall the history of the discovery dispute at issue:

- In originally propounding RFP No. 26, Plaintiffs were asking for a certain amount of, *inter alia*, [redacted] In doing so, they had not agreed to limit that request only to [redacted] that was not on stability. Sawai, in turn, had responded to that RFP by pressing multiple objections, including that turning over [redacted] could leave Sawai with insufficient [redacted] to use for regulatory purposes.

- Then, in September 2017, when Sawai agreed to turn over samples of the final tablets and the API [redacted], it explained that it was not waiving "*the ability to object*" to any of Plaintiffs' requests for "additional samples[redacted]" for the "reasons stated in Sawai's response to [RFP No. 26]." (D.I. 393, ex. 5 at 2 (emphasis added)) So, at that point it seems that, as far as Plaintiffs knew, if they later asked for additional [redacted], Sawai *might or might not* renew some or all of the same objections that it had originally made to RFP No. 26.

- Next, when Plaintiffs did renew their request for [redacted] in January 2018, they asked for "fifty (50) grams of Sawai's [redacted]" (*Id.*) Nowhere in that renewed request did Plaintiffs say or even hint that: (1) they had now acceded to Sawai's prior position that providing certain [redacted] (i.e., that on stability) was a non-starter due to regulatory concerns; or (2) they were only now asking about [redacted] other than that on stability.

- And importantly, in Sawai's counsel's January 2018 responses to Plaintiffs' request, counsel *did not actually renew or raise any objection* to the request (i.e., an objection based on the need to reserve [redacted] on stability). Instead, he simply told Plaintiffs that Strides did not have "any" [redacted]. (*Id.*, ex. 5 at 1; *id.*, ex. 6 at 1)[10]

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[10] Sawai suggests that the parties had meet and confers beyond the sample-related communications discussed above, during which it made clear that Strides had samples on stability that would not be provided to Plaintiffs. (*See, e.g.*, Tr. at 27 (Sawai's counsel explaining that he did not make this clear in his January 2018 e-mails because "I thought counsel would be aware of the conversations and the full . . . background of this dispute, which was . . . in that time frame . . . repeated. It was not just our response to the RFP. We had meet and confers where we discussed this with them[.]")) The problem is that the details of any such meet and confers are not further fleshed out in the record (such as via a declaration or otherwise), and

Thus, the Court cannot conclude that, when Plaintiffs made the renewed request for [redacted] in January 2018, they surely knew that Sawai was only going to be responding about the availability of [redacted] other than those on stability.[11]

In light of the above, the Court finds that Sawai's January 2018 e-mails were misleading, in that they reasonably led Plaintiffs to believe that Strides no longer had any [redacted] at all (when in fact, Strides did). (Tr. at 9 (Plaintiffs' counsel confirming that, in light of the January 2018 e-mails, it had exactly this understanding); D.I. 408 at 2 (Plaintiffs asserting that "[t]here is an obvious and material distinction between: (i) withholding samples on the ground that they are needed for regulatory purposes; and (ii) representing no such samples exist")) Had Sawai provided a more fulsome explanation of what it meant in those January 2018 e-mails, then the parties could have had further discussions regarding the issue. And those discussions, in turn, might well have led to litigation before the Court over whether it was appropriate for Sawai to refuse to provide the [redacted] that were on stability. (*See, e.g.*, D.I. 408 at 1 (Plaintiffs asserting that [redacted] was not required for ANDA approval and thus "Sawai could have produced the samples"); Tr. at 11 (Plaintiffs noting that "[s]ince that

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therefore this suggestion merely amounts to attorney argument that is unpersuasive in light of the record that *is* before the Court.

[11] Sawai also asserts that Astellas "knew (or should have known) from Sawai's ANDA, produced in April 2017[,] showing that Strides had [redacted] scheduled for stability testing in 2018 and beyond." (D.I. 398 at 3) In response, Plaintiffs note that Sawai's ANDA required only [redacted] testing of the [redacted] the [redacted] time period had run by [redacted], before Plaintiffs requested the samples. (D.I. 408 at 1) According to Plaintiffs, in light of Sawai's counsel's January 2018 e-mail representations that Strides did not have any [redacted] Plaintiffs believed at that time that "[Sawai] may not have been doing the further time point [stability testing]." (Tr. at 12; *id.* at 11, 31-32) That asserted belief seems like a reasonable one under the circumstances.

time point of [redacted] . . . they certainly didn't have to continue the stability testing"); Tr. at 31 (Plaintiffs asserting that "certainly the number of samples that are put on stability [for FDA stability testing] is not limited. And there's always extra that's put on stability.")) But, as Plaintiffs point out, "the issue that Sawai created by sending the e-mails where they said Strides represented to them that they had none of these samples, is that [such] discussion couldn't even have been had because [Sawai] said there were none." (Tr. at 31)

Therefore, Sawai's conduct with respect to the [redacted] amounts to a violation of the discovery rules, in that: (1) Sawai made an "incomplete [and/or] incorrect" disclosure to Plaintiffs about the existence of the samples; (2) it knew or at least should have known that the disclosure was insufficient; and (3) it thereafter failed to correct that statement. Fed. R. Civ. P. 26(e) (requiring a party who has responded to, *inter alia*, a request for production to supplement or correct its response "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing"); *Pouncy v. City of Chicago*, Case No. 15-cv-1840, 2017 WL 8205488, at *15 (N.D. Ill. Dec. 11, 2017) ("Under Rule 26(e) an attorney is obligated to supplement its disclosures . . . as soon as the party or its counsel knew or should have known that its disclosures were incomplete.") (internal quotation marks and citation omitted). Therefore, the Court must next assess whether "all references in Prof. Cima's rebuttal report discussing testing of the [redacted] should be stricken by applying the *Pennypack* factors. (*See* D.I. 393 at 4)

2. Application of the *Pennypack* Factors

Before applying the *Pennypack* factors, it is first important to take note of the specific content that Plaintiffs seek to strike from Professor Cima's April 2019 rebuttal report. Plaintiffs spell out these particular portions of the report in an exhibit to their letter, (D.I. 393, ex. 1 at ¶ 2), and the Court has reviewed this material. It appears that Plaintiffs are seeking to strike *all* discussion of *all* testing of the [redacted] including, for instance: (1) testing performed for ANDA approval, which was reviewed by the FDA prior to granting tentative approval, (*see id.*; *see, e.g.*, *id.*, ex. 16 at ¶¶ 241, 248); *and* (2) testing related to Sawai/Strides' long-term stability studies, (*id.*, ex. 1 at ¶ 2; *see, e.g.*, *id.*, ex. 16 at ¶ 254).

With regard to the first *Pennypack* factor, the Court is not convinced that Professor Cima's discussion of Sawai's testing of [redacted] performed for ANDA approval would have surprised Plaintiffs. For one thing, as even Plaintiffs acknowledge, Sawai's ANDA required [redacted], and such testing "occurred in March 2017, before the samples were requested." (D.I. 408 at 1) And second, the November 21, 2018 opening report of Plaintiffs' expert, Allan S. Myerson, Ph.D.—a report served many months before Dr. Cima's rebuttal report—discussed such testing. (*See, e.g.*, D.I. 393, ex. 15 at ¶¶ 36, 39, 41-43; *see also* D.I. 398 at 3) It was thus predictable that Professor Cima would provide rebuttal opinions with regard to such testing.

As for Professor Cima's reliance on long-term stability studies that Sawai performed on the [redacted] after January 2018, the "surprise" issue is a little more complicated. Plaintiffs surely would have been surprised to know that Sawai intended to rely on such testing in September 2018 (when Plaintiffs learned in advance of a Rule 30(b)(6) deposition that Strides still had such [redacted], and that Strides had conducted stability testing on those samples post-January 2018), for the reasons previously set out above. (D.I. 393 at 3) However, it is less

clear that *by the time of Dr. Cima's April 2019 report*, Plaintiffs would have been surprised to see Dr. Cima discussing these studies. That is because during the September 2018 Rule 30(b)(6) deposition, Plaintiffs were told that Strides was in fact conducting an "ongoing" stability study on [redacted] that would last [redacted]" (D.I. 398, ex. 20 at Sampathkumar Devarajan Transcript at 174-75; *see also* D.I. 398 at 3 (Sawai pointing out that Astellas "clearly knew" that Strides had [redacted] scheduled for stability testing in "2018 and beyond. . . . during Sawai/Strides fact depositions in . . . September 2018,[] but did not ask Sawai for [redacted] or move to compel"); Tr. at 25 (Sawai's counsel noting that following the September 2018 deposition, Plaintiffs "never moved to compel to get those samples that they're now claiming weren't required for the FDA. They didn't even write us a letter or call for production in the deposition of those samples."))[12] And in his November 2018 opening report, Professor Myerson noted that "[i]t appears that Sawai intends to perform [redacted]" (D.I. 393, ex. 15 at ¶ 56) Thus, with regard to these [redacted] stability studies, while Plaintiffs may have been surprised by Sawai's reliance on them as of September 2018, any such surprise would have dissipated soon thereafter.

What about prejudice? Surely Sawai's misleading statements regarding whether [redacted] existed as of January 2018 prejudiced Plaintiffs to some degree. When Plaintiffs were

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[12] Sawai actually contends that as of an even earlier July 2018 fact deposition, Plaintiffs were aware that Strides had [redacted] scheduled for stability testing in 2018 and beyond. (D.I. 398 at 3 & n.11) The Court has reviewed the portions of the July 2018 deposition that Sawai cites in support, but it does not agree that this testimony would have put Plaintiffs on notice that Strides was definitely conducting ongoing stability testing of [redacted]. (*See* D.I. 398 at 3 n.11 (citing *id.*, ex. 20 at Ozawa Transcript at 23, 91-92, 104-110, 153-56); Tr. at 12 (Plaintiffs' counsel noting that the July 2018 witness "seemed rather equivocal as to whether even the stability samples we were looking at were correct. Only when we got to September of 2018 did the Strides witness provide the data which showed they had actually continued the testing."))

told in January 2018 that no [redacted] existed, they understandably stopped trying to get access to such samples for testing purposes. Had Plaintiffs been able move for and get access to such samples quickly thereafter, they could have then tested the samples. The results of that testing might have helped them rebut Professor Cima's reliance on Strides' testing of the [redacted] for non-infringement purposes.[13]

That said, there is an unresolved question as to whether the prejudice Plaintiffs suffered could have been ameliorated, had Plaintiffs more quickly moved (in September 2018 or soon thereafter) to gain access to Sawai/Strides' [redacted] on stability. Plaintiffs say that it would have been fruitless to do so, as those samples were then (and are now) expired and thus unusable for testing purposes. (D.I. 393 at 3) Sawai seems to disagree, and may be taking the position that even today, the [redacted] on stability are unexpired and suitable for testing (though Sawai does not want Plaintiffs to get access to such samples, arguing that they are all needed for FDA stability testing purposes). (D.I. 398 at 3; Tr. at 25) The record is simply unclear as to who is right and as to whether such existing [redacted] were expired in September 2018 or thereafter.

In the end, the Court can conclude Sawai's discovery violation caused some amount of surprise and prejudice to Plaintiffs—though perhaps not to the degree that Plaintiffs have suggested. This *Pennypack* factor thus favors the Motion. But the *degree* to which it favors the

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[13] While Sawai asserts that there is no prejudice here because Plaintiffs could have made their own [redacted], (D.I. 398 at 2-3), the Court agrees with Plaintiffs that this is not a persuasive argument. That is because, *inter alia*, Sawai would have likely responded that such [redacted] were not representative of its own [redacted]. Indeed, Professor Cima suggested that different methods of making such samples may cause the properties of the samples to differ. (*See* D.I. 408 at 2)

Motion is unresolved, in light of the uncertainty regarding the expired/unexpired status of the remaining [redacted].

As to the second *Pennypack* factor—the ability of the moving party to cure any such prejudice—the record is also unclear. According to Plaintiffs, Sawai now represents that its [redacted]" if it is true that this means that the [redacted], then the samples would have expired in March 2018. In such a circumstance, Plaintiffs would then have been "unable to conduct their own testing on the unexpired [redacted]" and "[t]his prejudice [could not] be cured now by receiving the [redacted] as they have now expired." (D.I. 393 at 4) But, as noted above, it is not obvious that Plaintiffs *are* correct that the [redacted] on stability expired in March 2018. It is unclear to the Court whether Strides' further stability testing, [redacted], has or might show that its [redacted] *is* stable for longer (such that the [redacted] that Strides has on stability are not expired). (*See, e.g.*, D.I. 393, ex. 16 at ¶ 254 (Professor Cima opining that the stability testing done at the [redacted]) If the samples that still exist were not expired when Plaintiffs learned about them in September 2018 and/or if they are not expired as of the present day, then Plaintiffs could have earlier attempted to cure any such prejudice by seeking access to such samples as of September 2018 or soon thereafter. (D.I. 398 at 3; Tr. at 25) If Plaintiffs could have taken such steps and failed to do so, that would affect the outcome of this *Pennypack* factor. But as the Court has explained, it does not have a clear record on this point. Thus, the correct outcome as to this factor is uncertain.

The third *Pennypack* factor is the extent to which allowing the testimony would disrupt the order and efficiency of trial. At this point in the case schedule, with trial in this case just months away, (D.I. 372), and with the parties in the midst of pre-trial preparations, even if the [redacted] at issue were currently unexpired, there simply would not be time to: (1) litigate the issue of whether such samples should be produced; (2) have the samples be produced and tested; and (3) have the experts weigh in on what those test results mean. Nevertheless, the correct outcome as to this factor is also uncertain. That is because the degree to which this factor favors the Motion depends on the degree to which Plaintiffs are responsible (if at all) for not earlier moving to seek access to any unexpired [redacted].

With respect to the fourth *Pennypack* factor—whether Sawai acted willfully or in bad faith by failing to clearly set out in January 2018 that Strides did have [redacted]—courts have tended to reserve such a finding for clear, egregious examples of misconduct. *See Novartis Pharms. Corp. v. Actavis, Inc.*, Civil Action No. 12-366-RGA-CJB, 2013 WL 7045056, at *11 (D. Del. Dec. 23, 2013); *Withrow v. Spears*, 967 F. Supp. 2d 982, 1006 (D. Del. 2013) (citing cases). Under this *Pennypack* factor, courts may also consider the non-movant's justifications for failing to timely disclose the relevant information. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 299 (3d Cir. 2012).

Here, the Court does not have the evidence to suggest that Sawai's counsel's statements in January 2018 were meant to *intentionally* mislead Plaintiffs. The explanation that Sawai's counsel offers for these statements—that based on the prior litigation history in the case, when he sent the January 2018 e-mails, he believed that Plaintiffs' counsel understood that [redacted] on stability existed (but that Sawai considered them off limits to Plaintiffs)—is at least plausible. The Court does not have clear evidence to show that Sawai's counsel's explanation about his

own mental state is false. And in this case, the Court has not been presented with other examples of Sawai's counsel having engaged in a pattern of violations or deceptive conduct, which (had that occurred) might lead to a different conclusion. *See Withrow*, 967 F. Supp. 2d at 1006 (explaining that the Third Circuit has found a violation to have been done willfully and in bad faith when it was one in a line of violations by the non-moving party) (citing cases). Thus, this factor does not support grant of the Motion.

To be sure, as discussed above, the Court has found that the *effect* of the January 2018 e-mails was that they would reasonably lead Plaintiffs to believe that no [redacted] existed at the time. But it is one thing to come to that conclusion. It is another thing entirely to conclude that Sawai's counsel intentionally withheld evidence from Plaintiffs and then repeatedly lied about it.

An accusation that *that* type of conduct has occurred is—even in today's high-stakes, high-pressure world of complex civil litigation—earth-shaking. *See Goff v. Utah Funding Commercial, Inc.*, No. 2:09-CV-00680, 2009 WL 4665800, at *5 (D. Utah Dec. 2, 2009) ("Asserting that opposing counsel is lying and thereby implicitly asserting that he or she has fabricated evidence is a grave accusation with serious consequences."). It is the kind of thing that, if proven true, would potentially subject the accused attorney to discipline from a bar association, sanctions from a court and perhaps even disbarment. *See Darnell v. Woodbourne Investments, LLC*, 2:17-CV-00103-MCLC, 2018 WL 2138299, at *4 (E.D. Tenn. May 8, 2018) ("These are very serious accusations to make of an attorney, who as Mr. Vaughn knows, is an officer of the court. Accusing an attorney of unethical conduct, of intentionally misleading a court . . . can destroy an attorney's livelihood."), *reconsideration denied*, No. 2:17-CV-00103-MCLC, 2018 WL 4039287 (E.D. Tenn. Aug. 23, 2018); *Goff*, 2009 WL 4665800, at *5. It is the

type of allegation that can affect (and potentially end) careers. *Darnell*, 2018 WL 2138299, at *4; *Goff*, 2009 WL 4665800, at *5. It is the sort of thing that an officer of the court should hope and expect that he or she will never need to assert about an opponent in his or her entire career. It is the sort of allegation that, before it is made, should have caused the accusing attorney to have had many sleepless nights—not to mention innumerable conversations with colleagues (in order to help confirm that there could not be some other plausible explanation for what had happened).

Plaintiffs' counsel was, nevertheless, perfectly prepared to make this type of accusation here. Plaintiffs' counsel repeatedly asserted during telephonic oral argument that Sawai's counsel "not only withheld [the [redacted] but *intentionally lied* regarding whether they existed or not[,] *repeatedly*." (Tr. at 6 (emphasis added); *see id.* at 7-9 (Plaintiffs' counsel agreeing with the Court that what Plaintiffs' counsel was asserting was that Sawai's counsel "knew these samples existed" and "decided [that they] we[]re going to lie to [Plaintiffs], [they were] going to tell [Plaintiffs] a lie, an intentional falsehood that the samples don't exist, because [Sawai did not] want [Plaintiffs] to know that they exist and [Sawai is] going to hope that [Plaintiffs] don't find out"))

As the Court has explained above, it has concluded that the record is insufficient to support such a conclusion. Perhaps the Court is correct in so deciding; perhaps not. Maybe the Court simply does not have the courage of Plaintiffs' counsel's convictions.[14] But in the Court's

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[14] A key issue during oral argument on this portion of the Motion related to Sawai's counsel's assertion that, in certain "meet and confers" with Plaintiffs' counsel before the January 2018 e-mails, Sawai's counsel had "made clear" that Sawai was "not going to provide anything [regarding [redacted] that was] being used for FDA testing." (Tr. at 17) This argument (and it was only argument; Sawai's counsel did not provide a declaration supporting the assertion) was made to support Sawai's counsel's position that when the January 2018 e-mails were sent, Plaintiffs'

view, the most important thing here—even more important than whether it got this legal issue right or wrong—is even more basic. The most important thing is whether counsel (both accusing counsel in this case, and all counsel who may read this opinion) understands the *gravity of what was alleged* here. Too often in the current litigation landscape, it seems to the Court that it is precisely that concept—i.e., how serious it is to make an allegation of wrongdoing against a fellow member of the legal profession, a profession that rightly holds itself to a very high standard of integrity and ethics—that is getting lost, all in the rush to win.

Because the Court cannot find that Sawai's counsel acted willfully or in bad faith—and instead finds only that Sawai's violation amounted to negligent conduct—this factor is neutral in the Court's eyes.

As to the fifth *Pennypack* factor, regarding the importance of the testimony sought to be excluded, Professor Cima's discussion of [redacted] testing is important to Sawai's case. Sawai asserts that its ANDA product does not infringe because [redacted]

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counsel had to know that those e-mails were not addressing the [redacted] that existed and that was on stability. The Court later asked Plaintiffs' counsel to respond to this line of argument—i.e., to explain why it was not persuasive. In response, Plaintiffs' counsel said that he could not speak to that issue, because "I wasn't part of the meet and confers that led up to these e-mails. I joined the case around the time the e-mails were being sent." (*Id.* at 31) Three other attorneys for Plaintiffs were on the line during the oral argument teleconference. None spoke up to provide any further clarification as to what had or had not occurred on these prior telephonic meet and confers or to explain why Sawai's counsel's explanation of what had occurred was inaccurate.

Think about what this meant. One party's attorney was calling another party's attorney a liar and was accusing him of intentionally withholding/destroying evidence in a case—making arguably the most serious accusation that can possibly be made in litigation. And yet that same accusing attorney *was not involved in a significant number of prior discussions regarding the topic* in question and *could not even speak to what had occurred during those discussions.*

[redacted] (*See, e.g.*, D.I. 393, ex. 16 at ¶¶ 230, 243, 327, 329) This factor weighs against grant of the Motion.

In the end, with respect to several of the *Pennypack* factors, the record is unclear as to which way they should properly come out. Part of the uncertainty in the record could be due to the fact that the parties had several issues to cover in 6-page letter briefs, and there was not robust back-and-forth between the parties with respect to application of the *Pennypack* factors. In the Court's view, the key lingering (yet unclear) issue here is whether the [redacted] did indeed expire in March 2018—or whether the samples that still exist may not have expired when Plaintiffs learned about them in September 2018 (i.e., whether Plaintiffs could have earlier attempted to cure any such prejudice by seeking access to such samples as of September 2018 or soon thereafter).

For these reasons, before reaching a conclusion as to whether the Court should impose the extreme sanction of excluding some or all of Professor Cima's discussion of [redacted] testing, the Court finds that the fairest path forward is to allow the parties an additional opportunity to provide clarity on this key issue. By no later than **May 17, 2019**, Sawai shall submit a supplemental letter brief of no more than 2 pages (along with any accompanying declarations or exhibits) that addresses this issue. By no later than **May 24, 2019**, Plaintiffs shall submit a responsive supplemental letter brief of no more than 2 pages (along with any accompanying declarations or exhibits) that addresses this issue.

B. Whether Sawai's Conduct Amounts to Spoliation of Evidence

Plaintiffs further argue that because Sawai "deliberately failed to turn over [redacted] before they expired," and Plaintiffs have suffered as a result, the Court should find spoliation and then sanction Sawai by entering an adverse inference for Plaintiffs' use at trial. (D.I. 393 at 5;

see also D.I. 408 at 3; Tr. at 6-7) As has been noted above, it is not even clear to the Court that the [redacted] at issue are/were in fact expired. But beyond that, spoliation requires a finding that, *inter alia*, Sawai intentionally withheld evidence from Plaintiffs in bad faith. As discussed above, the facts here do not support such a conclusion.[15]

IV. CONCLUSION

For the foregoing reasons, the Court reserves decision on Plaintiffs' Motion with respect to whether certain material in Professor Cima's report should be stricken. It will resolve the issue after its review of the supplemental letters to be submitted (as described above). It DENIES the Motion as it relates to Plaintiffs' request regarding spoliation.

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 17, 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

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[15] The primary case that Plaintiffs cite in support of their argument for an adverse inference is *Mosaid Techs. Inc. v. Samsung Elecs. Co.*, 348 F. Supp. 2d 332 (D.N.J. 2004). (D.I. 393 at 5; D.I. 408 at 3) But the decision in *Mosaid* finding that spoliation occurred and that an adverse inference was warranted turned on the *Mosaid* Court's determination that Third Circuit law at the time did not require a finding of intentional, bad faith conduct before allowing a spoliation-related inference. *Mosaid*, 348 F. Supp. 2d at 337-38; *see also* (Tr. at 13, 19). Yet since that time, the Third Circuit has clearly ruled that intentional bad faith conduct *is* required before a finding of spoliation can be made. *Bull*, 665 F.3d at 79; *see also* (Tr. at 19). So the Court does not see how *Mosaid* is helpful to Plaintiffs.

marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Order.

Dated: May 14, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE