

**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

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 portions of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.’s (collectively, “Astellas” or “Plaintiffs”) Motion relating to their assertions that Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA Inc.’s (“collectively, “Sawai”) expert, Michael J. Cima, Ph.D., improperly raises in his February 22, 2019 “Rebuttal Expert Report” on Sawai’s non-infringement of United States Patent Nos. 7,342,117 (the “’117 patent”) and United States Patent No. 7,982,049 (the “’049 patent” and collectively with the ’117 patent, the “polymorph patents”) (the “Rebuttal Report”): (1) new claim constructions relating to the polymorph patents; and (2) new non-infringement

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.

theories.² (D.I. 393 at 1-3, 5-6; D.I. 408 at 3-4) With respect to these issues, the Court has considered the parties' letter briefs, (D.I. 393, 398, 408, 421), and the parties' arguments made during the April 17, 2019 telephonic argument, (D.I. 420 (hereinafter, "Tr.")).

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). 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

² The Court has or will resolve the other issues raised by Plaintiffs' Motion in separate Orders.

Plaintiffs first argue that in his Rebuttal Report, Professor Cima provided three new claim constructions for the polymorph patents (regarding the terms “characteristic peaks,” “DSC Analysis[,]” and “peak”). (D.I. 393 at 1-2) Plaintiffs also argue that Professor Cima relies upon a claim construction of the term “main peaks” that was expressly rejected by this Court. (*Id.* at 2) Plaintiffs request that the Court strike the applicable paragraphs from Professor Cima’s Rebuttal Report, and that Sawai be precluded from raising this subject matter at trial. (D.I. 393 at 2-3; *id.*, ex. 1 at 1-4) The Court considers these allegedly improper claim constructions in turn.

A. Claim Construction

1. “characteristic peaks”

The Court has construed the term “ α -form crystal[,]” found in certain claims of the '049 patent, to mean “ α -form crystal which is a term of reference for a polymorphic crystal form of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide that can be distinguished from other forms by its *characteristic peak(s)* and DSC analysis as identified in the specification[.]” (D.I. 259 at 38-39 (emphasis added); D.I. 335 at 5) In his Rebuttal Report, Professor Cima notes that Plaintiffs’ non-infringement experts “appear[] [to] believe” that “any PXRD method” can be utilized to determine whether a crystalline form has the requisite “characteristic peaks.” (D.I. 393, ex. 16 at ¶ 205 (emphasis in original)) Professor Cima opines that this is not consistent with the patents’ specifications, and that “the specification identifies a *specific PXRD method* used to determine if a form has the eight ‘characteristic’ peaks listed in Table 1 for the alpha form.” (*Id.* (emphasis added) (citing '117 patent, col. 2:6-48))³ Professor

³ The '049 patent is a continuation of the U.S. patent application that led to the '117 patent, and the patents therefore share a specification. (*See* '049 patent; D.I. 77 at 2)

Cima then goes on to describe the “specific PXRD method[,]” and further opines that utilization of other PXRD methods could result in a sample meeting the claimed peak limitations using one method but not another, thus rendering the claim indefinite. (*Id.* at ¶¶ 206-08)

Plaintiffs assert that since Professor Cima bases this “new claim construction[]” on the claims and patent specification, “there can be no excuse for withholding th[i]s[] construction[] until now, as [it] could have and should have been raised during the *Markman* process.” (D.I. 393 at 1-2) For its part, Sawai retorts that it could not have earlier raised this construction because it did not know during claim construction that Plaintiffs “intended to rely on . . . PXRD measurements using parameters significantly different than those seen in the '117 patent or typically used in the art (*e.g.*, with scanning speeds over 50x slower than those in the '117 patent)[.]” (D.I. 398 at 5; *see also* D.I. 421 at 2) Despite allegedly conducting PXRD testing of Sawai’s samples using scan rates up to 15,000 times slower than the ones disclosed by the patents, (D.I. 421 at 2; *see also* D.I. 398 at 5), Plaintiffs’ expert, Jerry L. Atwood, Ph.D., opined that “the rate and range at which an XRPD scan is made on a sample can affect whether discernible peaks can be observed[,]” (D.I. 398, ex. 18A at ¶ 16).

Professor Cima’s opinion with respect to “characteristic peaks” does not constitute an untimely or improper disclosure. For one thing, this term appears in the Court’s construction for the claim term “a-form crystal” and “characteristic peaks” did not appear in the parties’ proposed constructions for “a-form crystal.” (*See, e.g.*, D.I. 73, ex. A at 2) Thus, it is hard to see how Sawai could have addressed it during the prior claim construction process. Second, it is permissible for Professor Cima to respond to testing methods utilized by Plaintiffs’ experts—methods that Professor Cima may not have been aware *would* be utilized, prior to seeing Plaintiffs’ experts’ reports.

It may just be that this dispute will need to be addressed by the Court prior to trial, by way of another claim construction process. Claims may be construed “during various phases of litigation[,]” and not just following a *Markman* hearing; the Court may also “revisit[] and alter[] its interpretation of the claim terms as its understanding of the technology evolves.” *Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, 460 F.3d 1349, 1359 (Fed. Cir. 2006) (internal quotation marks and citations omitted); *see also, e.g., Amgen Inc v. Aurobindo Pharma Ltd.*, Civ. No. 16-853-GMS, 2018 WL 1061369, at *1 (D. Del. Feb. 27, 2018) (explaining that claim construction is a “fluid process” that is not final until judgment is entered and, until that time, “[t]he court may re-construct the claims if it finds the original claim construction to be in error based upon a more developed record, and/or may add claim constructions for terms that become disputed through the course of trial”) (internal quotation marks and citations omitted); *Vehicle IP, LLC v. Cellco P'ship*, C.A. No. 09-1007-LPS, 2017 WL 2345556, at *1 n.1 (D. Del. May 30, 2017) (same, citing cases); *Cubist Pharms., Inc. v. Hospira, Inc.*, 75 F. Supp. 3d 641, 658 (D. Del. 2014) (explaining that the court’s construction of claim terms need not be static and “[f]or bench trials, the court need not be concerned about confusing the jury with late changes to claim construction”).⁴

However, because Professor Cima is presenting a new view on how characteristic peaks may be assessed in his Rebuttal Report, the Court GRANTS Plaintiffs’ request for their expert(s) to file a short reply expert report in response. (D.I. 393 at 6; D.I. 408 at 4)

⁴ That said, the Court is not in a position to now rule on any dispute with respect to this portion of the construction for “ α -form crystal,” as the current issue before the Court is whether Professor Cima’s opinion with respect to this issue should be stricken from his report as an untimely or improper disclosure (not which side’s interpretation of the meaning of “characteristic peaks” is correct).

2. “DSC Analysis”

Claims 1 and 2 of the '117 patent both require the claimed crystals to have, *inter alia*, a heat absorption peak “at 142 to 146° C in the DSC analysis” (the “DSC limitations”).

Specifically, these claims recite:

1. A crystal of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide *having a heat absorption peak at 142 to 146° C. in the DSC analysis* and having main peaks at around 5.32, 8.08, 15.28, 17.88, 19.04, 20.20, 23.16 and 24.34 in the terms of 2θ(°) in the powder X-ray diffraction.

('117 patent, col. 12:19-24 (emphasis added) & Certificate of Correction)

2. A crystal of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide *having heat absorption peaks at 90 to 110° C. and at 142 to 146° C. in the DSC analysis* and having main peaks at around 9.68, 19.76, 20.72, 22.10 and 23.52 in the terms of 2θ(°) in the powder X-ray diffraction.

(*Id.*, col. 12:25-30 (emphasis added)) In their opening reports on non-infringement, Plaintiffs' experts opine that having a heat absorption peak “within the claimed range of 142 to 146°C” (i.e., at 143.28°C) meets the requirement of “having a heat absorption peak at 142 to 146°C in the DSC analysis.” (D.I. 393, ex. 15 at ¶ 5; D.I. 398, ex. 18A at ¶ 7)

In Professor Cima's opening invalidity report, he opines that testing of the α-form crystal would exhibit “a DSC peak *between* 142 and 146°C.” (D.I. 393, ex. 11 at ¶ 157 (emphasis added)) But then, in his Rebuttal Report, Professor Cima states with respect to such a peak:

Rather than requiring the peak *at* the full range of 142 to 146°C as claimed, [Plaintiffs' experts] appear to find it sufficient that the peak maximum appear *between* 142 and 146°C. This is not what is claimed or supported by the specification. [] Also, the DSC analysis should be done on a sample that is representative of what is in the final dosage form as a whole.

(*Id.*, ex. 16 at ¶ 218 (emphasis added)) Sawai asserts that these statements properly respond to Plaintiffs’ view that having a peak at 142 to 146°C in the DSC analysis means having a peak “anywhere ‘within the claimed range’”—that is, according to Professor Cima’s Rebuttal Report, the “at” in the DSC limitations “means ‘at’ and not ‘within the range[.]’” (D.I. 421 at 2)

In making this argument, however, Sawai never addresses the import of the assertion in Professor Cima’s opening report that the α -form crystal would exhibit “a DSC peak *between* 142 and 146°C.” (D.I. 393, ex. 11 at ¶ 157 (emphasis added)) And yet that seems to be Plaintiffs’ key point—that “Sawai seeks to change a construction it provided in its own opening reports.” (D.I. 408 at 4) As far as the Court can tell, that does appear to be what happened. Professor Cima’s new interpretation thus constitutes an untimely disclosure.

Weighing the *Pennypack* factors, however, the Court does not find that this disclosure warrants the extreme sanction of exclusion. To be sure, some factors support Plaintiffs’ request. Plaintiffs were likely surprised by the content of Professor Cima’s rebuttal report in light of the contradictory statement in his opening report. And Professor Cima’s opinion relating to the DSC limitations does not seem to be “absolutely critical” to his non-infringement opinion. (D.I. 398 at 6; *see also* D.I. 393, ex. 16 at ¶ 479; D.I. 408 at 4) However, the greater number of factors (and the weight of the evidence) supports denial of the request for exclusion. Plaintiffs have the ability to easily cure any prejudice by submitting a short reply expert report that addresses Professor Cima’s new opinion. (*See* D.I. 393 at 6; D.I. 408 at 4)⁵ Additionally, Plaintiffs do not

⁵ The Court notes that if and when the parties raise the claim construction issue relating to the DSC limitations with the Court, it is possible that the Court will not agree with Professor Cima’s interpretation of the DSC limitations in his Rebuttal Report. Here again, the Court cautions that it is not now substantively ruling on any dispute with respect to this term, as the current issue before the Court is whether Professor Cima’s opinion with respect to the DSC

suggest that allowing the disclosure would disrupt the order and efficiency of trial. And while the Court is unsure why Professor Cima's opinion seemingly changed from his opening report, the record does not demonstrate bad faith.

The Court thus DENIES Plaintiffs' Motion to Strike Professor Cima's opinions regarding the DSC limitations from his Rebuttal Report. Because Professor Cima is presenting a new view on these limitations, however, the Court GRANTS Plaintiffs' request for their expert(s) to file a short reply expert report in response. (D.I. 393 at 6; D.I. 408 at 4)

3. "peak"

In Plaintiffs' expert Professor Atwood's opening report, he opines that "a peak height needs to have sufficient signal to be identified as a peak." (D.I. 398, ex. 18 at ¶ 49) Professor Cima, in his Rebuttal Report, opines that Professor Atwood nevertheless "asserts certain statistically insignificant signals are 'peaks' in the PXRD testing he conducted on Sawai's samples, which a [person of ordinary skill in the art, or 'POSA'] would not consider peaks." (D.I. 393, ex. 16 at ¶ 189) Professor Cima then further opines that "a POSA would understand a 'peak' in a PXRD diffractogram as that term is used in the Asserted Claims to mean 'a signal that is substantially larger than the background noise.'" (*Id.* at ¶ 191)

Here, the Court is not persuaded that Professor Cima's opinion with respect to "peak" is an untimely or improper disclosure. Sawai contends that it was not aware that Plaintiffs' experts would "opine that certain signals that a POSA would actually consider to be nothing other than background noise constituted a 'peak[,]'" and that it therefore did not know prior to its review of

limitations should be stricken from his report as an untimely or improper disclosure (and not which side's interpretation of the limitations is correct).

Plaintiffs' expert reports that the term "peak" was in dispute. (D.I. 398 at 5-6; *see also* D.I. 421 at 2; Tr. at 46) This is a reasonable explanation for why Professor Cima's Rebuttal Report provided this opinion regarding how a POSA would interpret "peak" in the asserted claims. However, in light of the fact that Professor Cima is introducing, in effect, a new proposed construction for "peak" in his Rebuttal Report, the Court grants Plaintiffs' request that their expert(s) be permitted to file a short expert reply report(s) in response. (D.I. 393 at 6; D.I. 408 at 4)⁶

4. "main peaks"

During claim construction, the Court construed the claim term "main peaks," which appears in claims 1 and 2 of the '117 patent, to mean "peaks that are characteristic of the particular crystal form as distinguished from other crystal forms[.]" (D.I. 259 at 39; D.I. 335 at 5) In doing so, the Court rejected: (1) Defendants' arguments that this term was indefinite; and (2) Sawai's and certain other Defendants' arguments that if the term is not found indefinite, it should be construed to mean "'peaks with the largest relative intensities in the XRPD spectrum of a sample.'" (D.I. 259 at 24-32)

In Professor Cima's Rebuttal Report, he opines that "the [Court's] current construction [of 'main peaks'] gives 'main' no real meaning and makes it superfluous[.]" and that the alternative construction proposed by Sawai and other Defendants "is most in line with how a POSA would understand this term[.]" (D.I. 393, ex. 16 at ¶¶ 170, 172) Professor Cima then spends several paragraphs explaining why he believes this to be so. (*Id.* at ¶¶ 172-87) He

⁶ As with the terms above, the Court is not now in a position to rule on any dispute between the parties with respect to the construction of "peak," as that is not the issue currently pending before the Court.

concludes by stating that “the available intrinsic and extrinsic evidence (some of which was not before the Court) demonstrates that the current construction of ‘main peaks’ in Claim 1 of the ‘117 patent is incorrect[.]” (*Id.* at ¶ 187)

Plaintiffs request that the paragraphs in the Rebuttal Report relating to this opinion be stricken because “Plaintiffs should not be required to show infringement under this rejected construction.” (D.I. 393 at 3) Sawai responds that Dr. Cima’s opinions here do not constitute an improper or untimely disclosure because they are based in part on new evidence that Sawai uncovered subsequent to the *Markman* hearing. (D.I. 398 at 6; Tr. at 48-49) Specifically, Sawai points to a translation of a Japanese Priority Document and evidence developed during inventor depositions as the purportedly new evidence that supports its previously proposed (and rejected) construction. (*Id.*; *see also* D.I. 393, ex. 16 at ¶¶ 177, 185-86)

The Court agrees with Plaintiffs that they should not be required to demonstrate infringement under a claim construction that the Court rejected. At present, Professor Cima’s opinions described above regarding “main peaks” are irrelevant and thus inadmissible under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). *Cf. Anglefix, LLC v. Wright Med. Tech., Inc.*, No. 13-cv-2407-JPM-tmp, 2017 WL 2973989, at *7-9 (W.D. Tenn. July 12, 2017) (granting a *Daubert* motion where the expert’s opinion was inconsistent with the court’s claim construction rulings and was thus “inadmissible and irrelevant”); *Saffran v. Johnson & Johnson*, Civil Action No. 2:07-CV-451 (TJW), 2011 WL 197871, at *4 (E.D. Tex. Jan. 20, 2011) (granting plaintiff’s motion to preclude defendants’ experts from reintroducing rejected claim construction arguments). The instant Motion is not a *Daubert* motion, but it is nevertheless so clear that the opinions at issue are objectionable under *Daubert*’s relevance prong that relief should now be granted. Under these circumstances, the Court GRANTS Plaintiffs’ Motion with

respect to “main peaks” and will accordingly strike the relevant portions of Professor Cima’s Rebuttal Report, (*see* D.I. 393, ex. 1 at ¶ 1(d)), without prejudice to Sawai’s ability to re-introduce this material if the Court ultimately revises its construction for “main peaks” consistent with Professor Cima’s opinions.⁷

B. Non-Infringement Theories

Plaintiffs argue that in Professor Cima’s Rebuttal Report, Sawai relies on two new non-infringement theories that were never previously disclosed to Plaintiffs and that should therefore be stricken. (D.I. 393 at 5-6; D.I. 408 at 3) First, Plaintiffs point to Professor Cima’s argument that a property of [REDACTED]

[REDACTED] demonstrates Sawai’s non-infringement of the polymorph patents. (D.I. 393 at 5; *id.*, ex. 1 at ¶ 3(a)) To that end, Professor Cima explains that

[REDACTED]
[REDACTED]
[REDACTED] (*Id.*,

ex. 16 at ¶ 33 (citation omitted); *see also id.* at ¶ 235) Second, Plaintiffs argue that Professor Cima’s Rebuttal Report improperly points to new references to argue non-infringement that were never previously disclosed to Plaintiffs, including: (1) several [REDACTED]

formulations made by others; and (2) [REDACTED] that do not contain mirabegron.

(D.I. 393 at 5; *id.*, ex. 1 at ¶ 3(b)-(c)) Plaintiffs argue that without notice that Sawai would rely

⁷ If Sawai contends that new evidence warrants a revised claim construction for this term, it had better hurry up and seek such a new construction by motion. (*See* Tr. at 51-52) The Court offers no opinion as to whether Sawai has already waived its ability to obtain such a new construction by having failed to earlier raise the issue with the Court. (*Id.*)

on these theories prior to Professor Cima's Rebuttal Report, they could not obtain fact discovery regarding the theories or address them in their opening expert reports. (D.I. 393 at 5; D.I. 408 at 3-4)

In response, Sawai asserts that these theories are not untimely because they are responsive to Plaintiffs' testing and infringement positions first disclosed to Sawai in Plaintiffs' experts' opening reports. (D.I. 398 at 3-4) According to Sawai, prior to these reports, Plaintiffs had not put Sawai on notice of the testing that Plaintiffs' experts conducted from September 2017 to January 2018, nor did Plaintiffs previously assert that Sawai's ANDA product's [REDACTED]. (*Id.* at 4)⁸ Therefore, Sawai argues, Professor's Cima's assertedly new theories are necessary to rebut *Plaintiffs'* new theories and previously undisclosed testing. (*Id.*) Plaintiffs disagree, and point out that Sawai knew that Plaintiffs had samples of its ANDA product and intended to test them. (D.I. 408 at 3)⁹ Plaintiffs also assert that the way in which they ground the tablets into a powder for testing is "routine" and that "Sawai knew full well that Plaintiffs would argue that its [REDACTED] [REDACTED]" (*Id.*)¹⁰

⁸ Sawai contends that prior to reviewing Plaintiffs' opening expert reports, "Sawai had very little information on Astellas' [] infringement theory" relating to the polymorph patents because "Astellas' infringement contentions were vague and confusing[.]" (D.I. 398 at 3) However, Sawai never raised this issue with the Court via the Court's discovery dispute procedures. To the extent that Plaintiffs' contentions really were so vague and confusing that they did not provide fair notice of Plaintiffs' infringement contentions, Sawai could have used the Court's discovery dispute procedures to compel Plaintiffs to provide more detailed contentions in this regard.

⁹ This is certainly true. (*See, e.g.*, D.I. 393, ex. 5 at 3 (September 2017 e-mail from Plaintiffs' counsel to Sawai's counsel discussing testing of samples))

¹⁰ Plaintiffs do not provide any citations for these latter two points.

With respect to Professor Cima's discussion of [REDACTED] it does not appear that this material was offered to rebut some aspect of Plaintiffs' experts' testing. For example, this [REDACTED] [REDACTED] is first described by Professor Cima in the "Scientific and Technical Background" section of his Rebuttal Report. (*See, e.g.*, D.I. 393, ex. 16 at ¶¶ 33-35, 37-38, 57-60) Beyond that section, Professor Cima's references to [REDACTED] simply seem intended to support his opinion that, "based on [his] review of the ANDA and supporting documents as well as [his] knowledge and experience in this field" Sawai's ANDA product will contain [REDACTED] [REDACTED] (and thus will not infringe). (*See, e.g., id.* at ¶¶ 316, 321-22; *see also, e.g., id.* at ¶ 33 (referring to [REDACTED]); *id.* at ¶ 237 (explaining that a POSA would expect the [REDACTED] to be generated and maintained throughout the ANDA manufacturing process based on, *inter alia*, [REDACTED]) There is not any indication in the way Professor Cima discusses [REDACTED] that his reference to this evidence came about only in response to a point first made in Plaintiffs' opening expert report. This all suggests to the Court that it was not something particular about Plaintiffs' testing that triggered Professor Cima's desire to discuss [REDACTED].

As for Professor Cima's discussion of other [REDACTED], this too largely does not appear to have been prompted solely by a desire to rebut the force of Plaintiffs' experts' testing. For example, Professor Cima discusses other mirabegron formulations and other [REDACTED] in the contexts of: (1) providing the technology background regarding [REDACTED] (*see, e.g., id.* at ¶¶ 42, 150); (2) describing Sawai's development and manufacturing process regarding its ANDA product, (*id.* at ¶¶ 235, 282); and (3) opining that "based on [his] review of the ANDA and supporting documents as well as [his]

knowledge and experience in this field” Sawai’s ANDA product will contain [REDACTED]

[REDACTED] (and thus will not infringe), (*id.* at ¶¶ 316, 323).¹¹

While Professor Cima’s discussion of [REDACTED] and other formulations seem to amount to untimely disclosures, here too the *Pennypack* factors weigh against the extreme sanction of excluding these theories and evidence. Plaintiffs were likely surprised to see these theories in Professor Cima’s report, since they had not been disclosed to Plaintiffs before in Sawai’s non-infringement contentions. (*See* Tr. at 38) However, Plaintiffs may cure any prejudice by submitting short reply reports addressing this content, which is their requested alternative form of relief. (D.I. 393 at 6; D.I. 408 at 4) Plaintiffs do not suggest that allowing this testimony would disrupt trial. There is no evidence of bad faith on the part of Sawai. And Sawai contends that the testimony at issue is “important” and it explains why that is so. (D.I. 398 at 4)

Accordingly, the Court DENIES Plaintiffs’ motion to strike these theories and evidence from Professor Cima’s rebuttal reports, but GRANTS Plaintiffs’ request to provide a short reply report to address this content. *See, e.g., Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 499 (D. Del. 2019) (finding that the portion of the expert’s report that defendant sought to strike was untimely because it did not solely contradict or rebut evidence raised in defendant’s rebuttal report, but determining that the *Pennypack* factors did not weigh in favor of exclusion and that any prejudice could be cured by permitting defendant to file a sur-reply report).

III. CONCLUSION

Because this Memorandum Order may contain confidential information, it has

¹¹ A small portion of Professor Cima’s discussion regarding other formulations that Plaintiffs seek to strike does seem directly responsive to Plaintiffs’ experts’ testing. (*See, e.g.,* D.I. 393, ex. 16 at ¶ 452 (5th sentence only), ¶ 457 (3rd sentence only), ¶ 461 (2nd sentence only), ¶ 465 (6th sentence only))

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 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