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

| | | |
|---|---|---|
| VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD. and VIIV HEALTHCARE UK (NO. 3) LIMITED, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. 18-224-CFC-CJB |
| GILEAD SCIENCES, INC., | ) | |
| Defendant. | ) | |

**MEMORANDUM ORDER**

Presently pending in this patent infringement case between Plaintiffs ViiV Healthcare Co., Shionogi & Co., Ltd., and ViiV Healthcare UK (No. 3) Ltd. (collectively, "Plaintiffs" or "ViiV") and Defendant Gilead Sciences, Inc. ("Defendant" or "Gilead") are two discovery-related motions: (1) Defendant's motion requesting that the Court sanction Plaintiffs pursuant to Federal Rules of Civil Procedure 26 and 37, due to the substance of reports filed by Plaintiffs' expert witness, Dr. Alan Engelman, and events relating to a subsequent deposition of Dr. Engelman ("Defendant's Motion"), (D.I. 265); and (2) Plaintiffs' motion requesting that the Court sanction Defendant pursuant to those same Rules, due to alleged failures of disclosure regarding Defendant's expert witness, Dr. Douglas Richman, ("Plaintiffs' Motion"), (D.I. 277). For the reasons set forth below, the Court orders that both Motions be GRANTED in the manner set forth below.

## I. BACKGROUND

### A. Factual Background

#### 1. Dolutegravir™, Bictegravir™ and Plaintiffs' Infringement Allegations

This is a patent infringement case involving a single patent, United States Patent No. 8,129,385 (the "'385 patent" or the "patent-in-suit"). (D.I. 1 at ¶¶ 22-30) Plaintiffs collectively manufacture and market Dolutegravir, which embodies the invention of the '385 patent. (*Id.* at ¶¶ 21, 33, 35-36) Dolutegravir is an integrase-strand-transfer-inhibitor ("INSTI") medication used to treat HIV, and which allegedly shows certain benefits over predecessor treatments. (*Id.* at ¶ 21)

Defendant manufactures and markets a competitor medication, Bictegravir. (*Id*. at ¶¶ 51-59) Plaintiffs assert that Defendant directly infringes the patent-in-suit by way of making, using, selling, offering to sell or importing products containing Bictegravir, such as Defendant's product Biktarvy®, and that Defendant induces infringement of the patent by selling or otherwise supplying Bictegravir to others in combination with two other drugs. (*Id*. at ¶¶ 57, 77-79) Defendant is not alleged to literally infringe the '385 patent; instead, its product is alleged to infringe the patent via the doctrine of equivalents. (*Id.* at ¶¶ 82-85; D.I. 266 at 1)

**2. Defendant's Motion**

**a. Tsiang 2016 and the Peer Review Process**

The dispute that Defendant raises concerns Plaintiffs' expert, Dr. Engelman. Plaintiffs retained Dr. Engelman to opine on the insubstantial differences between Dolutegravir and Bictegravir. Dr. Engelman provided three reports: an opening report, (D.I. 266, ex. B), a reply report, (*id*., ex. G), and a supplemental report, (*id*., ex. D). In his reports and at his subsequent deposition in May 2020, Dr. Engelman discussed an article authored by Defendant's scientists: Manuel Tsiang, et al., *Antiviral Activity of Bictegravir (GS-9883), a Novel Potent HIV-1*

*Integrase Strand Transfer Inhibitor with an Improved Resistance Profile*, 60 Antimicrobial Agents & Chemotherapy 7086 (2016) ("Tsiang 2016"). (D.I. 266, ex. A) Tsiang 2016 provided a favorable review of Bictegravir, concluding that it "displayed statistically improved antiviral activity" compared to other drugs, including Plaintiffs' drug, Dolutegravir. (Tsiang 2016 at 7086; *see also id.* at 7092)

Defendant submitted an initial draft manuscript of Tsiang 2016 for peer review in July 2016. (D.I. 266, ex. C at BICVIIVUS2556855) As part of the peer review process, there were two anonymous reviewers who provided their feedback on the article: Reviewer # 1 and Reviewer # 2.

Reviewer # 2's comments on the article, which comprised about a half of a page in total, were more positive (or, depending on how you look at it, less negative) than those of Reviewer # 1. For example, Reviewer # 2 opened his comments by stating "Tsiang et al submit [a] comprehensive evaluation of 2nd generation INSTI [Bictegravir] from Gilead Sciences in vitro. The results in large part show similar behavior to [Dolutegravir], both of which are superior to [other] compounds, especially in antiviral resistance profiles." (*Id.*) Reviewer # 2 went on to say that most of his comments on the article were "minor in nature" and that there will be "significant interest in this study" from those in the field. (*Id.*) Reviewer # 2 then provided eight "comments." (*Id.*) Some of the comments simply suggested word changes ("Line 252, 'Vif' should be 'vif' (in italics)") or stylistic edits ("Authors need to pay much closer attention to use of abbreviations."), while others provided specific constructive criticisms. (*Id.*) One such criticism, for example, conveyed that "[the a]uthors should consider more rigorous treatment of

data [purportedly showing results similar to those obtained by Dolutegravir] by performing statistical comparison to determine in this and other cases whether the values are statistically similar or not." (*Id.*)

In contrast, Reviewer # 1, who wrote about one page of comments, began by noting that although the article presented a "thorough virological characteri[z]ation of a new INSTI, [B]ictegravir[,]" that was "of interest," nevertheless "some bias is present in the interpretation and presentation of the data." (*Id.* at BICVIIVUS2556854) Reviewer # 1's general complaint was that the "[d]ata should be presented in an objective way." (*Id.*) Further to this issue, Reviewer # 1 had more pointed criticisms, including:

- Reviewer # 1 criticized the manuscript's claim that Bictegravir had a "superior resistance profile" to Dolutegravir, especially because particular data in the manuscript showed that Bictegravir "shows a lower genetic barrier to resistance" than does Dolutegravir; Reviewer # 1 recommended that the authors re-word this statement to say that Bictegravir had a "comparable" profile to Dolutegravir and cautioned them to "remain scientific in the conclusions made." (*Id.*)

- Reviewer # 1 recommended that in summarizing the results of its data, Tsiang 2016 should "[s]tart with a statement about the structure of the compound" and "explain" that "[t]his molecule strongly resembles [Dolutegravir.]" (*Id.*)

- Reviewer # 1 noted that, with regard to Table 6 in the manuscript, "[Bictegravir] has a similar resistance profile than [Doultegravir], not a superior[r] profile[.]" (*Id.*)

- Reviewer # 1 also noted that certain edits should be made to a table in Figure 1 of the article, which compared the "[r]esistance profile[s]" of Bictegravir and Dolutegravir; that figure, which relied in part on certain data generated by third party Monogram Biosciences, Inc. ("Monogram Biosciences"), was said by Reviewer # 1 to create an "[i]mpression that [the]

representation is biased for [Bictegravir]." (*Id.*; *see also* Tsiang 2016 at 7092 (Figure 1))

- Reviewer # 1 also criticized the article in terms of what was depicted in its Figure 2, noting that "[h]ere data demonstrate a lower genetic barrier for [Bictegravir] than [Dolutegravir,] not a similar one" and went on to remind the authors to "[b]e honest!" (D.I. 266, ex. C at BICVIIVUS2556854)[1]

**b. Dr. Engelman's Reports**

In November 2019, Plaintiffs submitted Dr. Engelman's opening report, which is titled "Opening Report of Alan Engelman, Ph.D. Concerning Insubstantial Differences Between Dolutegravir and Bictegravir." (D.I. 266, ex. B) In this opening report, Dr. Engelman discussed Tsiang 2016. In doing so, he aimed at least two different lines of criticism at the article's suggestion that, in at least certain ways, Bictegravir performs better than Dolutegravir.

One line of criticism directly addressed the peer review process regarding the article (referenced above). Here, in paragraphs 246 and 247 of his report, Dr. Engelman explained that "[p]rior to being accepted for publication, Dr. Tsiang's manuscript was peer reviewed by *two scientists* with expertise in the field" and that "[t]he *two scientists* provided feedback on the article[.]" (*Id*. at ¶¶ 246-47 (emphasis added)) Thereafter, in paragraph 247, Dr. Engelman wrote that "[t]he *two scientists* . . . not[ed] that the article required further editing because there

[1] In summarizing the comments of the two Reviewers, the Editor of *Antimicrobial Agents & Chemotherapy* (the journal that would publish Tsiang 2016) picked up on Reviewer # 1's comments about bias, noting that "[a]lthough experiments are mostly well done, there is bias in the interpretation of the data, probably influenced by marketing strategies" and that "[a]lthough [Bictegravir] outperforms older INSTIs . . . , there is little evidence for a better performance than "Dolutegravir[,]" cautioning "[p]lease, . . . write objectively." (D.I. 266, ex. C at BICVIIVUS2556852)

was bias, 'probably influenced by marketing strategies,' and [that they reminded] Dr. Tsiang to write objectively." (*Id.* at ¶ 247 (emphasis added)) In support of this statement, Dr. Engelman included a string-citation to each of the five above-referenced sets of critical comments made by Reviewer # 1, complete with parentheticals that excerpted the text of those comments. (*Id.* (quoting D.I. 266, ex. C at BICVIIVUS2556854); *see* D.I. 358 (hereafter, "June 22 Tr.") at 31) At the end of that string citation, Dr. Engelman also included a citation to one comment that had been made by Reviewer # 2 ("'The results [of Bictegravir] in large part show similar behavior to [Dolutegravir.]'"). (D.I. 266, ex. B at ¶ 247 (quoting D.I. 266, ex C at BICVIIVUS2556855))[2]

Second, Dr. Engelman criticized Tsiang 2016's treatment and display of certain "fold change data" generated by Monogram Biosciences. This data demonstrates *in vitro* resistance profiles of various compounds against 47 HIV-1 patient-derived isolates with INSTI resistance mutations. A portion of Figure 1 of Tsiang 2016 is reproduced below which references this data:

[2] In paragraph 13 of his supplemental report, Dr. Engelman also made a direct reference to the peer reviewers who commented on Tsiang 2016. There he referenced the "*two reviewers*" and noted that "'*these individuals* . . . [thought that while] the experiments are mostly well done, there is bias in the interpretation of the data, probably influenced by marketing strategies[.]'" (D.I. 266, ex. D at ¶ 13 (April 2020 supplemental expert report) (emphasis added))

B

| Compound | % of Isolates[a] (Fold-Change vs. WT) | | | | Fold-Change vs. WT | | | |
|---|---|---|---|---|---|---|---|---|
| | (≤2.5) | (2.5 to <5) | (5 to <10) | (≥10) | Mean | Median | Range | p-value |
| BIC | 70 | 15 | 13 | 2 | 2.8 | 2 | 0.50 - 19 | 1 |
| DTG | 49 | 17 | 17 | 17 | 5.8 | 3.4 | 0.54 - 63 | 0.042 |
| EVG | 6 | 2 | 0 | 92 | >106 | >150 | 1.9 - >150 | <0.001 |
| RAL | 2 | 4 | 4 | 89 | >100 | >143 | 1.8 - >143 | <0.001 |

FIG 1 Resistance profile of BIC and other INSTIs against 47 HIV-1 patient-derived isolates with INSTI resistance mutations. (A) Bar graph of fold change in resistance. (B) Stratification of the clinical isolates based on fold change in resistance. Primary and other INSTI resistance mutations are listed. Primary INSTI resistance mutations are T66I/A/K, E92Q/G, T97A, Y143C/H/R, S147G, Q148H/K/R, and N155H, and other INSTI resistance mutations are H51Y, L68I/V, V72A/N/T, L74M, Q95K/R, F121C/Y, A128T, E138A/K, G140A/C/S, P145S, Q146I/K/L/P/R, V151L/A, S153A/F/Y, E157K/Q, G163K/R, E170A, and R263K in IN. Susceptibility was determined as the fold change in $EC_{50}$ versus that of the NL4-3 wild-type vector by Monogram Biosciences, Inc. The biological or lower clinical cutoffs for reduced susceptibility in this assay are 4.0 for DTG, 1.5 for RAL, and 2.5 for EVG. No cutoff has been determined for BIC.

(Tsiang 2016 at 7092) As shown above, the authors of Tsiang 2016 divided the results from the testing referenced in Figure 1B into certain data ranges (or "cutoff" points)—(1) "≤ 2.5"; (2) "2.5 to < 5"; (3) "5 to < 10"; and (4) "≥ 10"; they applied those ranges consistently to all four referenced compounds: Bictegravir ("BIC"), Dolutegravir ("DTG"), Elvitegravir ("EVG") and Raltegravir ("RAL"). (*Id.*) According to Tsiang 2016, the data summarized above purports to demonstrate that Bictegravir displayed improved antiviral activity against these 47 isolates as compared to EVG, RAL and Dolutegravir. (*Id.* at 7086)

In his opening report, Dr. Engelman had a number of concerns regarding Tsiang 2016's treatment of this data and other data related to it—particularly with regard to cutoff points used in the above Figure. For example, Dr. Engelman stated that the underlying fold change data for all 47 isolates, which is found in another table related to Tsiang 2016 ("Table S5"), showed that Bictegravir did not have an established clinical cutoff of 2.5; as a result, Dr. Engelman opined that Tsiang 2016 had simply "assumed [that this cutoff was appropriate to use] in the absence of clinical data." (D.I. 266, ex. B at ¶ 320) Dr. Engelman also noted that Monogram Biosciences had an established "lower clinical cutoff" of 4.0 for Dolutegravir; he thus argued that the

authors' decision to use a cutoff of 2.5 for the compound amounted to the use of an "arbitrary" figure. (*Id.* at ¶ 321) From there, Dr. Engelman suggested that the article's presentation of this cutoff data in Figure 1 and Table S5 was misleading. In that regard, he explained that the use of the "arbitrary" 2.5 cutoff had wrongly made it appear that there were significant differences between Bictegravir and Dolutegravir, and that "a person looking at Table S5 would not necessarily appreciate the similarity of the two compounds [i.e., Bictegravir and Dolutegravir] without using Monogram Biosciences' classification scheme to interpret this Monogram[]Biosciences data." (*Id.* at ¶ 322) Dr. Engelman went on to display the fold change data in tables that applied Monogram Biosciences' classification scheme, (*id.* at ¶ 324), which purportedly showed that "[t]he data from Tsiang 2016 Tables 1 and S5 . . . support [his] opinion that the *in vitro* data of [Dolutegravir] and [Bictegravir] are insubstantially different from one another." (*Id.* at ¶ 328)

**c. Dr. Engelman's Deposition**

Defendant's counsel took Dr. Engelman's deposition in May 2020. (D.I. 266, ex. E) There, Defendant's counsel directed a line of questioning at Dr. Engelman in order to test his criticisms of Tsiang 2016—and in particular, his criticisms of Tsiang 2016's treatment of the Monogram Biosciences data. During this line of questioning, Dr. Engelman revealed for the first time that he was, in fact, Reviewer # 2 on Tsiang 2016—a fact that Defendant states it was unaware of prior to the disclosure. (D.I. 266 at 1; D.I. 285 (hereafter, "June 15 Tr.") at 31-33) The exchange (which starts out with Defendant's counsel attempting to establish that Dr.

Engelman, prior to his work on this case, had no real experience with Monogram Biosciences or its data) went as follows:

> [Defendant's Counsel:] So the only time you've had anything to do with Monogram Biosciences assays is when you were being paid by ViiV's lawyers in this case, correct?
>
> [Dr. Engelman:] *I've . . . read about Monogram Biosciences and their results prior to this case. In particular, the Tsiang 2016 article which I read in 2016* which — *very carefully*, and which cites Monogram Biosciences. So I was surely aware of the use of Monogram Biosciences and the type of data they provided because it's my impression, as I opined in my reports, that much of the data that's included in Tsiang 2016 was generated by Monogram Biosciences. It's my testimony that I first read that article in 2016.
>
> [Defendant's Counsel:] You weren't a peer reviewer on that Tsiang 2016 article, were you?
>
> [Dr. Engelman:] I did serve as a peer reviewer on that article.
>
> [Defendant's Counsel:] Dr. Engelman, did you tell us in your expert reports that you were one of the peer reviewers of the Tsiang 2016 article?
>
> [Dr. Engelman:] I did not — I've peer reviewed hundreds of articles. Many of those that might be included in the reports. I did not tabulate that information.
>
> [Defendant's Counsel:] Dr. Engelman, did you disclose in your expert reports that you were, in fact, one of the two peer reviewers of the Tsiang 2016 article?
>
> [Dr. Engelman:] I peer reviewed more than one article that's included in my reports and I did not reveal that information.
>
> . . .
>
> [Defendant's Counsel:] . . . Did you talk about the peer review process for any article other than [the] Tsiang 2016 article in your expert reports, sir?

> [Dr. Engelman:] I believe Tsiang 2016 is the only peer review process for which I highlighted text from the peer reviewers.

(D.I. 266, ex. E at 255-58 (emphasis added)) Later, Defendant's counsel returned to the subject:

> [Defendant's Counsel:] You say in [paragraph] 246, [of Dr. Engelman's opening report,] 'Prior to being accepted for publication, Dr. Tsiang's manuscript was peer reviewed by two scientists with expertise in the field.' Do you see that?
>
> [Dr. Engelman:] I do.
>
> [Defendant's Counsel:] You did not disclose that you were one of those two scientists in your report, did you, sir?
>
> [Dr. Engelman:] I did not.
>
> [Defendant's Counsel:] And in fact, you didn't disclose it until I asked you under oath that question, correct?
>
> [Dr. Engelman:] That's correct.
>
> [Defendant's Counsel:] You weren't going to disclose it unless someone asked you under oath whether that was true, were you?
>
> . . .
>
> [Dr. Engelman:] My work with journals as a peer reviewer is a highly confidential process.

(*Id*. at 264-65)

During the deposition, Dr. Engelman went on to provide other testimony about his work as a peer reviewer on Tsiang 2016. For example, Defendant's counsel noted that in his opening report, Dr. Engelman wrote that "two scientists" (i.e., the peer reviewers) opined that the article required further editing because it was "biased, probably . . . influenced by marketing strategies." (*Id*. at 267 (internal quotation marks omitted)) During the deposition, however, Dr. Engelman

acknowledged that he was not the reviewer who had written that the article was "biased"—instead, Reviewer # 1 had said that. (*Id*. at 268) But after Defendant's counsel then noted that "you, as a peer reviewer of the Tsiang 2016 . . . manuscript, did not find it to be biased, correct?" Dr. Engelman replied "[n]ot as I reviewed it in the year 2016. But my opinion has since changed." (*Id*.; *see also id*. at 271) Moreover, although Dr. Engelman did not agree with Defendant's counsel's characterization that he was "the reviewer who did not have any problem with the [Tsiang] article," Dr. Engelman acknowledged that of the two peer reviewers, Reviewer # 1 "obviously saw more flaws than [Dr. Engelman] had" and that (unlike him) Reviewer # 1 had noted that Bictegravir had a "weaker barrier to resistance than [D]olutegravir." (*Id.* at 269-70) And he agreed that in his peer review, he did not comment or complain about the Monogram Biosciences cutoffs. (*Id*. at 270)

Dr. Engelman also explained how he had come to be a peer reviewer on Tsiang 2016 in the first place. He noted that he was one of three scientists whom Gilead suggested should be a reviewer for the paper. (*Id*. at 274) Because he was the only one of those three scientists who was a member of the editorial board for *Antimicrobial Agents & Chemotherapy* (the journal that published the article), Dr. Engelman's view was that "anyone with any common sense in this matter could have fully guessed that [he] was one of the two reviewers." (*Id*.) He acknowledged, however, that the peer review process was a "blind process[,]" in that the identity of reviewers (as here) were generally not revealed. (*Id*. at 275) And he then stated that the reason he had not previously disclosed his status as a peer reviewer was that "when I wrote this portion of the report, I didn't — I suppose I felt like it wasn't pertinent." (*Id.* at 275-76)

When asked if he had "made a mistake in not disclosing in [his] expert report" that he had been a peer reviewer on the article, he admitted that he "could have been more accurate if [he] would have identified [him]self" as Reviewer # 2. (*Id.* at 279) Additionally, Dr. Engelman revealed that "within the last one to two weeks" prior to his deposition, he had a conversation with Plaintiffs' counsel in which he revealed for the first time that he was one of the two peer reviewers on Tsiang 2016. (*Id.* at 263-64; *see also* D.I. June 15 Tr. at 40 (Plaintiffs' counsel confirming this fact during oral argument))

**3. Plaintiffs' Motion**

Plaintiffs' Motion relates to Dr. Douglas Richman. Dr. Richman was retained as an expert by Defendant in this case, and was asked to opine on "the differences between [B]ictegravir and [D]olutegravir from the point of view of a clinician and clinical virologist[.]" (D.I. 280, ex. A at ¶ 15)[3] Prior to his work for Defendant in this litigation, Dr. Richman also worked for Defendant in at least two different capacities, both of which brought him into some contact with Bictegravir.

First, Dr. Richman served as "Chair of an Independent Data Monitoring Committee for Gilead." (D.I. 293, ex. C)[4] The Data Monitoring Committee ("DMC") was involved in the Phase 2 and Phase 3 clinical trials of Defendant's drug, Biktarvy, which contains Bictegravir.

[3] Excerpts of Dr. Richman's expert report are found at D.I. 280, ex. A and D.I. 316, ex. F. Citations to either of these documents will simply be notated hereafter as being to the "Richman Report."

[4] The record sometimes refers to a Data *Monitoring* Committee, (D.I. 293, ex. C), but at other times refers to a Data *Management* Committee, (*e.g.*, D.I. 280, ex. B at 150). The Court understands these to refer to the same entity.

(D.I. 280, ex. B at 153) By way of background, the Phase 3 trials of Bictegravir (like other similar HIV treatments) were evaluated "by documenting [Bictegravir's] non-inferiority to existing regimen[s], as opposed to superiority over existing regimens." (Richman Report at ¶ 121; *see also* D.I. 280, ex. B at 139-41) Gilead's Phase 3 clinical trials were non-inferiority trials against two integrase-inhibitor-containing regimens: Triumeq® (in a trial designated the "1489" study) and Dolutegravir (in the "1490" study). (Richman Report at ¶ 121) Dr. Richman described these studies as having two "arms"—Bictegravir, and the comparator drug, i.e. Triumeq or Dolutegravir. (D.I. 280, ex. B at 121-22) He explained that the DMC's "primary responsibility" in these clinical trials was "to the safety of the participants." (*Id.* at 152) In furtherance of that goal, the DMC was sent "data about safety and efficacy in order to be independent adjudicators regarding whether a study is not endangering the safety of the study participants." (*Id.* at 152-53) In that regard, the DMC would review raw data on adverse events; these materials comprised "[two] looseleaf notebooks with . . . hundreds of pages in each . . . [describing every study participant] who had an adverse event including being run over by a bus or having a heart attack[.]" (*Id.* at 163; *see also id.* at 158; June 22 Tr. at 66) The DMC also examined this data for efficacy purposes, by "look[ing] at [whether] one arm [was] significantly different from the other, [in order to determine whether] there[ was] a concern about the risk of participants in one arm not receiving the best therapy"; if that occurred, the DMC would "then advise [Gilead] of a concern." (D.I. 280, ex. B at 153) A "summary" of this raw data—though not the raw data itself—would eventually be included in peer-reviewed published papers regarding the studies. (*Id.* at 172; *see also* June 22 Tr. at 67)

Second, Dr. Richman served on Gilead's Global Advisory Board ("GAB") from approximately 2005-15. (D.I. 280, ex. B at 107-08) The GAB met annually. (*Id.* at 120) At those meetings, Gilead's clinical development team would describe their proposed clinical study designs to the GAB; GAB members would in turn provide feedback on study design and drug development plans, including "whether the design in terms of the comparators [was] appropriate, [and] whether the candidate study subjects [were] appropriate in terms of [participant] inclusion and exclusion criteria[.]" (*Id.* at 110-11; *see also id.* at 121) According to Dr. Richman, the GAB did not speak with one voice, and members of the GAB sometimes had "different opinions." (*Id.* at 111) He also stressed that the GAB members' recommendations were not binding, as Gilead could "go[] back and either accept[] or ignore[] the advice." (*Id.*) Dr. Richman affirmed that when he was on the GAB, he was presented information about (and ultimately endorsed) a study design wherein Dolutegravir was to be the comparator drug to Bictegravir (i.e., the 1490 study). (*Id.* at 123-24, 130-31)

Defendant disclosed Dr. Richman as an expert witness in August 2019. (D.I. 293, ex. C) In that disclosure, Defendant mentioned that Dr. Richman had served as the Chair of the DMC, but Defendant did not mention Dr. Richman's work on the GAB. (*Id.*)

In January 2020, Dr. Richman served his rebuttal expert report. Therein, Dr. Richman drew the overarching conclusion that "[B]ictegravir and [D]olutegravir are *substantially different* in their dissociation half-life, drug-drug interactions, pharmacokinetic profiles, forgiveness, and *in vitro* resistance profile." (Richman Report at ¶ 206 (emphasis added)) In support, Dr. Richman opined (citing in part to Tsiang 2016) that Bictegravir had a better *in vitro* resistance

profile as compared to Dolutegravir. (*Id*. at ¶¶ 145, 171) And Dr. Richman also cited the fact that the 1490 study's clinical results showed that "[B]ictegravir [was] associated with fewer overall adverse events than [D]olutegravir." (*Id*. at ¶¶ 196-97) In Dr. Richman's opinion, this difference in adverse events supported the conclusion that Bictegravir was "more tolerable than [D]olutegravir" and thus provided a reason to prescribe it over Dolutegravir. (*Id.* at ¶ 198)

Dr. Richman's deposition was scheduled to occur on June 2, 2020. Ten days prior to the deposition, Defendant's counsel disclosed to Plaintiffs for the first time that Dr. Richman had been a member of the GAB. (D.I. 293, ex. D (May 21, 2020 letter from Defendant's counsel disclosing that "we have learned that in February 2015, Dr. Richman was also on a Gilead scientific advisory board"); *see also* D.I. 280, ex. B at 168-69 (Dr. Richman confirming during his June 2, 2020 deposition that the letter was referencing his service on the GAB)) Dr. Richman explained during the deposition that he had failed to previously disclose his service on the GAB because the Protective Order in this case only required him to disclose service on such committees for the five years prior to his retention; Dr. Richman stated that he had wrongly thought that his GAB service ended more than five years from the relevant date, but later realized it had not. (*Id.*; *see also* D.I. 293 at 1) During the June 2, 2020 deposition, Plaintiffs' counsel questioned Dr. Richman at length about his work on both the DMC and GAB. (*See generally* D.I. 280, ex. B)

**B. Procedural Background**

Plaintiffs filed the Complaint in this case in February 2018. In August 2019, United States District Judge Colm F. Connolly referred this case to the Court to resolve all disputes relating to discovery and the protective order. (Docket Item, August 19, 2019)

The parties jointly filed a motion for discovery dispute on June 2, 2020, which included Defendant's Motion regarding Dr. Engelman. (D.I. 259; D.I. 265) Short letter briefs were filed. (D.I. 266; D.I. 278) The Court heard oral argument on Defendant's Motion on June 15, 2020, but was not able to complete the argument on that date due to time constraints. (June 15 Tr.)

Plaintiffs filed their Motion regarding Dr. Richman on June 11, 2020. (D.I. 272; D.I. 277) Short letter briefs were filed. (D.I. 280; D.I. 293) Thereafter, on June 22, 2020, the Court heard the remainder of the argument regarding Defendant's Motion and also heard argument on Plaintiffs' Motion. (June 22 Tr.) Thereafter, because both parties' Motions raised "serious allegations of misconduct and significant requests for relief[,]" including requests for sanctions, the Court ordered supplemental briefing on the Motions. (D.I. 309) The parties filed their supplemental letter briefs on July 10, 2020. (D.I. 316; D.I. 317)

## II. DISCUSSION

In addressing both parties' Motions below, the Court will first set out the relevant legal standards. Next, the Court will assess Defendant's Motion concerning Dr. Engelman. Finally, the Court will assess Plaintiffs' Motion concerning Dr. Richman. Within each discussion of the relevant Motions, the Court will first assess whether each party's actions constitute violations of Rule 26. Thereafter, and because the Court will ultimately conclude that Rule 26 has been violated, it will go on to address what sanctions are appropriate pursuant to Rule 37.

### A. Legal Standards

#### 1. Rule 26

Rule 26(a)(2)(B) requires a testifying expert to prepare and sign a written report containing, *inter alia*, "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; [and] (ii) the *facts or data considered* by the witness in forming them[.]" Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii) (emphasis added). As a general matter, a party who "learns that in some material respect the disclosure [in such a report] . . . is incomplete or incorrect" must supplement or correct its disclosure, unless the additional or corrective information has otherwise been made known to the other parties during the discovery process or in writing. Fed. R. Civ. P. 26(e)(1)(A). With regard to expert witnesses, this general duty to supplement or correct extends "both to information included in the report and to information given during the expert's deposition." Fed. R. Civ. P. 26(e)(2).

#### 2. Rule 37

Rule 26 and the adversary system as a whole relies on truthful and accurate discovery responses. *See generally Gerke v. Travelers Cas. Ins. Co. of Am.*, 289 F.R.D. 316, 322 (D. Ore. 2013) ("The integrity of the [discovery] process depends on lawyers to perform the duty of disclosure imposed by the rules to ensure that all discoverable information—whether favorable or unfavorable to that lawyer's client—is provided to the opposing party.") In line with this, if a violation under Rule 26(a) and/or (e) is found, Federal Rule of Civil Procedure 37 provides

certain remedies.[5] Rule 37(c) provides that, in the event of such a violation, "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). In addition to or in lieu of excluding evidence, the Court may order payment of reasonable expenses, may inform the jury of the failure of disclosure, or may impose "other appropriate sanctions" including, without limitation, those listed in Rule 37(b)(2)(A)(i)-(vi). Fed. R. Civ. P. 37(c)(1)(A)-(C). The burden to demonstrate that a discovery failure was substantially justified or is harmless falls on the non-movant. *See, e.g.*, *MD Mall Assocs., LLC v. CSX Transp., Inc.*, CIVIL ACTION No. 11-4068, 2015 WL 12806503, at *1 n.2 (E.D. Pa. Dec. 16, 2015); *D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, Civil Action No. 03-1026 (MLC), 2006 WL 1644742, at *4 (D.N.J. June 8, 2006).

**B. Defendant's Motion/Dr. Engelman**

**1. Did Plaintiffs Violate Rule 26?**

In considering Defendant's argument that Plaintiffs have violated Rule 26, the Court must consider two disputed legal issues. First, it must assess Defendant's argument that Dr. Engelman's status as Reviewer # 2 amounts to "facts or data" pursuant to Rule 26(a)(2)(B)(ii). And second, if it does, the Court must then address whether, pursuant to the Rule's meaning, Dr. Engelman "considered" these facts or data in forming his expert opinions set out in his reports.

[5] In patent infringement actions, whether to assess Rule 37 sanctions is an issue of regional circuit law. *See ClearValue, Inc. v. Pearl River Polymers, Inc.*, 560 F.3d 1291, 1304 (Fed. Cir. 2009).

If both conditions are met, then this information should have been disclosed to Defendant pursuant to the Rule.

**a. Does Dr. Engelman's status as Reviewer # 2 constitute "facts or data" referenced by Rule 26(a)(2)(B)(ii)?**

The threshold dispute here is whether Dr. Engelman's status as Reviewer # 2 constitutes "facts or data considered by [Dr. Engelman] in forming" his expert opinions. *See* Fed. R. Civ. P. 26(a)(2)(B)(ii). Plaintiffs read the rule narrowly and assert that the phrase "facts or data" only refers to "factual materials" (like documents) that an expert reviews—and cannot encompass "intangible qualifications" like Dr. Engelman's "role[]" or "experience" as a peer reviewer. (D.I. 278 at 1 (emphasis omitted) (internal quotation marks omitted); D.I. 316 at 1 (internal quotation marks omitted); June 15 Tr. at 38; June 22 Tr. at 11-13) Defendant disagrees, and advances a broader interpretation of this part of Rule 26. (D.I. 266 at 1-2; D.I. 317 at 1; June 15 Tr. at 27-28; June 22 Tr. at 28-29)

It certainly seems, as both parties have suggested, that this precise legal issue does not often get litigated. (June 15 Tr. at 38; June 22 Tr. at 29) But while most of the opinions regarding Rule 26(a)(2)(B)(ii)'s reference to "facts or data" concern whether the expert considered particular documents for purposes of Rule 26 (thus warranting disclosure), courts have at times addressed whether "facts" other than those contained in documents are captured by the Rule.[6] In line with those cases, and for the following four reasons, the Court agrees with

[6] *See, e.g., In re Rail Freight Surcharge Antitrust Litig.*, MDL Dkt. No. 1869, 2013 WL 12384733, at *4-7 (D.D.C. Nov. 12, 2013) (holding that an expert witness considered information regarding his "experience[s]" with prior contract negotiations for purposes of Rule 26(a)(2)(B)(ii), when his expert report referenced the same); *see also Koninklijke Philips N.V. v.*

Defendant that Rule 26(a)(2)(B)(ii) encompassed the "fact" of Dr. Engelman's status as Peer Reviewer # 2.

First, the plain text of Rule 26 suggests that "facts or data" is not limited merely to documents—and thus could encompass the "fact" of one's experience. After all, as Defendant correctly points out, there are several other instances where Rule 26's provisions merely make reference to "documents." (D.I. 317 at 1) For example, Rule 26(a)(1)(A)(ii) requires that a party disclose, as part of its initial disclosures, "a copy—or a description by category and location—of all *documents*, . . . that the disclosing party . . . may use to support its claims or defenses[.]" Fed. R. Civ. P 26(a)(1)(A)(ii) (emphasis added). Rule 26(a)(3)(A)(iii) requires a party's pre-trial disclosures to contain "an identification of each *document* or other exhibit, including summaries of other evidence—separately identifying those items the party expects to offer and those it may offer if the need arises." Fed. R. Civ. P. 26(a)(3)(A)(iii) (emphasis added). And other provisions of Rule 26 shield from discovery, *inter alia*, "*documents and tangible things* that are prepared in anticipation of litigation or for trial" or require a that a party who seeks to establish privilege protection over such information must "describe the nature of *the documents*, communications, *or tangible things* not produced or disclosed[.]" Fed. R. Civ. P. 26(b)(3)(A) & (b)(5)(A)(ii) (emphasis added). The point is that when the drafters of Rule 26 wanted to limit the scope of a

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*Zoll Lifecor Corp.*, Case No. 2:12-cv-1369, 2017 WL 9509938, at *79-80 (W.D. Pa. May 12, 2017) (considering *sua sponte* whether the damages expert's citation to his "conversation" with the party's technical expert in his report sufficiently disclosed the underlying "facts or data" that were a part of that conversation for purposes of Rule 26(a)(2)(B)(ii), and indicating that it did not), *report and recommendation adopted in part, rejected in part sub nom.*, 2017 WL 3140798 (W.D. Pa. July 25, 2017).

provision to that involving "documents" or "tangible" things like documents, they knew how to do so (and did do so). But Rule 26(a)(2)(B)(ii) does not refer to "the *documents* considered" by the witness in forming his or her opinion—it refers to the "facts or data considered" by the witness. *See* Fed. R. Civ. P. 26(a)(2)(B)(ii). The use of this broader language is important here.

Second, the Advisory Committee Notes to Rule 26 support Defendant's interpretation of this part of the Rule. This "facts or data" language was adopted as part of the 2010 amendments to Rule 26, and it replaced the phrase "data or other information" that had previously been used in the Rule since 1993. Fed. R. Civ. P. 26 advisory committee's note to 2010 amendment (hereafter the "Note to 2010 Amendment"); *Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC*, Civil Action No. 15-cv-915-RGA, 2017 WL 6328149, at *2 (D. Del. Dec. 11, 2017). But the purpose of this change was simply to strengthen work product protection over materials such as draft expert reports—and thus to "limit disclosure to material of a factual nature by excluding theories or mental impressions of counsel." Note to 2010 Amendment; *see also Ansell*, 2017 WL 6328149, at *2. And in making this change, the Committee also took pains to note that the phrase "'facts or data' [should] be interpreted *broadly* to require disclosure of *any material* considered by the expert, from whatever source, that contains factual ingredients." Note to 2010 Amendment (emphasis added); *see also Ansell*, 2017 WL 6328149, at *2. The breadth with which "facts or data" is to be construed suggests that Dr. Engelman's experience as Reviewer # 2 is the type of "material" that is covered by the phrase. *See also In re Rail Freight Surcharge Antitrust Litig.*, MDL Dkt. No. 1869, 2013 WL 12384733, at *2-3, *6-7 (D.D.C. Nov. 12, 2013) (requiring an expert to disclose, pursuant to Rule 26(a)(2)(B), various types of details regarding

"[his] experience negotiating and reviewing hundreds of rail transportation contracts on behalf of numerous shippers," where the expert had referred to that experience in his report, or alternatively to remove such reference from the report, because it would be unfair for the expert to "speak generally about his experience with 'hundreds' of negotiations as a basis for his expert opinion while simultaneously refusing to give *any* details [about] these negotiations to the defendants") (emphasis in original).

Third, the content of Federal Rule of Evidence 703 supports Defendant's position. Rule 703 allows an expert to base his opinion on "*facts or data* in the case[,]" including those that the expert has "personally observed." Fed. R. Evid. 703 (emphasis added); *see also* Fed. R. Evid. 703 advisory committee's note to 1972 proposed rules (providing that facts or data underlying an expert opinion can arise from "firsthand observation"); *Array Techs., Inc. v. Mitchell*, Civ. No. 17-087 JCH/LF, 2020 WL 1514621, at *5 (D.N.M. Mar. 30, 2020) (allowing, under Federal Rule of Evidence 703, a party's expert to rely on his conversation with his client's employees). If "facts or data" in Rule 703 can relate to something other than documents or tangible items that an expert considered—including information that the expert knows due to personal observation—why would the reference to "facts or data" in Rule 26 have a narrower scope?

Fourth, it is important to note that Rule 26(e) envisions timely supplementation of discovery responses when responses are later found to be inaccurate or misleading. *See Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D.N.C. 2002) ("Rule 26(e) envisions supplementation when a party's discovery disclosures happen to be defective in some way so that the disclosure was incorrect or incomplete and, therefore, misleading."); *Keener v. United*

*States*, 181 F.R.D. 639, 640 (D. Mont. 1998) ("Supplementation under [Rule 26] means correcting inaccuracies, or filling the interstices of an incomplete report based on information that was not available at the time of the initial disclosure."). And in the Court's view, when one reviews the basic facts regarding this dispute, it does not take long to understand why Dr. Engelman's reports—in which he repeatedly noted how "Dr. Tsiang's manuscript was peer reviewed *by two scientists* with expertise in the field" (but failed to mention that *he* was one of those two scientists)—was misleading in a material way. (*See, e.g.*, D.I. 266, ex. B at ¶ 246 (emphasis added)) That omission was the kind of thing that screams out its need for correction. And this, in turn, simply underscores that had Dr. Engelman followed the dictates of Rule 26(a)(2)(B)(ii) in the first place, a correction would never have been needed.

After all, the infringement question in this high-stakes case is all about whether Defendant's drug is "insubstantially different" from Plaintiffs' drug. If Plaintiffs prove that it is, they will prevail on the infringement issue. But if Defendant's drug is more than insubstantially different, Defendant will prevail on that issue. Thus, Dr. Engelman's reports are meant to make Plaintiffs' case that the two drugs are very similar. In that regard, his reports criticize Tsiang 2016, which at times suggested that Defendant's drug is *superior to* Plaintiffs' drug. And in criticizing Tsiang 2016, Dr. Engelman emphasizes and adopts the criticism of Reviewer # 1—who not only had contradicted some of the draft manuscript's claims that Bictegravir was superior (and noted numerous examples of how the two drugs were instead similar), but who had gone beyond that by pointedly suggesting that the authors (who worked for Gilead) were guilty

of "bias[,]" should "write objectively" and should "[b]e honest!" (*Id*. at ¶ 247 (internal quotation marks and citations omitted))

But if you know all of the material facts, you can see a potential problem with this approach right away: it leaves Dr. Engelman open to a fairly obvious line of attack by Defendant. That is: (1) since during the peer review process, Dr. Engelman (as Reviewer # 2) did *not* articulate these same pointed concerns about "bias" or use the same harsh language as did Reviewer # 1 (and instead, touted how "comprehensive" the article was, and how it will be of "significant interest" to those in the field), (*id*., ex. C at BICVIIVUS2556855); (2) but then later, after being in the employ of Plaintiffs, Dr. Engelman adopted Reviewer # 1's language as his own and emphasized Reviewer # 1's criticisms in his expert report; then (3) Defendant will want to highlight this change of emphasis, in order to suggest that Dr. Engelman's current criticism of Tsiang 2016 is inauthentic and motivated only by the fact that he is now being paid by Plaintiffs. (D.I. 266 at 1; *id*., ex. E at 268)[7]

Yet this line of attack would not be available to Defendant unless it was *actually told* that Dr. Engelman was Reviewer # 2. And that makes Dr. Engelman's failure to disclose this fact a

[7] The Court is not suggesting that Defendant's criticisms in this regard are, *in fact*, accurate. They may be or they may not be; the Court takes no view. And, in Plaintiffs' favor here is that in his peer review of Tsiang 2016, Dr. Engelman did opine that the results of the study "in large part show *similar behavior* to" Dolutegravir—a conclusion that aligns nicely with Dr. Engelman's opinion in this case. (D.I. 266, ex. C at BICVIIVUS2556855 (emphasis added); *see also id*., ex. E at 269) The Court is simply pointing out that it is not hard to understand how Defendant, if appraised of all of the key facts about the peer review process, would reasonably seek to use those facts to try to discredit Dr. Engelman's criticism of Tsiang 2016.

misleading omission about an important issue in the case. It is the kind of thing that surely requires correction via Rule 26(e).

Plaintiffs, for their part, never credibly explain how these portions of Dr. Engelman's reports were *not* misleading. Indeed, during oral argument, the Court asked Plaintiffs' counsel how it would have been possible for Plaintiffs to keep Dr. Engelman's status as Reviewer # 2 from Defendant and still have a fair trial as to these issues. In that regard, the Court posited a hypothetical scenario wherein Defendant's counsel did not figure out that Dr. Engelman was a peer reviewer of Tsiang 2016 during the discovery process. (June 15 Tr. at 41) Would Plaintiffs and their counsel really have permitted that failure of disclosure to persist through to trial? (*Id.*) What if at trial, Dr. Engelman again adopted Reviewer # 1's criticisms of the article, but on cross-examination, Defendant's counsel noted that there was another anonymous reviewer who did not seem to share all of those same criticisms? (*Id.*) The Court asked Plaintiffs' counsel whether, in such a scenario, counsel "really [would] have not said anything about [Dr. Engelman's status as Reviewer # 2?]" To this question, Plaintiffs' counsel replied only: "Your honor, I don't think we got there, we got to that point, but I understand what you are saying, Your Honor." (*Id.*) In the moment, the Court understood this statement to amount to a tacit admission: that yes, of course, Plaintiffs would have had to disclose Dr. Engelman's status as Reviewer # 2 in such a scenario.

Therefore, for the four reasons set out above, the Court concludes that Dr. Engelman's status as a peer reviewer of Tsiang 2016 qualifies as relevant "facts or data" pursuant to the meaning of Rule 26(a)(2)(B)(ii).[8]

**b. Did Dr. Engelman "consider[]" his role or work as a peer reviewer of Tsiang 2016 in providing his expert opinions for purposes of Rule 26(a)(2)(B)(ii)?**

Having found that Dr. Engelman's status as Reviewer # 2 constitutes "facts or data" for purposes of Rule 26(a)(2)(B)(ii), the Court will now assess whether Dr. Engelman "considered" that fact in forming his expert opinions. It concludes that he surely did.

The term "considered" in Rule 26(a)(2)(B)(2) has been interpreted broadly by courts. It is understood to refer to "any information furnished to a testifying expert that such an expert generates, reviews, reflects upon, reads, and/or uses in connection with the formulation of his opinions, even if such information is ultimately rejected." *Synthes Spine Co., L.P. v. Walden*, 232 F.R.D. 460, 463 (E.D. Pa. 2005) (citing cases); *see also Ansell*, 2017 WL 6328149, at *1; *Helios Software, LLC v. SpectorSoft Corp.*, Civil Action No. 12-81-LPS, 2015 WL 3561367, at *2 & n.3 (D. Del. June 5, 2015); *Robocast, Inc. v. Apple, Inc.*, Civil Action No. 11-235 (RGA), Civil Action No. 10-1055 (RGA), 2013 WL 12155813, at *1-3 (D. Del. Sept. 18, 2013) (citation omitted) (concluding that an expert "considered" certain surveys for purposes of Rule 26(a)(2)(B)(ii) in forming his expert opinion, even where the surveys had been deleted from his

[8] Defendant did not suggest that Dr. Engelman's status as Reviewer # 2 would qualify as information that should have been included in his expert report pursuant to other portions of Rule 26(a)(2)(B), such as because it was a "basis" for his expert opinions pursuant to Rule 26(a)(2)(B)(i) or one of his "qualifications" pursuant to Rule 26(a)(2)(B)(iv). Thus, the Court does not consider those issues here.

computer at the time he wrote his report, and where the expert did not remember the surveys and did not review them when preparing the report, because: (1) the surveys contained "very similar" questions to those in surveys that were actually referenced in the report; (2) were of the same subject matter as the surveys in the report; and (3) it was "difficult if not impossible to believe that an expert whose opinions are predicated upon the creation of a statistically-meaningful effort could have, in the statistical sense, completely ignored the data that had previously been collected by him"), *report and recommendation adopted*, Civil Action No. 3:06-cv-0845, 2013 WL 12156411 (D. Del. Oct. 17, 2013). "In fact, if the subject matter of the materials sought to be protected relates to the facts and opinions the expert expresses in his report, a court should order disclosure when there is at least an ambiguity as to whether the materials informed the expert's opinion." *Robocast*, 2013 WL 12155813, at *3 (citing cases); *see also United States v. Dish Network, L.L.C.*, 297 F.R.D. 589, 595 (C.D. Ill. 2013).

Here, Dr. Engelman had to have "considered" his prior work as a reviewer for Tsiang 2016 in generating the opinions in his expert reports. That is, he necessarily must have "reflect[ed] upon" or "use[d]" his role as a reviewer when completing those reports. *See Synthes Spine*, 232 F.R.D. at 463. The Court so concludes for two reasons.

First, it is dispositive in the Court's view that in his report, Dr. Engelman: (1) specifically references the two peer reviewers; (2) cites to the specific comments of both reviewers; and (3) characterizes the meaning of those comments as it relates to the content of

Tsiang 2016. (D.I. 266, ex. B at ¶ 247; *see also* June 15 Tr. at 25; June 22 Tr. at 29)[9] How could Dr. Engelman not have "reflect[ed] upon" or "use[d]" his role as a peer reviewer when characterizing and opining on the substance of what he and his colleague peer reviewer wrote during that very peer review process? *Cf. In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 471 (S.D.N.Y. 2016) (reasoning that "it would be impossible for a witness to divorce herself from her memories about what occurred during a project in which she was an active participant and segregate that information from the documentary record in forming her [expert] opinions").[10]

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[9] To the extent that Plaintiffs point to Dr. Engelman's own assertion that he did not "rel[y] upon his peer-review experience" in coming to his expert opinions, (D.I. 278 at 1; *see also* D.I. 316 at 2; June 15 Tr. at 38), that is not dispositive here. *See, e.g.*, *Dish Network*, 297 F.R.D. at 595 (noting that courts generally do not allow an expert's statement that he did not "consider" certain material to be controlling in this analysis, as that "could become too easy a dodge") (internal quotation marks and citation omitted); *see also Robocast*, 2013 WL 12155813, at *3.

[10] Plaintiffs rely on *Fields v. Eli Lilly & Co.*, CASE NO. 2:13-CV-35-WKW, 2015 WL 13609685 (M.D. Ala. Mar. 26, 2015) for the proposition that "peer-review comments received by an expert are not discoverable under Rule 26(a)(2)(B)[.]" (D.I. 316 at 1) But Plaintiffs' citation to that case is inapposite, as *Fields* does not support this broadly-stated proposition. In *Fields*, which was a products liability case concerning the drug Prozac®, the Court declined to compel the plaintiff's expert witness to disclose a draft of his unpublished manuscript and peer reviewers' comments related to the manuscript. *Fields*, 2015 WL 13609685, at *1. But in doing so, the *Fields* Court never stated that peer review comments were not "discoverable" under Rule 26(a)(2)(B). Instead, based on the facts of that particular case, it concluded that the burden that production of this material would have on the peer reviewers' expectations of confidentiality outweighed the probative value of the discovery to the defendant. *Id.* In this case, by contrast, the reviewers' comments had already been produced in discovery and Dr. Engelman had actually *relied upon* those very comments to bolster his expert opinions. Additionally, the parties have agreed to a Protective Order in this case, which allows for truly confidential material to be protected from broader disclosure. (D.I. 32) For all of these reasons, the holding in *Fields* does not impact the Court's decision here.

Second, in forming his expert opinions here, Dr. Engelman also necessarily "considered" his prior review of the Monogram Biosciences data during the Tsiang 2016 peer review process. In one of his reports, Dr. Engelman opined on Tsiang 2016's presentation of data, including the fold change data referenced in Figure 1. (D.I. 266, ex. B at ¶¶ 277-83, 313-14, 318-28, 334-36, 354-57, 361-64 (*cited in* D.I. 317 at 1)) And at his deposition, Dr. Engelman confirmed that he was familiar with and was comfortable discussing this Monogram Biosciences data, all due to his prior work as a peer reviewer on Tsiang 2016 years earlier:

> In particular, *the Tsiang 2016 article which I read in 2016* which — *very carefully*, and which cites Monogram Biosciences. So I was surely aware of the use of Monogram Biosciences and the type of data they provided because it's my impression, as I opined in my reports, that much of the data that's included in Tsiang 2016 was generated by Monogram Biosciences. It's my testimony that *I first read that article in 2016*.

(D.I. 266, ex. E at 255-56 (emphasis added)) It seems plain, then, that Dr. Engelman necessarily "considered" his work as a peer reviewer when he was forming the expert opinions regarding this Monogram Biosciences data that are set out in his report.

For the above-referenced reasons, Dr. Engelman's failure to disclose his status and prior work as a peer reviewer of Tsiang 2016 amounted to a violation of Rule 26(a)(2)(B)(ii).

**2. Rule 37 Sanctions Against Plaintiffs**

Defendant seeks as a sanction, pursuant to Rule 37(c)(1), a jury instruction "that [Plaintiffs] failed to comply with [their] discovery obligations and that the jury may draw any reasonable inference, including an adverse one, from the failure to disclose Dr. Engelman's role as a peer reviewer on Tsiang 2016." (D.I. 266 at 2; *see also* D.I. 317 at 2-3; June 22 Tr. at 37-

38) Plaintiffs object to this sanction as "disproportionate" to the alleged violation. (D.I. 278 at 2; D.I. 316 at 2-3) Instead, they offer that if the Court finds that a sanction is appropriate, it should instead exclude only the four paragraphs of Dr. Engelman's reports that directly address the comments of the two peer reviewers for Tsiang 2016. (D.I. 316 at 3)[11]

In arguing about whether Defendant's proposed sanction was appropriate, or whether some alternative sanction should be imposed, neither side pointed the Court to a legal test that it should use, or to particular factors that it should consider. (D.I. 316 at 3; D.I. 317 at 3) The Court notes that often when a party is seeking an adverse jury instruction pursuant to Rule 37, the request is made in cases where the opposing side has spoliated or destroyed relevant evidence. In such cases, courts consider the following three factors in determining an appropriate sanction: (1) the violating party's degree of fault and personal responsibility; (2) the prejudice suffered by the opposing party; and (3) the availability of a lesser sanction that will avoid substantial unfairness to the opposing party and, if necessary, deter similar misconduct in the future. *GN Netcom, Inc. v. Plantronics, Inc.*, 930 F. 3d 76, 82-85 (3d Cir. 2019) (citing *Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 79 (3d Cir. 1994)); *CIGNEX Datamatics,*

[11] Plaintiffs alternatively suggest that the Court could "provide [Defendant] additional deposition time" with Dr. Engelman. (D.I. 316 at 3) But Defendant's counsel is not seeking additional deposition time, because counsel discovered the failure of disclosure in time to question Dr. Engelman about the issue at some length during his deposition. So the Court does not see how this proposal could be an adequate or necessary remedy here, and will not discuss it further below.

*Inc. v. Lam Rsch. Corp.*, C.A. No. 17-320 (MN), 2019 WL 1118099, at *2 (D. Del. Mar. 11, 2019).[12]

Here, the Court will use these three factors as guideposts for its analysis, even though this is not a case where the evidence at issue (i.e., Dr. Engelman's status as a peer reviewer) has been lost or destroyed. This also seems appropriate because both sides discussed the concepts animating these three factors in their briefing. (D.I. 316 at 1, 2-3; D.I. 317 at 2-3)

As to the first factor—degree of fault—the Court finds it weighs in favor of Defendant's proposed sanction (i.e., a sanction with greater impact than that proposed by Plaintiffs). This is because, for the reasons set out above in Section II.B.1, Dr. Engelman's status and role as Reviewer # 2 is the kind of thing that clearly should have been disclosed. Dr. Engelman's generic, third-person reference to himself and Reviewer # 1 as "two scientists" in his reports hid that fact. (D.I. 317 at 1 ("[Plaintiffs have] not explained why anyone would refer to himself in the third person if not to mislead.")) And the Court is hard-pressed to understand why Dr. Engelman and Plaintiffs' counsel failed to disclose the information prior to Dr. Engelman's deposition.

During his deposition, Dr. Engelman provided a number of explanations for the failure of disclosure, but none of them seem particularly persuasive. For example, at certain points, Dr. Engelman suggested that he had not disclosed his status as a peer reviewer because he did not

[12] Additionally, "a finding of bad faith is pivotal to a spoliation determination. . . . Withholding [evidence] requires intent." *Bull v. United Parcel Serv., Inc.*, 665 F.3d 68, 79 (3d Cir. 2012) ("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.").

think it was particularly material, since he had "peer reviewed hundreds of articles" and had "peer reviewed more than one article that's included in my reports [and yet had not revealed] that information." (D.I. 266, ex. E at 256-57; *id*. at 276 (Dr. Engelman responding that he had not disclosed the fact because "I suppose I felt like it wasn't pertinent")) But as Defendant's counsel aptly noted in response, Tsiang 2016 is pretty obviously *different* than all of these other articles—in that Dr. Engelman had actually commented on and cited to the peer review commentary for Tsiang 2016 in his reports (but had not done so as to any other cited article). (*Id*. at 257-58) At another point in his deposition, Dr. Engelman seemed to provide a different justification: "My work with journals as a peer reviewer is part of a highly confidential process." (*Id.* at 265) In other words, here it seems Dr. Engelman was suggesting that the reason he had not earlier disclosed his role was because he felt like he *could not* do so, due to the confidentiality inherent in the peer review process. But as Defendant's counsel noted during the deposition, Dr. Engelman's reports themselves were marked with the designation "Highly Confidential — Attorneys' Eyes Only"; thus, it did not make much sense to think that only *non-confidential* information could be shared in such a document. (*Id*. at 265-66; *see also* D.I. 316, ex. A)[13]

Even if Dr. Engelman could not have reasonably seen the need to disclose these facts,[14] his counsel (who knew about his status as a peer reviewer prior to his deposition) should have.

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[13] Indeed, the actual peer review comments were produced in discovery and were marked "Highly Confidential — Attorneys' Eyes Only." (D.I. 266, ex. C)

[14] Plaintiffs do note that this is "Dr. Engelman's first engagement as an expert witness." (D.I. 278 at 1; *see also* June 15 Tr. at 33-34, 37-38)

(June 15 Tr. at 40) Plaintiffs' counsel suggests that it failed to provide this information to Defendant's counsel because "Dr. Engelman confirmed he had not relied upon his peer-review experience in forming his opinions here[.]" (D.I. 278 at 1) But the Court has already explained above why that position is not legally supportable. And when the Court asked Plaintiffs' counsel if it would have permitted Dr. Engelman to rely on this same "two scientists" smokescreen while testifying on the subject at trial—all with Defendant's counsel, the Court and the jury none the wiser about the truth—Plaintiffs' counsel all but conceded they would not have. (June 15 Tr. at 41 ("Your Honor, I don't think we got there, we got to that point, but I understand what you are saying, Your Honor.")) Of course they would not have. How could the right answer be anything different? If Plaintiffs' counsel or Dr. Engelman would not have disclosed these facts, then at trial, the factfinder would have been seriously misled into thinking that Dr. Engelman was *not* one of these two peer reviewers. And that same factfinder could then have been watching Dr. Engelman support the position of these two "other" reviewers by largely echoing the criticism of Tsiang 2016 made by Reviewer # 1 (i.e., the person who was *not him*)—all while failing to mention that Reviewer # 2 (i.e., the person who *was him*) had not made many of those same criticisms. These facts needed to be disclosed.[15]

The second factor—the prejudice suffered by Defendant—weighs in Plaintiffs' favor. Defendant's counsel discovered the failure of disclosure on its own during Dr. Engelman's

[15] Thus, in the Court's view, the decision by Plaintiffs to withhold this information was intentional. Plaintiffs knew or should have known that the information was material to the case and that it should have been disclosed, but Plaintiffs did not disclose it.

deposition. Therefore, Defendant's counsel was able to examine the witness about the issue for some time during the deposition. And because of this, to the extent Dr. Engelman would testify about Tsiang 2016 at trial, Defendant would be able to cross-examine him there about the lack of disclosure. Even Defendant's counsel admitted that in light of this, "the prejudice is not gigantic[.]" (June 15 Tr. at 33)

The third factor—the availability of a lesser sanction that will avoid substantial unfairness to Defendant and will deter similar misconduct in the future[16]—tips the analysis in Plaintiffs' favor. This is because although many other possible sanctions would not be both proportional to the violation and/or sufficient to deter such misconduct in the future, at least one such alternative sanction would fit this bill.

With regard to alternative sanctions that do not seem appropriate, the Court has considered the possibility of imposing a monetary sanction. *See* Fed. R. Civ. P. 37(c)(1)(A). But it agrees with Defendant that, absent an exorbitant penalty, this path would not amount to a sufficient deterrent in a case where Plaintiffs are seeking "billions in damages[.]" (D.I. 317 at 3) And the Court has no reliable metric to use, were it to attempt to fashion a large enough monetary penalty to really make a difference from a deterrence perspective.

Other possible sanctions would be too harsh under the circumstances. Rule 37 does provide for more severe sanctions than the requested jury instruction, such as directing a finding

[16] The Court notes that this is the second time in this case that it has sanctioned Plaintiffs pursuant to Rule 37, having previously assessed costs against them for wrongly terminating the deposition of one of their fact witnesses. (D.I. 193)

of fact or dismissing the action. Fed. R. Civ. P. 37(b)(2)(A)(i) & (v); *Magnetar Techs. Corp. v. Six Flags Theme Park Inc.*, 886 F. Supp. 2d 466, 481 (D. Del. 2012) ("[E]ntering a judgment against a party is a last resort and should be imposed if no alternative remedy is available."). But such dramatic steps would not be warranted here, and Defendant is not seeking them.

As for Plaintiffs' proposed remedy, it too does not do the trick. Plaintiffs would simply have the Court strike four paragraphs in the reports. (D.I. 316 at 3 (citing *id.*, ex. A at ¶¶ 246-48; *id.*, ex. B at ¶ 13)) Importantly, while these four paragraphs do include the references to the Tsiang 2016 peer reviewers' comments, they do not include those paragraphs in which Dr. Engelman characterizes the Monogram Biosciences data. So Plaintiffs' remedy would not even address the entirety of the relevant content relating to Dr. Engelman's prior experience as a peer reviewer for Tsiang 2016.

And yet, the Court is also not convinced that Defendant's proposed sanction is a right-sized response. Plaintiffs are correct that "courts typically impose adverse jury instructions [] in cases involving missing or destroyed evidence[,]" (D.I. 316 at 2-3 (citing cases)), and this is not such a case.[17] Moreover, in the Court's view, a jury instruction of the type proposed by Defendant is a very significant remedy, one that could have the effect of influencing the jury's

[17] That said, federal courts have occasionally found that an adverse inference instruction was a proper sanction for violations of Rules 26 and 37, even in cases (like this one) where the violation at issue did not involve the destruction of evidence. *See, e.g.*, *Fanelli v. BMC Software, Inc.*, CIVIL ACTION NO. 1:11-CV-436-LMM, 2015 WL 13122473, at *4 (N.D. Ga. Apr. 29, 2015); *McCloud v. Goodyear Dunlop Tires N. Am., Ltd.*, No. 04-1118, 2007 WL 2584289, at *4-5 (C.D. Ill. Aug. 23, 2007).

ultimate verdict.[18] In a case involving important, life-sustaining medications and (potentially) billions of dollars in damages, the Court is concerned that imposition of this remedy would unduly distract the factfinder from what really should control the outcome: the merits of the evidence presented by both sides. And in a case where (though fortuitously, and no thanks to Plaintiffs) there is no real lingering prejudice to Defendant due to the violation, the proposed jury instruction seems a step too far.

In the Court's view, the most appropriate remedy would be to strike the entirety of Dr. Engelman's reports that in any way relate to Tsiang 2016. That outcome would deal directly with the entire subject matter related to Plaintiffs' discovery violations, not just a part of it. And it would reflect the seriousness of those violations, as it would strike a substantial portion of Dr. Engelman's testimony.

In sum, as the analysis of the above three factors indicates, Dr. Engelman's failure to disclose his role as a peer reviewer of Tsiang 2016 was not substantially justified. In the Court's view, reasonable people could not differ as to whether Dr. Engelman should have disclosed his

[18] The Court recognizes that our Court has at times referred to an adverse jury instruction as a remedy that is "'limited in scope[.]'" *Micron Tech., Inc. v. Rambus Inc.*, 917 F. Supp. 2d 300, 325 (D. Del. 2013); *see also Mosel Vitelic Corp. v. Micron Tech., Inc.*, 162 F. Supp. 2d 307, 315 (D. Del. 2000). To be sure, especially in cases where evidence has been destroyed, such a jury instruction might well be viewed this way, especially in contrast to the harm caused by lost evidence. *See In re Wechsler*, 121 F. Supp. 2d 404, 427 (D. Del. 2000). But as noted above, this case does not involve the destruction or spoliation of evidence. And in the Court's view, an instruction to the jury that it may draw an adverse inference against a party for discovery misconduct seems like a pretty "powerful" tool. *Union Pump Co. v. Centrifugal Tech. Inc.*, 404 F. App'x 899, 906 (5th Cir. 2010); *Morris v. Union Pacific R.R.*, 373 F.3d 896, 900 (8th Cir. 2004). And while reasonable minds can disagree, the Court is just not certain that the utilization of such a "powerful" tool is warranted here.

status as Reviewer # 2: he should have, and his counsel should have disclosed that fact when they became aware of it. *See Fitz, Inc. v. Ralph Wilson Plastics Co.*, 174 F.R.D. 587, 591 (D.N.J. 1997) (noting that "'[s]ubstantial justification' requires 'justification to a degree that could satisfy a reasonable person that parties could differ as to whether the party was required to comply with the disclosure request'") (citation omitted); *see also Grider v. Keystone Health Plan Central, Inc.*, 580 F.3d 119, 140 n.23 (3d Cir. 2009). Nor was that failure harmless, in that the record indicates it was not the product of an honest mistake or inadvertence, and Defendant was not otherwise aware of the information that was being withheld.[19] *See Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.*, 60 F.3d 153, 156 (3d Cir. 1995); *Klatch-Maynard v. Sugarloaf Twp.*, Civil Action No. 3:06-cv-0845, 2011 WL 2006424, at *3 (M.D. Pa. May 23, 2011). However, in light of the Court's analysis above, the right remedy for this violation is that all portions of Dr. Engelman's reports that reference Tsiang 2016 should be stricken.

[19] Plaintiffs argued that Dr. Engelman's failure of disclosure was harmless, because Defendant should have been able to figure out on its own that Dr. Engelman was Reviewer # 2. More specifically, Plaintiffs position is that: (1) because Dr. Engelman was one of three scientists whom Defendant recommended be appointed as a peer reviewer for Tsiang 2016; and (2) Dr. Engelman had an editorial role with the journal that published Tsiang 2016; then (3) "Dr. Engelman and [Plaintiffs] reasonably believed that [Defendant] was aware that he peer-reviewed Tsiang[ 2016]." (D.I. 316 at 2; *see also id.*, ex. J at BICVIIVUS0293878; June 15 Tr. at 43) However, Defendant's counsel denied that Defendant had in fact known, prior to Dr. Engelman's deposition, that Dr. Engelman was one of the two peer reviewers. (June 15 Tr. at 34) And there is no dispute that the peer review process used in Tsiang 2016 was anonymous, such that the publishing journal did not alert Defendant or anyone else as to whom the reviewers were. (*Id.*) So based on the record here, this omission was not harmless. Indeed, had Defendant's counsel not figured out that Dr. Engelman was Peer Reviewer # 2 through counsel's deposition questioning, the harm from this lack of disclosure would only have intensified as the case got closer to trial.

### C. Plaintiffs' Motion/Dr. Richman

#### 1. Did Defendant Violate Rule 26?

The Court next turns to Plaintiffs' assertion that Defendant violated Rule 26. By the time of oral argument, Plaintiffs had narrowed their argument as to what type of violation had occurred. During oral argument, Plaintiffs' counsel made clear that Plaintiffs were *not* asserting that Defendant violated the Rule by failing to disclose Dr. Richman's role on the DMC or GAB earlier than it did, nor by failing to earlier disclose the fact that in those roles, Dr. Richman had reviewed and had input into clinical trials involving Bictegravir and Dolutegravir. (June 22 Tr. at 58-59 ("[Plaintiffs' Counsel]: Our request for sanctions does not lie in the . . . failure to . . . disclose Dr. Richman's status in those clinical trials previously."))[20] Instead, Plaintiffs are arguing that the alleged Rule 26 violation is Defendant's failure to disclose certain *documents or materials* that Dr. Richman reviewed regarding Bictegravir while serving on these committees—i.e., that those documents/materials amount to "facts or data considered" by Dr. Richman in forming his expert opinion, pursuant to Rule 26(a)(2)(B)(ii). (*Id*. at 59-61 (Plaintiffs' counsel

[20] Prior to this, Plaintiffs had been arguing (a little awkwardly) that Defendant's failure to earlier disclose Dr. Richman's "roles" on the DMC and GAB (and what those roles entailed) was *also* a violation of Rule 26. (D.I. 280 at 1 & n.1) The Court describes this position as "awkward" only in the sense that in making this argument, Plaintiffs were also simultaneously acknowledging that they did not believe it to be correct. That is, (as Plaintiffs had argued regarding Defendant's Motion) Plaintiffs did not actually believe that the failure to disclose prior "roles" like these amounts to a failure to disclose "facts or data" under the meaning of Rule 26(a)(2)(B)(ii). (June 22 Tr. at 46; D.I. 317 at 3) Thus, Plaintiffs had only been making this argument in the alternative—i.e., only if the Court found that Defendant's Motion was well-taken would Plaintiffs then wish to argue that under a similar rationale, Defendant's failure to earlier disclose Dr. Richman's roles on these committees was a Rule 26 violation. (June 22 Tr. at 46; D.I. 280 at 1 n.1)

stating that Defendant's violation was the "failure to disclose these documents" and that Dr. Richman "did rely on those documents" in forming his expert opinion); *see also id*. at 85; D.I. 316 at 3 (Plaintiffs asserting that the "raw safety data and other committee materials Dr. Richman reviewed in his roles on Gilead's clinical trials are 'facts or data' subject to Rule 26, and should have been produced and identified"); *id*. (Plaintiffs asserting that Dr. Richman's "failure to disclose the documents and data that he received during those trials violates the 'facts or data' requirement of Rule 26(a)(2)(B)")) Here, in light of the broad way the term "considered" in Rule 26(a)(2)(B)(ii) has been interpreted by courts, the Court agrees with Plaintiffs that Dr. Richman necessarily "considered" any raw safety data-related documents or materials that he previously reviewed while serving on the DMC or GAB, to the extent that data involved: (1) Bictegravir/Bicktarvy; and/or (2) a comparison of Bictegravir to Dolutegravir.

With regard to his work with the DMC, the Court understands that Dr. Richman reviewed certain raw safety and efficacy data concerning Bictegravir regarding the 1489 study and the 1490 study (in which Bictegravir was compared to Dolutegravir to determine whether it was not inferior to Dolutegravir)—data that Defendant has not disclosed to Plaintiffs. (D.I. 293, ex. B at 152-53, 160-61; D.I. 316, ex. G at 140-41) In his expert report, Dr. Richman cited to results from the 1489 study and 1490 study to help support his conclusion that Bictegravir had an improved *in vitro* resistance profile as compared to Dolutegravir. (Richman Report at ¶¶ 121, 169, 171) And in that report, he also cited the 1490 study's results in opining, *inter alia*, that "[B]ictegravir [was] associated with fewer overall adverse events than [D]olutegravir." (*Id*. at ¶¶ 196-97; *see also id.* at ¶ 198) So the subject matter of the raw data regarding Bictegravir that he

reviewed while on the DMC surely "relates to the facts and opinions [he] expresse[d] in his report[.]" *Robocast*, 2013 WL 12155813, at *3. Were some of that raw data to contradict the overarching conclusions that Dr. Richman drew from the two studies, Plaintiffs might want to know that, in order to effectively cross-examine Dr. Richman. Thus, the Court concludes that Dr. Richman can be said to have "considered" this raw data for purposes of Rule 26, such that Defendant would be required to disclose it.

Defendant argues to the contrary—i.e., that Dr. Richman could not have "considered" this raw data in forming his expert opinions—because Dr. Richman: (1) did not have access to that raw data when drafting his expert reports; and (2) instead only reviewed published summary data regarding the 1489 and 1490 studies when working on those reports. (D.I. 293 at 1-2 (citing *id.*, ex. B at 171-76); *see also* June 22 Tr. at 85)[21] Yet as was noted above, *see supra* n.9, Dr. Richman's statements about what he did and did not review or consider in forming his opinions are not dispositive. *See Dish Network*, 297 F.R.D. at 595-96; *Robocast*, 2013 WL 12155813, at *2-3. Instead, the key factor is the similarity between the materials in question and the subject matter of Dr. Richman's expert opinions. And as the Court has explained, such similarity exists here.

[21] The record is unclear as to how much of his "raw" data there is, or how it differs from the published "summary" data that Dr. Richman states that he relied on. But it is clear to the Court that this raw data exists and that it has not been produced to Plaintiffs. (*See* June 22 Tr. at 49, 53-55, 85) And Defendant has not raised any argument under Rule 26(b) that the "burden or expense" of producing such materials "outweigh[] [their] likely benefit." Fed. R. Civ. P. 26(b)(1).

As for the materials that Dr. Richman reviewed when he was on the GAB, the Court too finds that Defendant's decision to withhold them amounts to a Rule 26 violation. The record indicates that when Dr. Richman was on the GAB, he reviewed "candidate protocols" relating to the 1489 and 1490 studies; in the latter study, Dolutegravir was deemed an appropriate comparator drug to Bictegravir. (D.I. 280, ex. B at 121-24, 130-31) And as noted above, in his rebuttal report, Dr. Richman compared Bictegravir and Dolutegravir and opined that Bictegravir showed an "improved *in vitro* resistance profile" and "fewer overall adverse events" as compared to Dolutegravir. (Richman Report at ¶¶ 171, 196-97) The subject matter of Dr. Richman's work on the GAB, including his review of the above-referenced candidate protocols, clearly overlaps with that of his expert opinions. And it is hard to believe that while composing his reports, Dr. Richman did not in some way reflect on or take into account his GAB experience with the 1489 and 1490 studies, as in those reports, Dr. Richman was opining on his view of the results of those very studies. Thus, the Court finds that Dr. Richman "considered" this prior work, and that it was a Rule 26 violation to withhold the candidate protocols or other similar materials regarding the 1489 and 1490 studies that Dr. Richman reviewed while on the GAB.

**2. Rule 37 Sanctions Against Defendant**

With regard to Plaintiffs' Motion, Plaintiffs seek one of two sanctions: (1) to strike Dr. Richman's testimony, or (2) to order Defendant to produce the raw data and documents that Dr. Richman had access to during the 1489 and 1490 study clinical trials, and to provide Plaintiffs with two hours of additional deposition time. (D.I. 316 at 3)

In situations where a party has violated Rule 26, and where the opposing party requests that related testimony be stricken, our Court typically turns to the "*Pennypack* factors" to determine whether such a request is warranted. Those factors include: (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). As the Court has previously noted, because the "[t]he exclusion of critical evidence is an extreme sanction," 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).

Here, while the Court agrees that the requested document production and additional deposition time are in order, it concludes that the *Pennypack* factors do not warrant striking the portions of Dr. Richman's report at issue. Although Defendant's failure to produce the relevant documentation may have been a surprise to Plaintiffs, a number of the other factors militate against a motion to strike. Producing these documents and allowing this additional deposition testimony would allow Plaintiffs to cure any prejudice. Trial is now set for March 2021, (Docket Item August 6, 2020; Docket Item, September 30, 2020), which leaves plenty of time to accomplish this work. And the Court finds no evidence of bad faith (and Plaintiffs assert none).

(*See* D.I. 316 at 3) Indeed, it is not even clear whether this data (which was otherwise summarized in materials available to Plaintiffs) will even be helpful to Plaintiffs' cause.[22]

The parties shall meet and confer in a timely fashion to discuss the provision of any accessible relevant documents and on the timing of a supplemental deposition.

## III. CONCLUSION

For the reasons set out above, the Court orders that Plaintiffs' and Defendant's Motions for sanctions are GRANTED in the manner set out herein.

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 **November 2, 2020**, 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: October 28, 2020

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE

[22] As to the last *Pennypack* factor, the Court does not have much of a record to determine the relative importance of Dr. Richman's testimony on these subjects.