

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC,

Plaintiff,

v.

BAXALTA INC., BAXALTA US INC., and
NEKTAR THERAPEUTICS,

Defendants.

No. 16-cv-1122-RGA

MEMORANDUM ORDER

Presently before the Court are Plaintiff's motions to strike. (D.I. 214, 240). I have reviewed the parties' briefing. (D.I. 215, 221, 224, 241, 273, 277).

I. BACKGROUND

Plaintiff asserts claims 1–9 of U.S. Patent No. 9,364,520 (“the ’520 patent”). (D.I. 1). The ’520 patent is directed to forms of factor VIII, “a protein necessary for normal blood clotting in response to injury.” (D.I. 99 at 1). The patent claims factor VIII conjugates not found in nature, made up of recombinant factor VIII and one or more biocompatible polymers chemically bonded to factor VIII at the protein region known as the “B-domain.” (*Id.* at 1, 3). The claimed factor VIII conjugates are formed through a process called pegylation, which is the conjugation of recombinant factor VIII with polyethylene glycol (“PEG”), a biocompatible polymer. (*Id.* at 5). Claims 1 and 9 are independent claims. Claims 2–8 depend from claim 1.

The accused product is Adynovate, a pegylated factor VIII used to treat hemophilia A. (D.I. 28 ¶ 25; D.I. 247 at 1). Hemophilia A is a congenital bleeding disorder caused by deficient or defective factor VIII. '520 patent at 1:25–32.

Plaintiff has filed two motions to strike portions of Defendants' expert testimony. In the first motion, Plaintiff moves to strike (1) Dr. Rausser's opinions in his reply expert report based on allegedly late-disclosed foreign profits documents, and (2) Dr. Tuddenham's opinions in his reply expert report based on allegedly new indefiniteness and noninfringement theories.¹ (D.I. 214, 215). In the second motion, Plaintiff moves to strike Dr. Zalipsky's opinions in his reply expert report based on allegedly new indefiniteness and lack of written description theories. (D.I. 240, 241).

II. 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(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless.” To determine whether a failure to disclose was harmless, courts in the Third Circuit consider the *Pennypack* factors: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the possibility of curing the prejudice; (3) the potential disruption of an orderly and efficient trial; (4) the presence of bad faith or willfulness in failing to disclose the evidence; and (5) the importance of the information withheld. *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home*

¹ Plaintiff also argues for exclusion of Dr. Zalipsky's opinions in his reply expert report based on the same indefiniteness and noninfringement opinions as in Dr. Tuddenham's report. (D.I. 215 at 8). Plaintiff's substantive arguments, however, refer solely to Dr. Tuddenham's testimony. (*Id.* at 16–19). In addition, Plaintiff's motion only requests striking “portions of two expert reports.” (D.I. 214). Therefore, I will consider Plaintiff's first motion to strike as limited to the testimony in Dr. Rausser and Dr. Tuddenham's reply expert reports. (*See* D.I. 215).

Ownership Ass'n, 559 F.2d 894, 904–05 (3d Cir. 1977)). “[T]he exclusion of critical evidence is an ‘extreme’ sanction, not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of the evidence.” *Id.* The determination of whether to exclude evidence is within the discretion of the district court. *Id.*

III. ANALYSIS

A. Dr. Rausser’s Testimony Based on Foreign Profits

Dr. Rausser, in his reply expert report, relies on supplemental forecasts of Adynovate’s worldwide operating costs, including research, development, regulatory, and royalty costs. (D.I. 216, Ex. J ¶¶ 70–74; D.I. 215 at 5–6). Defendants produced the forecasts in August 2018, after the close of fact discovery. (D.I. 215 at 5–6). Notably, Dr. Rausser criticizes Plaintiff’s expert, Dr. Addanki, for inflating his figures by relying on Adynovate’s gross profits rather than specific operating profits. (D.I. 216, Ex. J ¶¶ 11, 13, 17, 26, 146, 167, 170, 171, 179). Plaintiff argues that Dr. Rausser’s testimony should be stricken because the forecasts were late-disclosed and Defendants’ witnesses indicated that such forecasts did not exist. (D.I. 215 at 9). Defendants assert that the forecasts did not become relevant until Plaintiff revealed its “surprise” Nash Bargaining theory of damages in Dr. Addanki’s opening expert report. (D.I. 221 at 11–13).

As a preliminary matter, I do not think Dr. Addanki’s report is relevant.² The record shows that Plaintiff made several requests for Defendants’ worldwide financials. (*See* D.I. 216, Ex. B). Defendants were aware of those requests by June 2018, at the latest, when Plaintiff submitted a letter to the Court outlining the parties’ related discovery dispute. (D.I. 172 at 1). Plaintiff specifically indicated that Defendants had failed to produce “units, costs, profitability, and forecast data” for “all factor VIII products, including exports for sale in Europe and Asia.”

² For a substantive analysis of Dr. Addanki’s purported reliance on the Nash theory, see the *Daubert* order.

(D.I. 172 at 2). At the subsequent discovery hearing, Defendants dropped their objections and agreed to a document swap. (D.I. 180 at 39:11–40:13). Defendants then produced updated financials reflecting Adynovate and Advate’s worldwide sales and forecast information, which did not include the supplemental operating costs. (D.I. 215 at 4).

Based on the updated financials, Plaintiff deposed Baxalta’s Rule 30(b)(6) witness for financial topics, Wolfgang Hackel, who is Baxalta’s Head of Finance in Research and Development. (D.I. 215 at 4). Mr. Hackel indicated that full profit and loss statements, which would include specific categories of operating costs, were not available for Adynovate or Advate, because that information is not broken down at the product level. (*See, e.g.*, D.I. 216, Ex. E at 107:12–108:24). Other Baxalta witnesses agreed. (D.I. 221 at 5). Defendants do not dispute that its “witnesses testified that [Baxalta] did not have product-specific profit and loss (‘P&L’) statements, and that the financial documents that Bayer marked [for deposition] lacked certain cost information.” (D.I. 221 at 2). Instead, Defendants argue that Plaintiff is at fault because it “never asked the witnesses nor Defendants whether such cost information existed.” (*Id.*).

Defendants’ argument is illogical. Plaintiff, having been told that no such statements exist, would have no reason to probe further or suspect that Defendants were withholding information. Therefore, I find that the record shows Defendants engaged in bad faith or willfulness in failing to disclose the supplemental financials during fact discovery. Thus, the fourth *Pennypack* factor weighs in favor of exclusion.

In contrast, the first two *Pennypack* factors weigh against exclusion. Plaintiff argues that it has spent hours deposing fact witnesses on Baxalta’s costs, and “[a]llowing Defendants to use [the] belatedly produced and likely fabricated profitability information at this late stage to call

into question Dr. Addanki's damages analysis would be prejudicial to [Plaintiff.]" (D.I. 215 at 13). Dr. Addanki, however, was able to consider the supplemental forecasts and Dr. Rausser's reply report before submitting his own reply report. (D.I. 215 at 16). Defendants also offered Plaintiff an opportunity to depose the relevant witnesses on the supplemental forecasts, including an extension for Dr. Addanki's reply report, which Plaintiff refused. (*Id.* at 15). I do not think Plaintiff has identified any substantial prejudice. Plaintiff will have the opportunity to address the validity of the supplemental forecasts at trial through deposition testimony, testimony from Dr. Addanki, and cross-examination of Dr. Rausser.

The third *Pennypack* factor is neutral. I do not anticipate that either allowing or excluding Dr. Rausser's testimony will impact the trial schedule or interfere with an orderly and efficient trial.

The fifth *Pennypack* factor weighs against exclusion. The supplemental financials have a limited scope of relevance. Dr. Rausser only relies on them to estimate certain worldwide costs for Adynovate in 2017 and 2018, and Advate in 2017. (D.I. 216, Ex. J ¶¶ 70–74). Defendants assert that Dr. Rausser primarily uses another earlier produced document for the years 2014–2016. (D.I. 221 at 9). The bulk of what Plaintiff seeks to strike from Dr. Rausser's reply report relates to critiques of Dr. Addanki for relying on gross profits. As discussed, Dr. Addanki has had the opportunity to respond in his own reply report and will testify at trial.

Therefore, on balance, the *Pennypack* factors weigh against exclusion.

In the alternative, Plaintiff argues that Dr. Rausser's analysis should be stricken because it contradicts Baxalta's corporate testimony and relies on litigation-inspired documents. (D.I. 215 at 14–16 (citing *In re IH 1, Inc.*, 2015 WL 5679724 (D. Del. Sept. 25, 2015))). This appears to be a *Daubert* argument. *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993); *see also*

In re IH 1, 2015 WL 5679724 at *2 (excluding expert opinions under *Daubert* for relying on financial projections not made in the ordinary course of business). Putting aside the fact that Plaintiff has filed a separate *Daubert* motion (D.I. 243), I do not think *Daubert* supports exclusion. It is not clear that the supplemental forecasts are litigation-inspired documents—Plaintiff has merely shown that the forecasts might be inconsistent with Baxalta’s previous Rule 30(b)(6) testimony. (*See* D.I. 221 at 16–17). Plaintiff’s arguments go towards the weight and credibility of Dr. Rausser’s opinions, which can be addressed through cross-examination and otherwise at trial.

Therefore, Dr. Rausser may testify based on the supplemental forecasts.³

B. Dr. Tuddenham’s Testimony on Noninfringement and Indefiniteness

Plaintiff asserts that Dr. Tuddenham’s reply expert report introduces new noninfringement and indefiniteness theories related to “functional factor VIII activity.” Regarding noninfringement, Dr. Tuddenham opines that Adynovate does not retain “functional factor VIII activity” because it has a “two-fold loss of specific activity” as compared to unpegylated factor VIII. (D.I. 216, Ex. N ¶¶ 13, 46–51, 61). Regarding indefiniteness, Dr. Tuddenham opines that “functional factor VIII activity” and “at the B-domain” render the claims indefinite because the patent fails to describe the amount of functional factor VIII activity that must be retained, or the assay conditions needed to determine functional factor VIII activity. (D.I. 216, Ex. N ¶ 52). Notably, the phrase “functional factor VIII activity” is not in any claim,

³ I believe this resolves the parties’ dispute about Defendants’ “may call” witness, Mariya Raveendran. (*See* D.I. 326 at 21–24). Ms. Raveendran may provide testimony limited to the supplemental forecasts.

but is a limitation based on the “functional factor VIII polypeptide” and “at the B-domain” claim terms. (D.I. 215 at 6).⁴

Defendants do not dispute that Dr. Tuddenham discloses new theories. Instead, Defendants argue that the theories were necessary to rebut the new infringement theory disclosed by Plaintiff’s expert, Dr. Ravetch. (D.I. 221 at 17–18). Dr. Ravetch opines that Adynovate meets the “isolated polypeptide conjugate” limitation because it is the product of non-random pegylation, that is, pegylation targeting the B-domain. In his analysis, Dr. Ravetch states that, compared to Adynovate, “previous attempts at extending factor VIII half-life using ‘random’ pegylation that did not target any particular location on factor VIII showed significant activity loss. ’520 patent at 3:50–57 (half-life improvement ‘at a cost of 2-fold activity loss’).” (D.I. 216, Ex. R ¶ 106). Defendants argue that Dr. Ravetch thus relies on a “2-fold activity loss” as evidence of random conjugation, or, lack of activity loss as evidence of non-random conjugation. Defendants assert that the latter is a new infringement theory, which Dr. Tuddenham properly rebuts in his reply report. (D.I. 221 at 18).

I do not think Dr. Tuddenham’s noninfringement theory is responsive to Dr. Ravetch’s report. Dr. Ravetch does not argue that non-random conjugation, as required by “an isolated polypeptide conjugate,” is met by Adynovate’s lack of activity loss. Rather he focuses on the fact that non-random conjugation does not “target any particular location on factor VIII,” which

⁴ Plaintiff submitted a notice of supplemental authority alleging that Defendants are attempting to reargue claim construction in violation of the Court’s recent orders on summary judgment and motions in limine. (D.I. 343). I do not think either order is relevant to the present motion to strike. Rather, Plaintiff appears to be making a new argument that Defendants’ experts import a “specific activity” requirement inconsistent with the patent’s definition of “functional factor VIII polypeptide.” (See D.I. 348). Even putting aside how the argument was raised, I do not think it has merit. The patent’s definition of “functional factor VIII polypeptide” merely states that a functional polypeptide is “capable, in vivo or in vitro, of correcting human factor VIII deficiencies,” without any discussion of the level of factor VIII activity required. ’520 patent at 9:39–43. Moreover, Defendants’ experts expressly rely on the patent’s definition as the basis for their opinions. (D.I. 216, Ex. N ¶¶ 33, 47, Ex. O ¶¶ 58, 147).

he contrasts to Adynovate's conjugation process that targets the B-domain. (D.I. 216, Ex. R ¶ 106). Therefore, I find Defendants failed to properly disclose Dr. Tuddenham's new noninfringement theory.

Defendants admit that Dr. Tuddenham's indefiniteness theory does not directly relate to any of Plaintiff's expert testimony. Instead, Defendants argue that his indefiniteness opinion is so intertwined with his noninfringement opinion that both rebut Dr. Ravetch's new infringement theory. (D.I. 221 at 18).⁵ As discussed, I do not think Dr. Ravetch raises a new infringement theory. Therefore, I find Defendants also failed to properly disclose Dr. Tuddenham's new indefiniteness theory.

I apply the *Pennypack* factors to determine whether Defendants' failures to disclose warrant exclusion.

Under the first two *Pennypack* factors, Plaintiff argues that it is prejudiced because fact discovery has ended, and it never had the chance to "question Defendants' witnesses on their understanding of 'functional factor VIII activity,' how to measure such activity, if an industry standard applies, if it is found in Adynovate, and so on." (D.I. 215 at 18). Defendants assert that Plaintiff "questioned at least three fact witnesses about the activity of Adynovate® and Factor VIII generally." (D.I. 221 at 19). Plaintiff distinguishes between questioning on general factor VIII activity and the "specific activity" described by Dr. Tuddenham. (*See* D.I. 224 at 10).

I think Plaintiff is unlikely to suffer any significant prejudice if the disputed testimony is permitted. Plaintiff has been able to conduct discovery on Adynovate's factor VIII activity and

⁵ Specifically, Defendants argue that infringement and indefiniteness "are two sides of the same coin," citing *Bayer Intellectual Prop. GmbH v. Warner Chilcott Co.*, 2015 WL 1849015 (D. Del. Apr. 21, 2015). (D.I. 221 at 18). Defendants misread *Bayer*. The court noted that indefiniteness and *claim construction* "are two sides of the same coin." *Id.* at *2. The court was addressing summary judgment for indefiniteness and never discussed infringement. *Id.* at *1-2.

will have the opportunity to address Dr. Tuddenham’s “specific activity” theory at trial.

Therefore, the first two factors weigh against exclusion.

The third *Pennypack* factor is neutral. Neither party argues that the outcome of this motion will disrupt trial. (D.I. 215 at 18; D.I. 221 at 20).

Under the fourth *Pennypack* factor, Plaintiff argues that Defendants acted in bad faith, as shown by (1) Defendants’ failure to justify Dr. Tuddenham’s opinions as necessary to rebut Dr. Ravetch’s new infringement theory, and (2) the fact that Dr. Tuddenham’s opinions contradict Defendants’ admission that “Adynovate® retains functional factor VIII activity.” (D.I. 215 at 18–19; D.I. 216, Ex. L, RFA No. 45).

I do not think Plaintiff has shown evidence of bad faith. First, Defendants’ failure to justify their new theories indicates a failure to properly disclose those theories but does not in itself show bad faith. Second, I do not think Dr. Tuddenham’s analysis is necessarily contrary to Defendants’ prior admission. The request for admission does not specify the amount of functional activity retained. (D.I. 216, Ex. L, RFA No. 45). Dr. Tuddenham opines that Adynovate retains about 48% of the specific activity of unpegylated factor VIII, which he finds insufficient to show retention of functional activity as required by the claims. (D.I. 216, Ex. N ¶¶ 46–50). He does not opine that Adynovate fails to retain any functional activity. Therefore, the fourth factor is neutral.

Under the fifth *Pennypack* factor, Plaintiff argues that Defendants’ new theories lack importance because they were not previously raised. (D.I. 215 at 19).⁶ I do not think the fact that a party failed to raise an argument necessarily indicates anything about the importance of

⁶ Plaintiff also argues that the indefiniteness theory “makes no sense” because “functional factor VIII activity” is not a claim term. Plaintiff rebuts its own argument by acknowledging that Dr. Tuddenham relies on the “functional factor VIII polypeptide” and “at the B-domain” claim terms, with the latter requiring that the conjugate retain functional factor VIII activity. (D.I. 215 at 6).

that argument. However, Defendants also fail to present evidence to the contrary. (D.I. 221 at 20). Therefore, the fifth factor is neutral.

On balance, the *Pennypack* factors weigh against exclusion.

C. Dr. Zalipsky's Testimony on Indefiniteness and Lack of Written Description

Plaintiff asserts that Dr. Zalipsky's reply expert report introduced new invalidity theories based on indefiniteness and lack of written description. Both theories relate to the Court's construction of "an isolated polypeptide conjugate" as "a polypeptide conjugate where conjugation was not random." (D.I. 195 at 4). Dr. Zalipsky opines that the Court's construction is indefinite because a person of ordinary skill in the art would be unable to determine whether a conjugate is random. (D.I. 242, Ex. A ¶¶ 215–19). Similarly, he opines that the '520 patent lacks written description because it fails to show possession of a non-random conjugate. (*Id.* ¶ 230).

As with Dr. Tuddenham's testimony, Defendants do not dispute that Dr. Zalipsky offers new theories. Rather, they argue that those theories are in response to new infringement theories disclosed by Plaintiff's expert, Dr. Russell. (D.I. 273 at 1). Specifically, Defendants assert that Dr. Russell identifies two conditions that promote random conjugation—an excess of PEG and longer reaction times. (D.I. 273 at 11 (citing D.I. 275, Ex. 8 ¶¶ 37–60)). Defendants argue that, based on those conditions, the conjugates claimed in the '520 patent are the product of random conjugation. Therefore, the claimed conjugates cannot meet the "isolated polypeptide conjugate" limitation and the '520 patent is invalid for indefiniteness and lack of written description. (*Id.*).

Defendants mischaracterize Dr. Russell's testimony. Dr. Russell evaluated at least six factors that may render a reaction random. (D.I. 275, Ex. 8 ¶ 44). Dr. Zalipsky focuses on just

two of those factors to conclude that, based on Dr. Russell's analysis, the claimed conjugates are the product of random conjugation, making the patent invalid. Dr. Zalipsky thus goes beyond rebuttal to advance new legal theories, which are, at best, loosely related to Dr. Russell's testimony. Therefore, I find Defendants failed to properly disclose Dr. Zalipsky's new indefiniteness and written description theories.

I apply the *Pennypack* factors to determine whether Defendants' failure to disclose warrants exclusion.

Under the first two *Pennypack* factors, Plaintiff argues that it is prejudiced because Defendants' late-disclosed theories impose an additional burden on Plaintiff that will detract from Bayer's trial preparation and cannot be cured at this late stage. (D.I. 241 at 8–9). In response, Defendants argue that Plaintiffs had the opportunity to cure any prejudice by accepting Defendants' offer to serve a sur-reply. Defendants assert that a sur-reply would not have been unduly burdensome because Plaintiff only seeks to strike seven paragraphs of Dr. Zalipsky's report. Further, Plaintiff had five weeks to review the report prior to deposing Dr. Zalipsky. Plaintiff had the opportunity to question Dr. Zalipsky on his new invalidity theories and chose not to. (D.I. 273 at 2–3, 16–17). Plaintiff argues that it does not have an affirmative burden to cure prejudice caused by Defendants' late-disclosure.

It seems that any prejudice Plaintiff may suffer could have been cured. Although Plaintiff is not obligated to cure prejudice of Defendants' making, the fact that Plaintiff chose not to spend any effort addressing Dr. Zalipsky's new theories, via a sur-reply or in deposition, indicates that Plaintiff did not view the new theories as having a substantial impact on the case. It thus follows that Plaintiff is unlikely to suffer any significant prejudice from Dr. Zalipsky's

testimony related to those theories. Therefore, the first and second factors weigh against exclusion.

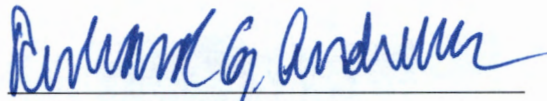
The remaining *Pennypack* factors are neutral. Neither party argues that the outcome of this motion will disrupt trial. (D.I. 241 at 9; D.I. 273 at 18). I find no evidence that Defendants acted in bad faith or willfully in failing to properly disclose the new theories. And, for the same reason that I find insignificant prejudice to Plaintiff, I find that the new theories lack importance.

Therefore, on balance, the *Pennypack* factors weigh against exclusion.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's motions to strike (D.I. 214, 240) are **DENIED**.

IT IS SO ORDERED this 22 day of January 2019.


United States District Judge