IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS	
CORPORATION, NOVARTIS)
CORPORATION, NOVARTIS AG, and)
NOVARTIS PHARMA AG,)
Plaintiffs,))
v.) Civil Action No. 12-366-RGA-CJB
ACTAVIS, INC. and ACTAVIS)
ELIZABETH LLC,)
)
Defendants.)

MEMORANDUM ORDER

In this Hatch-Waxman action filed by Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis" or "Plaintiffs") against Defendants Actavis, Inc. and Actavis Elizabeth LLC (collectively, "Actavis" or "Defendants"), Novartis alleges infringement of U.S. Patent Nos. 6,465,504 (the "504 Patent") and 6,596,750 (the "750 Patent") (collectively, the "patents-in-suit"). Pending before the Court is Novartis' letter motion to strike the supplemental expert report of Actavis' expert Kenneth N. Raymond, Ph.D. ("Motion"). (D.I. 157)¹ For the following reasons, the Court DENIES the Motion.

Our Court has treated motions to strike as non-dispositive motions, which may be resolved by the Court pursuant to 28 U.S.C. § 636(b)(1)(A) and D. Del. LR 72.1(a)(2). See, e.g., Withrow v. Spears, Civil Action No. 12-06-LPS-CJB, 2013 WL 4510305, at *1 n.1 (D. Del. Aug. 22, 2013); Wyeth Holdings Corp. v. Sandoz, Inc., Civ. Action No. 09-955-RGA-CJB, 2012 WL 1669555, at *1 (D. Del. May 10, 2012). This is in line with decisions of other courts in this Circuit, which have also treated such motions as non-dispositive, at least where the decisions were not determinative of a party's claims (just as it is not here). See, e.g., Hawkins v. Waynesburg Coll., Civil Action No. 07-5, 2007 WL 2119223, at *1 n.1 (W.D. Pa. July 20, 2007); Reedy v. CSX Transp., Inc., Civil Action No. 06-758, 2007 WL 1469047, at *1 n.1 (W.D. Pa. May 18, 2007).

I. BACKGROUND

A. Procedural Posture

On June 6, 2012, this case was referred to the Court by Judge Richard G. Andrews to hear and resolve all pretrial matters, up to and including case-dispositive motions. On June 18, 2012, the Court entered a Scheduling Order in the case. (D.I. 27) Fact discovery closed on August 1, 2013. A pre-trial conference is scheduled for January 10, 2014, and a bench trial is to begin on January 27, 2014.

The initial Scheduling Order contemplated three rounds of expert reports: (1) opening reports from the party who has the initial burden of proof; (2) rebuttal reports; and (3) reply reports limited in scope to "respond[ing] to secondary considerations raised by Plaintiffs' rebuttal expert reports[.]" (D.I. 27 at ¶3(h)(1)) The Scheduling Order also provided that "[n]o other expert reports will be permitted without either the consent of all parties or leave of the Court," (id.), but a subsequent Court order (issued at the parties' joint request) did set a deadline for "[a]ll and final supplementation under [Fed. R. Civ. P.] 26(e), unless good cause shown upon a motion for leave," (D.I. 96). Pursuant to multiple Court-ordered amendments to these expert-related deadlines (all also issued at the parties' joint request), opening expert reports were due on September 4, 2013; rebuttal reports were due on October 15, 2013, reply reports were due November 11, 2013, and final supplementation under Fed. R. Civ. P. 26(e) ("Rule 26(e)") was due on December 20, 2013. (D.I. 121; D.I. 150)

Actavis produced the opening report of its expert, Dr. Raymond, on September 4, 2013. (D.I. 157 at 1; D.I. 160, ex. C (hereinafter, "Raymond Report")) In response, Novartis produced the rebuttal report of its expert, Robert C. Hider, Ph.D., on October 15, 2013. (D.I. 160, ex. F

(hereinafter "Hider Rebuttal")) Actavis subsequently produced two additional reports by Dr. Raymond. The first reply report, responding to portions of the Hider Rebuttal regarding secondary considerations of nonobviousness (also referred to as "objective considerations of nonobviousness"), was timely produced and is not at issue in this Motion. (*Id.*, ex. D (hereinafter "Raymond Reply")) At issue is the second of these reports, which is titled "Supplemental Expert Report" and purports to respond to other opinions set out in the Hider Rebuttal relating to the alleged validity of the patents-in-suit. (*Id.*, ex. E at ¶ 2 (hereinafter "Raymond Supplement")) Actavis served the Raymond Supplement on November 25, 2013. (*Id.* at 24-25) Nine days later, on December 4, 2013, Novartis took the deposition of Dr. Raymond. (D.I. 157 at 1; D.I. 163, ex. 1 at 1)

On November 27, 2013, Novartis filed its letter-motion to strike the Raymond Supplement. (D.I. 157) The Court ordered expedited briefing on the Motion, and briefing was completed on December 13, 2013. (D.I. 167)

B. Content of the Expert Reports

As they are relevant to the issues described below, the Court will first summarize certain content of the Raymond Report, the Hider Rebuttal, and the Raymond Supplement.

1. Raymond Report

The Raymond Report, which spans 84 pages and 255 paragraphs, explains the bases for Dr. Raymond's main conclusions that: (1) the asserted claims of the patents-in-suit are not entitled to a priority date earlier than October 30, 2000, because the earlier patent applications to which Novartis claims priority for the patents-in-suit were not enabling; and (2) the asserted claims of the patents-in-suit are invalid as either anticipated or obvious over certain prior art.

(See Raymond Report at ¶¶ 1-3) The expert opinions at issue here relate to the first conclusion.

To give context to his opinion regarding the priority date of the patents-in-suit, Dr. Raymond explains that:

[U]nder 35 U.S.C. § 112, a patent's specification must adequately disclose to one of ordinary skill in the art how to make the claimed invention without undue experimentation, the so-called enablement requirement. Under 35 U.S.C. § 101, any patentable invention must also be useful, the so-called utility requirement. If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement. These requirements under 35 U.S.C. §§ 101 and 112 are analyzed from the perspective of a person of ordinary skill in the art as of the filing date of the alleged invention.

(*Id.* at ¶ 21) The patents-in-suit both claim priority to U.S. application No. 09/202,769 (the "769 Application"), filed on June 24, 1997, which claims foreign priority to Swiss application No. 1593/96 (the "Swiss Application"), filed June 25, 1996 (collectively, the "Priority Applications").² (*Id.* at ¶ 82 (internal citations omitted)) The '750 Patent issued from a division of the application that issued as the '504 Patent. (*Id.* (internal citation omitted)) On October 30, 2000, U.S. application No. 09/699,765 (the "'765 Application") was filed as a continuation-in-part of the '769 Application. (*Id.* at ¶ 110)

To support the alleged enablement of the Priority Applications, Novartis' Interrogatory Responses pointed to certain statements contained in their specifications. (*Id.* at $\P\P$ 173-77)³

The Priority Applications share a common specification. (Raymond Supplement at \P 7 & n.2)

This language indicated generally that the claimed compounds are useful as iron chelators in the treatment of iron overloaded humans, and that, in particular doses, they "are able, e.g. in an animal model" to prevent the deposition of iron, and to cause excretion of iron "in the case of existing iron deposits in the body." (Raymond Report at ¶¶ 175, 177 (internal quotation

However, Dr. Raymond concludes that the asserted claims of the patents-in-suit are not entitled to a priority date earlier than the filing date of the '765 Application. (*Id.* at ¶¶ 1, 110, 165)

According to Dr. Raymond, that application supplied vital information that was missing from the Priority Applications—data from *in vivo* animal tests conducted with the claimed compounds, which allegedly demonstrated the compounds' utility for the excretion of iron. (*Id.* at ¶ 110)

The Raymond Report opines that because the Priority Applications lacked such data, a person of ordinary skill in the art reading the applications would not have understood that the claimed compounds had any utility as therapeutic iron chelation agents (and would only have gained such an understanding after the filing of the '765 Application, which supplied such data). (Id. at ¶ 166-86) Dr. Raymond explains that "[i]n order to have a reasonable expectation that a compound would have [] pharmacological activity [as an iron chelator useful for treating excess iron] in humans or animals . . . one of ordinary skill in the art would have to have been presented with adequate data showing in vivo activity in an appropriate animal model." (Id. at ¶ 170; see also ¶ 186 (explaining that "a person of ordinary skill in the art would need to view data from appropriate in vivo tests to be reasonably convinced that a compound would work as an iron chelator in human or animal therapy")) Dr. Raymond opines that the absence of supporting data would prevent a person of ordinary skill in the art from drawing any conclusions about the claimed compounds, and instead that person would accept the statements "merely as a hypothesis or object of future research." (Id. at ¶ 176; see also id. at ¶¶ 178-79 (explaining that such statements would not have indicated to the person of ordinary skill in the art that the claimed compounds and methods would work because they indicated that the in vivo animal experiments

marks and citations omitted))

described could be performed, but were not actually performed))

Dr. Raymond elaborates that if such experiments had been performed, "a person of ordinary skill in the art would have expected to see data included" as "[t]hat was (and remains today) a central tenet of the scientific method." (Id. at ¶ 179) That is, "[i]f one has actually undertaken an experiment, a scientist expects another scientist to provide sufficient information regarding the experimental protocol, the use of an appropriate control, and empirical results sufficient for one of ordinary skill to attempt to replicate the experiment(s) and the result(s)." (Id.) But according to Dr. Raymond, "[t]he bare statements in the [relevant applications] contain no supporting data, and therefore no measure of the degree of alleged iron chelation, statistical analysis, or controls." (Id. at ¶ 180)

Dr. Raymond also argues that, contrary to Novartis' position in its Interrogatory Responses, an internal report ("Internal Report") containing *in vivo* data that applicants submitted to the PTO during prosecution of the '769 Application did not demonstrate utility of the claimed compounds. (*Id.* at ¶¶ 187-94) For one thing, Dr. Raymond opines, the only date shown on the report is the date on which it was faxed, and thus the person of ordinary skill in the art would have no way of knowing when the data contained in the report was generated. (*Id.* at ¶ 189) Second, the report did not contain, *inter alia*, data relating to toxicity of the claimed invention, which the person of ordinary skill in the art would have expected to see. (*Id.* at ¶¶ 190-94)

2. Hider Rebuttal

The relevant section of the Hider Rebuttal is titled "The Compounds & Methods of Treatment Disclosed in the Patents-in-Suit are Useful." (Hider Rebuttal at 57) Therein, Dr. Hider opines that, contrary to the opinion of Dr. Raymond, the person of ordinary skill in the art

would have believed the claimed compound to be useful based on the disclosures in the Priority Applications, even in the absence of certain data. (Id. at ¶ 148)

In the first sub-section of this section, Dr. Hider explains that he has reviewed the Swiss Application, and sets out several reasons why the person of ordinary skill in the art would have had no reason to doubt the assertions contained in that specification that the claimed compound would be useful in chelating iron. (Id. at \P ¶ 148-92)⁴ First, Dr. Hider explains that a person of ordinary skill in the art would have known that high levels of iron were associated with iron overload disease. (Id. at ¶ 156) Second, he asserts that such a person would have known that chelating such excess iron with a compound could be useful in treating iron-overload disease. (Id.) Third, Dr. Hider asserts that the person of ordinary skill in the art would have concluded that the claimed inventions would chelate metal ions based on their structures, as described in the relevant applications. (Id. at ¶¶ 157-60) Fourth, he contends that the Swiss Application explicitly references several in vivo experiments, and the person of ordinary skill in the art would have expected that the claimed compounds would have already demonstrated utility in vitro before being put into the animal models disclosed in that application. (Id. at ¶ 161-66) Fifth, Dr. Hider asserts that the in vivo tests described in the relevant specification (in certain rat and primate models) establish the usefulness of the claimed compounds. (*Id.* at ¶¶ 168, 170-83) Sixth, Dr. Hider points to the dosing ranges disclosed in the relevant specification, which he contends indicates that the applicants were in possession of biological data relating to the useful pharmacological activity of the disclosed compounds. (Id. at ¶ 184-85) Finally, Dr. Hider

In this section, Dr. Hider cites to the Raymond Report only twice. (*Id.* at ¶ 148 (citing to Raymond Report at ¶ 167); *id.* at ¶ 159 (citing to Raymond Report at ¶ 136))

explains that the patent application was submitted by Ciba-Geigy, a company with a reputation as a global leader in iron chelation research; he asserts that the person of ordinary skill in the art would have no reason to disbelieve statements about research results from that group. (*Id.* at ¶¶ 187-92)

In another sub-section, Dr. Hider opines that the Internal Report further confirmed the utility of the claimed invention. (*Id.* at ¶¶ 193-97) According to Dr. Hider, it included data that is consistent with and supports the statements in the specifications of the Priority Applications. (*Id.*)

Moreover, in a sub-section entitled "Response to Certain of Dr. Raymond's Opinions[,]" Dr. Hider explains his disagreement with certain of Dr. Raymond's views regarding the utility of the claimed invention. (*Id.* at ¶ 208-15) Among other things, Dr. Hider expresses his contrary view to Dr. Raymond's opinion that a person of ordinary skill in the art would have expected to see underlying data included in the relevant applications. (*Id.* at ¶ 208) According to Dr. Hider, "the required tests to determine pharmacological activity were well known in the literature"; thus, the person of ordinary skill in the art would have had no reason to disbelieve that experiments had been performed, and the biological data was summarized in a way that indicated that the claimed invention was useful in treating iron overload. (*Id.*) Dr. Hider also expresses his disagreement with, *inter alia*, Dr. Raymond's opinion that a person of ordinary skill in the art "would not have been able to draw any conclusions about the disclosed compounds, compositions, and methods of treatment in the absence of any underlying data." (*Id.* at ¶ 209) Dr. Hider explains that as of the relevant time frame, other compounds such as DFO and L1 were known to be useful for chelating metals, specifically iron, and thus a person of ordinary skill in

the art would have had no reason to disbelieve that deferasirox had the properties disclosed in the specifications. (*Id.*)

3. Raymond Supplement

The Raymond Supplement is 23 pages long and contains 49 numbered paragraphs.

(Raymond Supplement) At the outset of the Report, Dr. Raymond clearly states the intent behind its submission: "I have reviewed and considered the portions of the [Hider Rebuttal] that relate to the alleged validity of the Patents-in-Suit I disagree with certain of Dr. Hider's opinions and conclusions and discuss those disagreements below." (*Id.* at ¶ 2) More specifically, the content of the report is focused on supporting Dr. Raymond's opinion that "a number of Dr. Hider's conclusions regarding the alleged utility of the [Priority Applications] are inconsistent with the scientific method, and thus, cannot support a conclusion that based on the Priority Applications, a person of ordinary skill in the art at the time would have understood deferasirox to be useful in chelating iron in humans and animals." (*Id.* at ¶ 7) The Raymond Supplement next contains two paragraphs relating to the general principles of the scientific method, which cite to several supporting exhibits. (*Id.* at ¶ 8-9)

The bulk of the Raymond Supplement consists of the next section, entitled "Novartis' Alleged Evidence of Utility of the Priority Applications is Not Persuasive." (*Id.* at ¶ 10-40) Therein, Dr. Raymond attacks Dr. Hider's assertions that the person of ordinary skill in the art, a trained scientist, would have no reason to doubt the assertions in the Priority Applications and "would have simply assumed that both *in vitro* and *in vivo* tests had been undertaken and had generated meaningful results." (*Id.* at ¶ 14 (citing Hider Rebuttal at ¶¶ 155, 161, 168-83))

In critiquing this opinion, Dr. Raymond offers further context for his prior opinion that

Applications. (*Id.* at ¶¶ 16-37) He notes first that, as indicated in the Hider Rebuttal, iron chelators were known at that time to be difficult to develop. (*Id.* at ¶ 16) Second, as is also described in the Hider Rebuttal, he cites a long history of failure that preceded discovery of the claimed compound. (*Id.* at ¶ 17) Third, also mentioned in the Hider Rebuttal, Dr. Raymond notes that there was uncertainty in the industry regarding the utility of Dr. Hider's own compound, L1. (*Id.* at ¶ 18-20) Given this uncertainty regarding the most promising orally active chelator at the time, he states that the person of ordinary skill in the art would have doubted the assertions of utility in the Priority Applications without supporting data. (*Id.*)
Fourth, he asserts that it would violate the basic tenets of the scientific method for a person of ordinary skill in the art to simply accept the unsupported assertions in those applications that a compound useful in chelating iron had been invented. (*Id.* at ¶ 21) As is indicated above, it is notable that the arguments Dr. Raymond makes to support the necessity of data are tethered to portions of the Hider Rebuttal.

Dr. Raymond next expresses his disagreement with Dr. Hider's argument that because the specification of the Priority Applications referenced *in vivo* experiments, a person of ordinary skill in the art would have expected the compounds to have already demonstrated *in vitro* utility. (*Id.* at ¶ 23-28) Similarly, Dr. Raymond disputes Dr. Hider's assertion that the person of ordinary skill in the art would understand from the Priority Applications that the inventors had performed *in vivo* tests in rats and monkeys, without seeing evidence that such tests had actually been performed and/or data and experimental controls from such tests. (*Id.* at ¶¶ 29-37)

Dr. Raymond additionally reiterates his opinion that the "Internal Report" fails to

establish the utility of the Priority Applications. (*Id.* at \P 38) He again notes that the report only listed the date on which it was faxed, and he states that it does not contain toxicity testing data. (*Id.* at \P 39-40)

Next, Dr. Raymond responds to Dr. Hider's opinion that the person of ordinary skill in the art would have no reason to disbelieve that the claimed invention had the properties disclosed in the Priority Applications in the absence of underlying data, because as of 1996, other compounds such as DFO and L1 were known to be useful for chelating metals. (*Id.* at ¶ 41) Dr. Raymond explains that, unlike in the Priority Applications, papers published on these other compounds "include examples of the *in vitro* and *in vivo* data a person of ordinary skill in the art would need to support a compound's utility for chelating iron in overloaded humans." (*Id.* at ¶¶ 41-45) In the final paragraph at issue, Dr. Raymond purports to correct an assertion by Dr. Hider relating to a particular test used to identify iron chelation. (*Id.* at ¶ 47)⁵

II. LEGAL STANDARD

The Federal Rules of Civil Procedure require a testifying expert to prepare and sign a written report containing, *inter alia*, "a complete statement of all opinions the witness will express and the basis and reasons for them . . . at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(B)(i) & (a)(2)(D). Thereafter, if a party "learns that in some material respect the disclosure . . . is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process

The final substantive paragraph of the report, in which Dr. Raymond corrects a statement in his opening report that the Examiner did not cite or consider a particular piece of prior art, (Raymond Supplement at ¶ 48), is not at issue in this Motion, (D.I. 157 at 1-2 & n.2).

or in writing," it must supplement or correct its disclosure. Fed. R. Civ. P. 26(e); see also Invista N. Am. S.A.R.L. v. M&G USA Corp., Civ. No. 11-1007-SLR-CJB, 2013 WL 3216109, at *1 (D. Del. June 25, 2013). However, "parties may not use their obligation to supplement [under Rule 26(e)] as an excuse to violate the clear terms of a Scheduling Order, unilaterally buying themselves additional time to make disclosures, thereby unduly prejudicing other parties and potentially delaying the progress of a case." Abbott Labs. v. Lupin Ltd., Civil Action No. 09-152-LPS, 2011 WL 1897322, at *3 (D. Del. May 19, 2011); see also Invista N. Am. S.A.R.L., 2013 WL 3216109, at *1.

"If a party fails to provide information or identify a witness [in the manner required by the Court under Rule 26], the party is not allowed to use that information or witness . . . at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). If an expert report is stricken, that action effectively precludes the expert from testifying as to the subject matter and opinions contained in the report. *See, e.g., Invista N. Am. S.A.R.L.*, 2013 WL 3216109, at *2 (noting that exclusion of expert opinion and testimony may occur via Rule 37(c)(1), in light of a party's failure to comply with Rules 26(a) or (e)); *see also Kenexa Brassring, Inc. v. Taleo Corp.*, 751 F. Supp. 2d 735, 759 (D. Del. 2010).

Although a court clearly has the authority to strike an expert report and exclude expert testimony pursuant to Rule 37, it should be mindful that because "[t]he exclusion of critical evidence is an extreme sanction," this remedy should not be imposed where an untimely or

Because the discovery matter at issue here is not unique to patent law, the law of the Third Circuit applies. See Invista N. Am. S.A.R.L., 2013 WL 3216109, at *1 (citation omitted); Bridgestone Sports Co. Ltd. v. Acushnet Co., No. CIVA 05-132 JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (citing Micro Chem, Inc. v. Lextron, Inc., 317 F.3d 1387, 1390-91 (Fed. Cir. 2003)).

improper expert disclosure amounts to only a "slight deviation from pre-trial notice requirements" or occasions only "slight prejudice" to the movant. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks and citations omitted). Instead, exclusion should be reserved for circumstances amounting to "willful deception or flagrant disregard of a court order by the proponent of the evidence." Id. at 792 (internal quotation marks and citations omitted); see also Bridgestone Sports Co., Ltd. v. Acushnet Co., No. CIVA 05-132 JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007) (noting that while the decision to exclude expert testimony is context-specific, "evidence should be excluded sparingly and only in circumstances involving litigation conduct that is clearly unprofessional or inappropriate, and in circumstances creating prejudice to the party against whom the evidence is offered"); Praxair, Inc. v. ATMI, Inc., 231 F.R.D. 457, 463 (D. Del. 2005) (internal quotation marks and citations omitted), rev'd on other grounds, 543 F.3d 1306 (Fed. Cir. 2008) (finding that although exclusion of expert testimony is a "harsh measure [that] should be avoided where possible" it can be appropriate to prevent against the "flouting of discovery deadlines," so as to maintain "fidelity to the constraints of Scheduling Orders and deadlines[, which] is critical to the Court's case management responsibilities").

In considering whether to exclude an untimely or otherwise improper expert disclosure,

Actavis argues that the Motion is actually a premature motion *in limine*, since it seeks to preclude submission of certain evidence at trial, and asserts that the requested relief should have been sought via a motion *in limine*. (D.I. 160 at 1-2) The Court disagrees, as this dispute focuses on whether Actavis has complied with the Court's Scheduling Order regarding submission of expert reports, and is not "merely a motion to exclude evidence." *See Attachmate Corp. v. Health Net, Inc.*, No. C09-1161 MJP, 2010 WL 5185391, at *3 (W.D. Wash. Dec. 16, 2010) (considering, and rejecting, a similar argument on the same grounds). As previously noted, the grant of a motion to strike pursuant to Rule 37 (premised on violations of Rule 26) can properly result in the exclusion of expert testimony at trial.

the Third Circuit has directed district courts to weigh certain factors, known as "the *Pennypack* factors": (1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply with the court's order; 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).

III. DISCUSSION

A. Timeliness of the Raymond Supplement

The timeliness and propriety of the Raymond Supplement turns on whether permissible Rule 26(e) supplementation includes expert testimony intended to rebut the opinions of an opposing expert. Actavis argues that the Raymond Supplement, which was served after the deadline for reply reports had passed, but before the deadline for final Rule 26(e) supplementation, is "an entirely appropriate supplementation" under Rule 26(e). (D.I. 160 at 2) Novartis disagrees, asserting that the Raymond Supplement is not proper Rule 26(e) supplementation, and is thus an untimely expert report. (D.I. 157 at 1; D.I. 162 at 1-3)

The Court agrees with Novartis that the Raymond Supplement is not the kind of

Some courts also evaluate the non-movant's explanation for the failure of timely disclosure as a separate *Pennypack* factor; others tend to incorporate that issue into the analysis of the "bad faith or willfulness" factor. *See Withrow*, 2013 WL 4510305, at *12 & n.11. Here, the parties have not referenced Actavis' explanation for its actions as a separate factor. (*See* D.I. 157 at 2; D.I. 160 at 5-6) The Court will thus consider that explanation in relation to the "bad faith or willfulness" factor.

supplementation permitted by Rule 26(e). Courts have repeatedly emphasized the limited scope of supplementation permitted by Rule 26(e); such supplementation is proper "only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report." Brucker v. Lowe's Home Ctrs., Inc., No. 2:10-cv-405-FtM-29SPC, 2012 WL 2225818, at *2 (M.D. Fla. June 15, 2012) (internal quotation marks and citations omitted); see also Akeva L.L.C. v. Mizuno Corp., 212 F.R.D. 306, 310 (M.D.N.C. 2002) (explaining that "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) (noting that "[s]upplementation 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"). In light of its limited purpose, Rule 26(e) is *not* intended to provide parties an opportunity "to include new examples and illustrations to bolster previous opinions." Apple, Inc. v. Motorola Mobility, Inc., No. 11-cv-178-bbc, 2012 WL 5416941, at *28 (W.D. Wis. Oct. 29, 2012); see also Boca Raton Cmty. Hosp., Inc. v. Tenet Healthcare Corp., No. 05-80183-CIV, 2006 WL 5309506, at *3 (S.D. Fla. Oct. 18, 2006) (explaining that "to the extent the [supplemental report] seeks to 'clarify' [expert's] earlier opinions by bolstering them in view of [defendant's] subsequent objections, this is not proper supplementation").

The problem with Actavis' argument—that the Raymond Supplement is proper under Rule 26(e)—is that such content is not the kind of supplementation contemplated by that Rule, but is instead what would normally be found in a rebuttal report (here, a reply report) responding

to Dr. Hider's opinions. *See Hans v. Tharaldson, Civil No. 3:05-cv-115, 2011 WL 6937598, at *10 (D.N.D. Dec. 23, 2011) (noting that "[t]he function of rebuttal evidence is to explain, repel, counteract or disprove evidence of the adverse party") (internal quotation marks and citations omitted). That is, here: (1) the Raymond Report had set out Dr. Raymond's opinions on a topic (whether a person of ordinary skill in the art would have believed the claimed compounds to be useful, based on the disclosures in the Priority Applications); (2) the Hider Rebuttal responded with specific reasons as to why Dr. Hider disagreed with that opinion; and then (3) in the Raymond Supplement, Dr. Raymond addressed Dr. Hider's contrary reasons, and explained why those reasons should not be found persuasive. (D.I. 160 at 5 (explaining that the Raymond Supplement "merely provides additional bases for [Dr. Raymond's] opinions that the claims are invalid and reasons why Dr. Hider's contrary opinions are incorrect"); see also id. at 1 (noting that the report "simply [] supplements Dr. Raymond's previously stated invalidity opinions by providing additional details in response to the previously undisclosed opinions of Novartis' expert Dr. Hider"))¹⁰

The only paragraph of the Raymond Supplement that does clearly fall into one of the two categories of permissible Rule 26(e) supplementation is paragraph 48, which corrects an inaccuracy in the Raymond Report.

The content of the Raymond Reply—the one identified "reply report" that Dr. Raymond prepared in this case—emphasizes that the Raymond Supplement is really a rebuttal report. In the Raymond Reply's second paragraph, Dr. Raymond states that he reviewed the portions of the Hider Rebuttal relating to secondary considerations of nonobviousness, disagreed with certain of Dr. Hider's opinions on that topic, and would discuss his disagreements in the remainder of the reply. (Raymond Reply at ¶ 2) Dr. Raymond uses almost identical language in the second paragraph of the Raymond Supplement in describing the purpose of that report—that he reviewed the portions of the Hider Rebuttal relating to "the alleged validity of the Patents-in-Suit[,]" that he disagreed with certain of Dr. Hider's opinions on that topic, and would discuss those disagreements in the remainder of the supplement. (Raymond Supplement at ¶ 2) The first explanation is how one would describe the purpose of a rebuttal (or reply) report—and the

Courts considering this issue have concluded that permissible Rule 26(e) supplementation does not encompass such rebuttal material. See Sancom, Inc. v. Owest Commc'ns Corp., 683 F. Supp. 2d 1043, 1063 (D.S.D. 2010) (concluding that report at issue "does not qualify as a supplemental report under Rule 26(e) because it does not correct inaccuracies or add information that was unavailable to [expert] at the time of the initial report" but instead, in responding to new arguments by plaintiff's expert, "reads more like a rebuttal report offered solely to contradict or rebut expert testimony"); Sandata Techs., Inc. v. Infocrossing, Inc., Nos. 05 Civ. 09546(LMM)(THK), 06 Civ. 01896(LMM)(THK), 2007 WL 4157163, at *5 (S.D.N.Y. Nov. 16, 2007) (finding that "supplemental" expert report was clearly "a reply/rebuttal to [plaintiff's] expert's report" and that such content "is simply not the type of additional or corrective information contemplated by Rule 26") (internal quotation marks omitted); Equant Integrations Servs., Inc. v. United Rentals (N. Am.), Inc., 217 F.R.D. 113, 116 (D. Conn. 2003) (concluding that a report that clearly replied to the opposing party's expert report was not Rule 26(e) supplementation but a reply report, and explaining that defendant "may not circumvent the requirement that a rebuttal report be filed by arguing that the report is merely a Rule 26(e)(1) supplementation") (internal quotation marks and citation omitted). 11 A contrary conclusion—that expert rebuttal reports qualify as proper Rule 26(e) supplementation—could create "absurd"

second is too.

See also East West, LLC v. Rahman, No. 1:11CV1380 (JCC/TCB), 2012 WL 4105129, at *7 (E.D. Va. Sept. 17, 2012) (finding that a report did not contain proper Rule 26(e) supplementation but was instead a rebuttal report, and explaining that "[c]haracterizing the instant report as 'supplementation' does not give [d]efendants free reign to file expert reports, rebuttal or otherwise, until the last moment before trial"); Keener, 181 F.R.D. at 640-41 (rebuttal opinions do not qualify as proper Rule 26(e) supplementation).

procedural problems, as "each party could claim the right to continually 'supplement' its expert reports in response to the last expert report its adversary had submitted[,]" leading to the filing of a never-ending stream of supplemental reports right up to the date of trial. *Sandata*, 2007 WL 4157163, at *5; *see also Beller ex rel. Beller v. United States*, 221 F.R.D. 696, 701-02 (D.N.M. 2003). That kind of "supplementation" is not what Rule 26(e) contemplates, and thus, the Raymond Supplement is not proper under Rule 26(e).¹²

Thus, the Raymond Supplement is the kind of report that normally should have been filed by the deadline for reply reports, November 11, 2013. The problem here is that Actavis could not have filed it then—because the parties had jointly stipulated (and the Court had thereafter ordered) that the only type of reply report permitted on validity/invalidity was one addressing solely Dr. Hider's opinions on "secondary considerations[.]" (D.I. 27; D.I. 121) In its briefing, Novartis asserts that, to the contrary, the parties had "agreed that reply reports could be served on any issue for which the party bore the burden of proof[,]" citing an April 2013 e-mail exchange between counsel as support. (D.I. 162 at 3 n.6 (emphasis added); see also D.I. 162, ex. C at 1; D.I. 167, ex. 1 at 2) However, Actavis disputes that any such agreement was reached with regard to validity/invalidity issues (and the record does not make it clear one way or the other). (D.I. 163, ex. 1 at 2) And it points persuasively to the fact that the last Stipulation filed by the parties regarding reply reports (one filed after the April 2013 e-mail exchange cited by Novartis),

The Court agrees with Novartis that the cases cited by Actavis for the proposition that proper Rule 26(e) supplementation includes reports in which "an expert expands on his previously disclosed theories[,]" (D.I. 160 at 4), either involve one of the narrow scenarios permitted by Rule 26(e) (i.e., correcting a mistake or making an initial report complete) or do not specifically address the permissible scope of Rule 26(e) supplementation, (see D.I. 162 at 2 & n.2-4).

provides only for "reply expert reports to respond to secondary considerations raised by Plaintiffs' rebuttal expert reports[.]" (D.I. 121 at 1)

Taken together, all of this indicates that the Raymond Supplement is not a report explicitly called for by the then-applicable Scheduling Orders in the case. (D.I. 121; D.I. 150)

Its service on November 25, 2013, then, was in violation of those orders. In such a circumstance, the Court turns to the *Pennypack* factors to determine whether the report should be stricken, and Dr. Raymond precluded from opining on topics addressed therein at trial.

B. Applying the *Pennypack* Factors

a. Surprise or prejudice to the moving party and the ability of the moving party to cure any such prejudice

The Court will take the first two *Pennypack* factors together: the extent to which the Raymond Supplement came as a surprise to Novartis or would otherwise prejudice Novartis, and whether any such prejudice could be cured. *Pennypack*, 559 F.2d at 904.

With regard to the issue of surprise, Novartis claims that the report "surprise[d] [it] with positions that had never before been articulated in the case (or at least not on the bases articulated included in the new report)." (D.I. 157 at 1) However, as explained *supra*, in the main, the Raymond Supplement responds to arguments made by Dr. Hider about the utility of the Priority Applications; in doing so, Dr. Raymond also further elaborates upon opinions offered in his opening report. Although Novartis points to allegedly "new theories" contained in the Raymond Supplement, (*id.* at 3 & n.5; D.I. 162 at 2 n.5), the Court is not persuaded that such content was either wholly new nor unexpected. ¹³ Rather, the content of the Raymond Supplement could be

Specifically, in arguing that the Raymond Supplement "provides brand new bases for his opinions[,]" Novartis points to the following: (1) "new arguments about the 'scientific

fairly described just as Actavis has—as providing "additional details [regarding Dr. Raymond's previously stated invalidity opinions] in response to" arguments contained in the Hider Rebuttal. (D.I. 160 at 1) This is not a scenario where Dr. Raymond generated an entirely new theory, one never before fairly disclosed, and then Actavis sprung it on Novartis weeks before trial. Novartis had to have assumed that Dr. Raymond would have *some* response to the Hider Rebuttal

method"; (2) "new argument based on the alleged lack of in vitro data"; (3) new exhibits; and (4) "improper further opinions that should have been included" in an earlier-filed report. (D.I. 162 at 2 & n.5; see also D.I. 157 at 3 & n.5) Yet while the "arguments" in these portions of the Raymond Supplement may arguably have been new, they (1) directly related to theories or bases of Dr. Raymond's opinions that were not new at all (because they were disclosed in the Raymond Report); and (2) were specifically tailored to address assertions made in the Hider Rebuttal about those theories or bases of opinion. For example, as to the scientific method, Dr. Raymond argued in his opening report that the person of ordinary skill in the art reading the Priority Applications would not think that the referenced in vivo experiments had actually been performed, given the absence of supporting data. (Raymond Report at ¶ 179) Dr. Raymond further opined that this is due to the scientific method, which dictates that a scientist will provide "sufficient information" regarding experiments undertaken, in order to allow other scientists to try the experiments for themselves. (Id.) The Raymond Supplement's statements regarding the scientific method and its relationship to the issue of utility simply provided additional detail regarding this theory—detail that was offered to rebut counter-arguments Dr. Hider made about that same topic area in the Hider Rebuttal. (See, e.g., Raymond Supplement at ¶¶ 6-9, 21, 24, 26, 30-31) As to the arguments regarding the alleged lack of in vitro data, in the paragraphs that Novartis cites, (see D.I. 162 at 2 n.5 (citing Raymond Supplement at ¶¶ 27-28)), Dr. Raymond was actually responding to Dr. Hider's assertions that a person of ordinary skill in the art reading the Priority Applications would have expected that the claimed compounds had already demonstrated utility in vitro before being put into the animal models disclosed in the applications. To the contrary, Dr. Raymond argued that no amount of in vitro testing alone could establish deferasirox's utility in treating iron overload in humans. (Raymond Supplement at ¶¶ 27-28) Dr. Raymond had made a related point in his opening report, opining that, "[i]n order to have a reasonable expectation that a compound would have [] pharmacological activity in humans or animals . . . one of ordinary skill in the art would have to have been presented with adequate data showing in vivo activity in an appropriate animal model." (Raymond Report at ¶ 170; see also id. at ¶ 69) As to the new exhibits included in the Raymond Supplement, they either relate generally to the scientific method, or they support Dr. Raymond's responsive arguments to points made by Dr. Hider. (See Raymond Supplement) And the "improper further opinions" that Novartis references either respond directly to Dr. Hider's opinions, or provide further detail regarding Dr. Raymond's previously-disclosed opinions that are, notably, tethered to information contained in the Hider Rebuttal. (See id.)

regarding the issues of utility first called out in the Raymond Report. It could not have reasonably expected that Dr. Raymond would have been precluded thereafter, in any form, from sharing the substance of that response with Novartis and the Court.

As to prejudice, Novartis first argues that "[b]y unfairly raising [] new arguments and evidence in a 'supplemental' report, *instead of an opening report where they belonged*, Novartis has no opportunity left [to address those arguments or evidence in the Hider Rebuttal]." (D.I. 157 at 3-4 (emphasis added)) But as even Novartis acknowledged in later briefing, the bulk of the contested Raymond Supplement could not have been provided in an opening report, since it contains responses to Dr. Hider's arguments on previously-raised topics. Instead, it is the kind of material that would be "due on the deadline for reply reports[,]" (D.I. 162 at 3), had the Court-ordered schedule in this case not precluded that. Put another way, Novartis cannot claim prejudice from loss of the "opportunity" to respond *in the* Hider Rebuttal to Dr. Raymond's arguments that were primarily generated *in response to* the Hider Rebuttal.

Second, Novartis argues that it was prejudiced by the Raymond Supplement because it was served only "four business days[]" before Dr. Raymond's scheduled deposition, just before "a holiday weekend." (D.I. 157 at 4)¹⁴ The Court credits Novartis' claims of prejudice to some extent here. Receiving a report not specifically called for by the Scheduling Order from Dr. Raymond, just days before his deposition, had to have disrupted Novartis' planning for the

If, as Novartis later argued, the agreed-upon schedule allowed for the Raymond Supplement to be filed by the November 11, 2013 deadline for reply reports, then Novartis would have an additional argument as to prejudice here. That is, Novartis could claim that a report that should have been served on November 11 was instead served 14 days later on November 25, giving it 14 fewer days than it should have had to digest the material before Dr. Raymond's December 4, 2013 deposition. However, as the Court has noted, the relevant Court-ordered schedule did not allow for such a reply report to be served on November 11.

deposition itself. That report provided Novartis with new arguments and exhibits to contend with and review in a fairly circumscribed time period, and the timing of its submission ended up generating litigation with the Court during that stretch. Had the report (even though not called for by the Scheduling Order) been provided a few weeks earlier, Novartis might at least have been able to sufficiently digest it before Dr. Raymond's deposition and to have avoided litigation over it altogether.

However, in cases where the non-movant produced the report at issue before the expert's deposition, courts have tended to find that any such prejudice is curable in some form. Novartis went ahead with its planned deposition of Dr. Raymond on December 4, 2013, though in doing so, it attempted to ask Dr. Raymond only questions regarding his initial report. (D.I. 167, ex. 1 at 1)¹⁶ The case law suggests that any prejudice that Novartis suffered can be cured by permitting Novartis to take an additional deposition of Dr. Raymond, limited to the content of the

See, e.g., Invista N. Am. S.A.R.L., 2013 WL 3216109, at *2 (finding that even if there were some prejudice with respect to expert's supplemental report, any such prejudice was curable by plaintiff, as the report was served about two weeks before the expert's deposition); MobileMedia Ideas, LLC v. Apple Inc., 907 F. Supp. 2d 570, 610 n. 22 (D. Del. 2012) (denying motion to strike supplemental report where defendant marked the report as an exhibit at expert's deposition and questioned him about it); Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., No. C.A. 04-1371-JJF, 2006 WL 2435083, at *1 (D. Del. Aug. 22, 2006) (rejecting a party's claim that it would be prejudiced by a supplemental expert report where the party had almost three weeks to review the report before having the opportunity to depose the expert); see also Woodson v. Rodriguez, No. C 07-04925 CW (LB), 2011 WL 1654663, at *3 (N.D. Cal. Apr. 28, 2011) (finding that untimely reply report did not cause defendants to suffer any harm where it was served ten days before expert's deposition and thus actually helped defendants by allowing them to prepare for that deposition and by "more specifically articulating [expert's] previously expressed opinions").

The parties dispute whether this attempt was successful, or whether Novartis actually asked questions also relating to the content of the Raymond Supplement. (D.I. 163, ex. 1; D.I. 167, ex. 1)

Supplemental Report.¹⁷ Because trial is quickly approaching, the Court agrees with Novartis that it "should not be expected to halt its pretrial preparations and fly across the country to" conduct the deposition under these circumstances. (D.I. 162 at 4) For this reason, the Court will grant Novartis' request that Dr. Raymond appear for the additional limited deposition at the office of Novartis' counsel in Boston, Massachusetts. (*Id.* at 5)¹⁸

For the foregoing reasons, while the surprise/prejudice factor mitigates slightly in favor of Novartis' position, the ability to cure any prejudice weighs against a grant of the Motion to Strike.

b. Potential disruption to trial

The next *Pennypack* factor requires the Court to assess whether allowing testimony based on the Raymond Supplement would potentially disrupt the trial proceedings. *Pennypack*, 559 F.2d at 904. The thrust of Novartis' argument here is that there is little time in the schedule for a limited supplemental deposition, as trial is scheduled for the end of January 2014, and such a deposition would cut into Novartis' pre-trial preparations. (D.I. 157 at 4; D.I. 162 at 4) However, any disruptions to the trial preparation process has been mitigated by the fact that the

Indeed, Novartis has reserved 80 minutes for such an additional limited deposition of Dr. Raymond. (D.I. 163, ex. 1 at 1 & ex. A at 264)

Novartis also requests that "the Court confirm that Novartis's experts may respond to the 'supplemental' report from Dr. Raymond with testimony at trial and need not serve yet another report before doing so." (D.I. 162 at 5) At this stage, Novartis need not and should not serve another expert report from Dr. Hider. The Court assumes that counsel for both sides will, in good faith, attempt to come to a shared understanding about the type of trial testimony from Dr. Hider that can fairly be said to be within the scope of the material in the Hider Rebuttal and properly responsive to the content of the Raymond Supplement (no different from what the state of affairs would be if the Raymond Supplement had been filed as a reply report). If they cannot, the parties can raise the issue with the District Court at the upcoming pretrial conference.

parties have been aware for some weeks now that such a deposition is a possibility. And it will also be mitigated, at least in part, by the Court's order that Dr. Raymond appear for his deposition at the offices of Novartis' counsel.

In light of Novartis' failure to identify any further specific disruption to trial that would occur if the Raymond Supplement is permitted, the Court finds that this factor weighs against a grant of the Motion to Strike.

c. Alleged bad faith or willfulness

The Court must also assess whether Actavis acted willfully or in bad faith by serving the Raymond Supplement in contravention of the Court's Scheduling Order. *Pennypack*, 559 F.2d at 904-05. Novartis argues that the timing of the new report (on a holiday week and the eve of Dr. Raymond's deposition) and Actavis' attempt to characterize it as supplemental "suggest[] a lack of good faith." (D.I. 157 at 4)

Courts have tended to reserve a finding that a party acted willfully or in bad faith for clear, extreme examples of such conduct. *Withrow*, 2013 WL 4510305, at *17 (citing cases). Here, the record, while a bit mixed, is not sufficiently strong to warrant a finding of willfulness or bad faith. On the one hand, Actavis' primary argument as to why it served the Raymond Supplement when it did—that the Report is proper Rule 26(e) supplementation—is not particularly strong, nor well-supported under the law. But on the other hand, the content of the Raymond Supplement (even had it never been served in the form of a report) might well have come up at Dr. Raymond's deposition (were Dr. Raymond asked about, or otherwise moved to respond to, certain arguments about utility made in the Hider Rebuttal). Had that happened, Dr. Raymond likely would have been permitted to testify about the material at trial, on the grounds

that it constituted permissible elaboration on the subject matter of his initial report. (*See, e.g.*, D.I. 160 at 5 & ex. B at 29-31) By providing Novartis with the Raymond Supplement when it did, Actavis could have been attempting in good faith to avoid later disputes about the scope of permissible trial testimony, while still giving Novartis some (albeit rather limited) time to prepare to address this material at the deposition. (D.I. 160 at 6); *cf. Woodson v. Rodriguez*, No. C 07-04925 CW (LB), 2011 WL 1654663, at *3 (N.D. Cal. Apr. 28, 2011).

In light of the record here, one that does not clearly show bad faith or willfulness, the Court finds that this factor weighs against a grant of the Motion to Strike.

d. Importance of testimony from Dr. Raymond

The final *Pennypack*, factor directs the Court to analyze the importance of Dr. Raymond's testimony to Actavis. *Pennypack*, 559 F.2d at 904. In weighing this factor, this Court has previously explained that "[c]ourts favor the resolution of disputes on their merits[,]" *Abbott Labs.*, 2011 WL 1897322, at *5, and that "[t]his is particularly true with respect to the validity of patents[,]" *id.* (citing *United States v. Glaxo Grp. Ltd.*, 410 U.S. 52, 69 (1973) ("[T]here is a public interest favoring the judicial testing of patent validity For when a patent is invalid, the public parts with the monopoly grant for no return, the public has been imposed upon and the patent clause subverted.")). Here, the Raymond Supplement relates to Dr. Raymond's (previously expressed) opinion that the person of ordinary skill in the art would not have understood the claimed invention to be useful in chelating iron in overloaded humans from the content (or lack thereof) of the Priority Applications. This issue is a key part of Actavis' invalidity defense. *See Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358-59 (Fed. Cir. 1999) (explaining that a patent may be invalid for lack of utility pursuant to 35 U.S.C.

§ 101). Thus, the content of the Raymond Supplement is important to Actavis' defenses and counterclaims in this action, as is his ability to respond to Dr. Hider's views on the utility issue.

The Court finds that this factor clearly weighs against a grant of the Motion to Strike.

e. Conclusion

In accordance with the analysis above, the Court finds that nearly all of the *Pennypack* factors militate against granting the "extreme sanction" called for by the Motion to Strike. This analysis drives the conclusion that the submission of the Raymond Supplement, while outside the boundaries of what was specifically called for by the Scheduling Order, is ultimately harmless and should be permitted.

IV. CONCLUSION

For the foregoing reasons, it is hereby ORDERED that Novartis' Motion to Strike is DENIED. The Raymond Supplement will be allowed, and Dr. Raymond will be permitted to testify with respect to its contents at trial. Novartis will be permitted an additional deposition of Dr. Raymond, limited to the content of his supplemental report, that shall take place at the office of Novartis' counsel in Boston, Massachusetts (unless the parties jointly agree to some other location).

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 **December 30, 2013** for review by the Court, along with a submission demonstrating why there is good cause for the redactions and why disclosure of the redacted material would "work a clearly defined and serious injury to the party seeking"

redaction. *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: December 23, 2013

Christopher J. Burke

UNITED STATES MAGISTRATE JUDGE