NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS IRELAND LIMITED, **Plaintiff,** **v.** **LUPIN INC., LUPIN PHARMACEUTICALS, INC., and TEVA PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. 21-14271 (SRC) (JSA)** **(CONSOLIDATED)** **OPINION**

JESSICA S. ALLEN, U.S.M.J.

This is a consolidated Hatch-Waxman patent case. Plaintiff, Jazz Pharmaceuticals Ireland Limited, asserts that Defendants Lupin Inc., Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals, Inc.'s proposed ANDA products infringe forty-eight (48) claims across twelve (12) patents covering Plaintiff's branded drug Xywav®, which is an FDA-approved treatment for cataplexy and/or excessive daytime sleepiness associated with narcolepsy.

Plaintiff's initial Complaint was filed on July 28, 2021, followed by five related Complaints, which have been consolidated for all purposes into this action. (*See* ECF Nos. 47, 81, 116, 195). Currently before the Court is Plaintiff's motion to strike allegedly new prior-art references and invalidity theories contained within two of Defendants' opening expert reports—the Amended Expert Report of Michael Crowley, Ph.D. (the "Crowley Report") and the Opening Expert Report of S. Craig Dyar, Ph.D. (the "Dyar Report") (sometimes, collectively, "the Reports"). (*See* ECF Nos. 240, 247). Defendants oppose the motion. (ECF No. 244). No oral argument was heard. *See* Fed. R. Civ. P. 78. For the reasons set forth below, and for good cause

shown, Plaintiff's motion is **GRANTED IN PART AND DENIED IN PART**.

I. BACKGROUND[1]

A. Relevant Procedural History

Several Scheduling Orders have been entered in this consolidated action. (*See* ECF Nos. 34, 74, 81, 116, 143, 195, 201, 217, 239). Relevant here, Lupin served Amended Invalidity Contentions on July 22, 2022, and again on January 4, 2024, and Teva served Invalidity Contentions on September 22, 2023. (*See* Declaration of Liza M. Walsh, Esq. ("Walsh Decl.") Exs. 1-2, 14, 16; ECF No. 244-1). Following the close of fact discovery, the parties timely served their opening expert reports on April 21, 2025. (*See* ECF No. 217).[2]

By letter dated April 24, 2025, Plaintiff advised the Court that it claimed to have "identified new theories, prior art, and prior art combinations in Defendants' opening expert reports that were not disclosed in their invalidity contentions." (ECF No. 229). On May 1, 2025, the Undersigned held a Case Management Conference, wherein the parties were directed to informally address the issue and then submit a status letter on or before May 9, 2025. (*See* Transcript of Case Management Conference, dated May 1, 2025 ("Tr."), 10:20-14:4; ECF No. 235).

In their May 9th submission, the parties advised that they had narrowed their disputes over expert reports and sought additional time to further meet-and-confer. (ECF No. 234). Ultimately, the parties were not able to resolve their disputes. As such, the Court instructed the parties to file any motions to strike opening expert reports by June 20, 2025, and held the balance

[1] The Court assumes the parties are familiar with the extensive history of this case. Only the background relevant to the present motion is set forth herein.

[2] The parties agreed to consolidation of these case for all purposes, including permitting Defendants to rely on each other's contentions. (*See* ECF No. 46-1 at 2; *see also* ECF No. 244 at 1 n.1). Accordingly, Dr. Crowley and Dr. Dyar each submitted single invalidity reports on behalf of both Defendants. (*Id.*)

of expert discovery in abeyance pending the outcome of the motions. (*See* ECF No. 239).[3]

On June 20, 2025, Plaintiff filed the present motion to strike, contending that the Reports each contain new invalidity theories and new prior-art references not previously disclosed in Defendants' Invalidity Contentions. (ECF No. 240).

B. Relevant Patents At Issue

The Crowley Report addresses four (4) patents in the case, which the parties refer to as the "Mixed Salts Patents"—U.S. Patent Nos. 8,591,922 ("the '922 patent"), 9,132,107 ("the '107 patent"), 8,901,173 ("the '173 patent"), and 11,554,102 ("the '102 patent"). (*See* ECF No. 241 at 2; *see also* Walsh Decl., Ex. 3 (the Crowley Report)). The Mixed Salts Patents claim "novel pharmaceutical compositions that Plaintiff invented while developing its Xywav® product." (*Id.*) The active ingredient in Xywav® is "oxybate," and the Mixed Salts Patents cover the Xywav® oxybate composition, which is a mixture comprised of 48% calcium oxybate, 21% magnesium oxybate, 23% potassium oxybate, and 8% sodium oxybate. (*See id.*)

The Dyar Report is directed to U.S. Patent No. 11,426,373 ("the '373 patent"). (*See* ECF No. 241 at 2-3; *see also* Walsh Decl., Ex. 4 (the Dyar Report)). Plaintiff contends the '373 patent claims "novel discoveries that [Plaintiff] made during clinical testing of Xywav®." (ECF No. 241 at 2). According to Plaintiff, "during the development of Xywav®, [Plaintiff's] scientists expected that Xywav® would be bioequivalent to a different oxybate product already on the market[,] a 100% sodium oxybate product called Xyrem®," but "unexpectedly found something very different." (*Id.* at 3). In short, Xyrem® was best taken on an empty stomach, because if Xyrem® was taken with food, there was increased absorption time (T_{max}) and

[3] The parties' dispute relating to Plaintiff's infringement expert report is the subject of Defendants' motion to strike, (ECF No. 242), which is being addressed in a separate opinion and order.

decreased effectiveness (C_{max}). (*Id.*) Unlike Xyrem®, Plaintiff's scientists allegedly found that Xywav® does not exhibit significantly delayed or decreased absorption rates in the presence of food. (*Id.*) According to Plaintiff, the claims of the '373 patent relate to methods of treating patients based on that discovery. (*Id.*)

C. Current Dispute

The Crowley Report contains three clear theories of invalidity directed to the Mixed Salts Patents:

- Ground 1: Obviousness over the Cook Publication, which identifies sodium, potassium, magnesium, and calcium oxybate as pharmaceutically acceptable, alone or in combination. See Crowley Report, Ex. 3 at ¶ 4 (summary), ¶¶ 152-239 (Ground 1);

- Ground 2: Obviousness over the Cook Publication in combination with Conte ('030 patent) and/or Gessa ('632 patent), which confirm the suitability and preference for the same four oxybate salts (sodium, potassium, magnesium, and calcium), and Karppanen, which provides teachings and motivation to reduce sodium by adding potassium, magnesium, and calcium specifically. Id. at ¶ 5 (summary), ¶¶ 240-255 (Ground 2); and

- Ground 3: Obviousness over the Xyrem® Label—which includes explicit FDA warnings about high sodium content—in combination with Cook, Conte, Gessa, and Karppanen. Id. at ¶ 6 (summary), ¶¶ 256-360 (Ground 3).

(*See* ECF No. 244 at 4; *see also* ECF No. 241 at 7).

The Dyar Report opines that the asserted claims of the '373 patent are invalid for at least four reasons:

> (1) obvious in view of the '922 patent; (2) obvious in view of the '922 patent in combination with Borgen; (3) obvious in view of the '922 patent in combination with the Xyrem® label; and (4) anticipated by the '922 patent.

(*See* ECF No. 244 at 7-8; *see also* ECF No. 241 at 9).

The parties agree the Reports contain the above opinions and that they are generally consistent with the disclosures in Defendants' Invalidity Contentions. (*See* ECF No. 244 at 4, 7-

8; ECF No. 241 at 7-9). However, Plaintiff contends that the Reports contain additional theories and references that exceed what was disclosed in Defendants' Invalidity Contentions. (*See* ECF No. 241 at 1). Thus, according to Plaintiff, Defendants were required to seek leave to amend their contentions pursuant to Local Patent Rule 3.7 and establish "good cause." (*See id.* at 1, 17). Plaintiff further contends that because Defendants have not moved to amend and cannot establish good cause, the Court should strike the following undisclosed references, twenty-six (26) paragraphs in the Crowley Report, and thirty-nine (39) paragraphs in the Dyar Report, appearing as:

> **(1)** the Crowley Report's alleged substantive reliance on references, "FDA Regulations"[4] and "Noro"[5];[6]
>
> **(2)** a new obviousness theory in the Crowley Report reliant on a reference identified as "Palma"[7];[8]
>
> **(3)** a new solubility theory in the Crowley Report, including reliance on references "USP"[9] and "Page"[10];[11]
>
> **(4)** an allegedly new sodium reduction theory in the Dyar Report;[12] and
>
> **(5)** the Dyar Report's inclusion of an allegedly new inherency theory.[13]

(*See* ECF No. 244 at 12-17, at times, collectively, "the allegedly new theories and references").

Defendants counter that what Plaintiff describes as the allegedly new theories and

[4] Reference attached to Walsh Decl., at Ex. 7.
[5] Reference attached to Walsh Decl., at Ex. 8, and in certified translated form at Ex. 9.
[6] Crowley Report, ¶¶ 111, 113-15, 141, 143, 146, and 274.
[7] Reference attached to Walsh Decl., at Ex. 12.
[8] Crowley Report, ¶¶ 144, 253, 275, and 292-93.
[9] Reference attached to the Walsh Decl., at Ex. 10.
[10] Reference attached to the Walsh Decl., at Ex. 11.
[11] Crowley Report, ¶¶ 134-139, 147-151, 177, and 276.
[12] Dyar Report, ¶¶ 215-221, 299, 330-32, 353, 355, 360-61, 405, 435-36, 455, 457, 462, and 464.
[13] Dyar Report, ¶¶ 224-31, 335, 348, 363, 439, 451, 466, 492, 503-04.

references were either properly disclosed in Defendants' Invalidity Contentions or otherwise did not have to be disclosed, in accordance with the Local Patent Rules. (ECF No. 244 at 1). Specifically, Defendants contend that Reports contain no new theories. Further, Defendants contend that any references not previously identified in their Contentions were included in the Reports merely for background purposes, as complimentary proof, or as evidence of a motivation to combine, as permitted by the Local Patent Rules. (*See id.* at 1-2). Therefore, according to Defendants, no motion to amend was required. (*Id.*) Defendants further contend that, even assuming the Reports contain new theories or references not otherwise permitted, the controlling standard for exclusion is not the amendment standard of Local Patent Rule 3.7 as suggested by Plaintiff, but rather, the Third Circuit's multi-factor test for analyzing a request to exclude expert testimony set forth in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977) (at times, "*Pennypack"*). (*See id.* at 11).

II. LEGAL STANDARD

"The Local Patent Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case." *Amgen Inc. v. Kashiv Biosciences LLC*, 2019 WL 5445974, at *1 (D.N.J. Oct. 24, 2019).[14] The Patent Rules "are designed to require the parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Id.* (internal quotation omitted).

Pursuant to Local Patent Rule 3.3, a party opposing an assertion of patent infringement must serve on all parties its "Invalidity Contentions," which shall contain, among other things, the following information: (a) the identity of each item of prior art that allegedly anticipates each

[14] The Local Patent Rules "were adopted verbatim from the Northern District of California and are identical to those adopted in Eastern District of Texas. Accordingly, courts in this District look to these 'sister-courts' for guidance with respect to issues not commonly addressed in this District." *Curia IP Holdings, LLC v. Salix Pharm., Ltd.*, 2025 WL 1627251, at *3 (D.N.J. Feb. 18, 2025).

asserted claim or renders it obvious, (b) an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness, (c) a chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found, and (d) a detailed explanation of the bases for the asserted grounds of invalidity based on enablement or written description under 35 U.S.C. § 112. *Id.*

"Invalidity contentions . . . take the place of a series of interrogatories that [plaintiff] would likely have propounded had the patent local rules not provided for streamlined discovery." *Evolusion Concepts, Inc. v. Cross Eng'g, LLC*, 2019 WL 13149923, at *1 (S.D. Cal. Apr. 8, 2019). However, despite Rule 3.3's requirement that prior art references be included in invalidity contentions, an expert may permissibly refer to previously undisclosed references when such references are not being used to support a claim limitation—several examples include references used as: "(1) background material relevant to the technology at issue; (2) state of the art; and (3) establishing what one of skill in the art would have known at the time of the invention." *Ziilabs, Inc., Ltd. v. Samsung Elecs. Co. Ltd.*, 2015 WL 7303352, at *2 (E.D. Tex. Aug. 25, 2015); *see Celgene v. Hetero Labs, Ltd.*, 2021 WL 3701700, at *2 (D.N.J. June 15, 2021). Likewise, experts may also rely on previously undisclosed references to provide support for "motivations to combine," as these are not required disclosures under Local Patent Rule 3.3. *See Azurity Pharms., Inc. v. Amneal Pharma., LLC*, 2023 WL 2817367, at *3 (D.N.J. Jan. 9, 2023) (Rule 3.3 does not require a defendant to disclose "motivations to combine" in contentions); *Celgene*, 2021 WL 3701700, at *2 (undisclosed reference may be used for "supplemental motivations to combine or complimentary proof").

At the same time, a party cannot simply justify "the non-disclosure of prior art references . . . by affixing the label of background materials." *Evolusion Concepts, Inc.*, 2019 WL

13149923, at *1. Thus, if a party develops new theories of invalidity or relies on new references after serving its contentions, Local Patent Rule 3.7 requires the party to seek leave to amend its contentions, which may be granted "only by order of the Court upon a timely application and showing of good cause." *Id.*; *see O2 Micro Int'l Ltd. v. Monolithic Pwr. Sys., Inc.*, 467 F.3d 1355, 1365-66 (Fed. Cir. 2006).

Courts have repeatedly avowed that Rule 3.7 is the proper vehicle to seek to add new theories or references in patent cases, and that parties should not embed new theories or references within expert reports. *See, e.g.*, *Celgene*, 2021 WL 3701700, at *2 ("Given the purpose behind the patent local rules' disclosure requirements, 'a party may not use an expert report to introduce new infringement theories, new infringing instrumentalities, new invalidity theories, or new prior art references not disclosed in the parties' infringement contentions or invalidity contentions.'") (quoting *Verinata Health, Inc. v. Sequenom, Inc.*, 2014 WL 4100638, at *1 (N.D. Cal. Aug. 20, 2014))); *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, 2014 WL 997532, at *7 (D.N.J. Jan. 6, 2014), *aff'd*, 2014 WL 1494592 (D.N.J. Apr. 16, 2014). However, this District's Patent Rules are notably silent on the remedy for noncompliance. *See Taro Pharm. Indus. Ltd. v. Novitum Pharma, LLC*, 2020 WL 1673045, at *10 n.4 (D.N.J. Apr. 6, 2020) ("While it is apparent that Defendant has violated [the Local Patent Rules], the Local Patent Rules are silent on the remedy to be applied."). As detailed below, this absence of a remedy in the Rules has apparently created diverging views among courts in this District regarding the proper standard to apply when evaluating a noncomplying party's inclusion of new references and/or theories in expert reports.

Again, Plaintiff submits that the appropriate standard for Defendants' noncompliance is governed by Local Patent Rule 3.7, which requires Defendants to move to amend and establish

good cause. According to Plaintiff, the proper remedy is to strike those portions of the Reports containing the allegedly new references and theories. (*See* ECF No. 241 at 12; ECF No. 247 at 4). Some courts in this District have adopted this approach by considering the party's failure to seek leave to amend under Rule 3.7 and establish good cause. These courts have found that such noncompliance with the Local Patent Rules alone warrants striking new theories and references revealed for the first time in an expert's report. *See, e.g.*, *Janssen Pharms., Inc. v. Mylan Labs Ltd.,* 2023 U.S. Dist. LEXIS 90278, at *35 (D.N.J. May 23, 2023), *aff'd*, 2025 U.S. App. LEXIS 7190 (Fed. Cir. Mar. 28, 2025); *Celgene*, 2021 WL 3701700, at *2; *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, 2017 U.S. Dist. LEXIS 195828, at *37-41 (D.N.J. Nov. 29, 2017), *aff'd*, 2018 U.S. Dist. LEXIS 88948 (D.N.J. May 29, 2018); *Merck*, 2014 WL 997532, at *7.[15]

In comparison, Defendants submit the proper standard is governed by Federal Rule of Civil Procedure 37(c)(1) and a balancing of the *Pennypack* factors identified by the Third Circuit[16] to determine whether exclusion of the new theories and references is proper. (*See* ECF No. 244 at 10-11). In support of their position, Defendants rely on cases which employ this approach. (*See id*. at 11 (citing *Azurity Pharms., Inc.*, 2023 WL 2817367, at *3, and *Otsuka Pharm. Co. v. Torrent Pharms., Inc.*, 133 F. Supp. 3d 721, 729 (D.N.J. 2015))); *see also, e.g.*, *Janssen Pharm., Inc. v. Alkem Lab. Ltd.*, 2025 WL 2355957, at *3 (D.N.J. Aug. 14, 2025).[17]

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[15] As explained by the court in *Merck*, if a party develops a new theory of infringement or invalidity, Rule 3.7 places the burden on that party to show good cause to amend their contentions to include the new theory. *Id.* at *7. If, however, a party seeking to advance a new theory were allowed to skip the amendment process and simply insert a new theory into an expert report, it would shift the burdens involved – that is, it would effectively relieve the moving party of having to show good cause under the Local Patent Rules and have the practical effect of requiring a showing of prejudice to warrant exclusion of the untimely theories or references involved. *Id.* The *Merck* court found it "could not allow" the burden to be shifted in this way. *Id.*

[16] Although this is a patent case, the Federal Circuit applies regional circuit law to evidentiary rulings not unique to patent law. *See, e.g., Insite Vision Inc. v. Sandoz, Inc*., 783 F.3d 853, 864–65 (Fed. Cir. 2015) (applying Third Circuit law).

[17] Although not raised by the parties, the Undersigned notes that other courts in this District have considered such applications to strike without specific reference to Patent Rule 3.7 or the *Pennypack* factors. *See, e.g.*, *Bausch*

The *Pennypack* factors are: (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence. *Id.* at 904-05.[18]

Reconciling these competing standards is not the threshold issue. Rather, this Court first must consider "whether the expert has permissibly specified the application of a disclosed theory or impermissibly substituted a new theory altogether." *Celgene*, 2021 WL 3701700, at *2. Only if this Court finds the Reports contain a newly disclosed theory or reference is it necessary to determine the proper legal standard for exclusion. Of course, what is "new" in a patent expert's report can be a nuanced evaluation, and several courts have noted the following general, overarching approach to the issue now before the Court:

> The threshold question in deciding whether to strike an expert report or, in this case, select portions of an expert report, is whether the expert has permissibly specified the application of a disclosed theory or impermissibly substituted a new theory altogether. When the line between permissible application of a disclosed theory and impermissible substitution of a new theory blurs, the district court revert[s] to a simple question: will striking the report result in not just a trial, but an overall litigation, that is

Health Ireland Ltd. v. Padagis Israel Pharm. Ltd., 2022 WL 4366413, at *8-9 (D.N.J. Sept. 21, 2022); *King Pharm. Inc. v. Sandoz, Inc.,* 2010 WL 2670804, at *1 (D.N.J. June 29, 2010).

[18] As an aside, the Court observes that the Federal Circuit has applied the Local Patent Rule 3.7-motion-to-amend approach in one District of New Jersey case, and the Federal Rule of Civil Procedure 37(c)(1) and *Pennypack* factors approach in a District of Delaware case. *Compare Janssen Pharms., Inc.*, 2025 U.S. App. LEXIS 7190, at *9-10 (appeal from District of New Jersey, affirming exclusion based on violation of Local Rules without considering *Pennypack* factors), *with Astellas US LLC v. Hospira, Inc.,* 2022 WL 17998229, at *3 (Fed. Cir. Dec. 30, 2022) (appeal from District of Delaware, affirming exclusion based on balance of *Pennypack* factors). The Federal Circuit's application of these different approaches quite possibly is due to the District of New Jersey's adoption of Local Patent Rules, whereas the District of Delaware has not.

more fair, or less?

Sonos, Inc. v. Google, LLC, 2023 WL 2918751, at *2 (N.D. Cal. Apr. 12, 2023) (internal quotes and cites omitted); *see also Celgene*, 2021 WL 3701700, at *2 (Hochberg, J. (Ret.), stating, "[t]he Special Discovery Master will apply the overarching question, 'will striking the report [portion or reference] result in not just a trial, but an overall litigation, that is more fair, or less?'") (quoting *Verinata*, 2014 WL 4100638, at *3).

III. ANALYSIS

Plaintiff raises five objections to the substance of the Reports. Each is addressed separately below.

A. Dr. Crowley's Reliance on the FDA Regulations and Noro[19]

Plaintiff does not dispute that Defendants' Invalidity Contentions disclose that a person of ordinary skill in the art ("POSA") would have been motivated to reduce the amount of sodium present in Xyrem®. (*See* ECF No. 247 at 8-9). Nor does Plaintiff appear to dispute that, at times, Defendants' Invalidity Contentions refer generally to "Noro" and the "FDA Regulations" when discussing a desire to reduce sodium content. (*See* ECF No. 244 at 11-12 (citing Defendants' Invalidity Contentions, Walsh Decl., Ex. 14 at 2, 5; Walsh Decl. Ex. 1 at 35, 46))). Rather, Plaintiff contends that Defendants introduce a new theory of obviousness in the Crowley Report by, for the first time, specifically relying on "Noro" and the "FDA Regulations" for the express purpose of supporting their invalidity theory. (ECF No. 241 at 15; ECF No. 247 at 8-9).

Defendants contend that the challenged paragraphs in the Crowley Report, including Noro and the FDA Regulations, are being used for precisely the same purpose as their Contentions, and thus, there is no new theory presented. (ECF No. 244 at 11-12). In addition,

[19] Crowley Report, ¶¶ 111, 113-15, 141, 143, 146, and 274.

Defendants note that Plaintiff was aware of the FDA Regulations and Noro, having cited and discussed these references at length in Plaintiff's responsive Validity Contentions. (*See* ECF No. 244 at 14).

The question boils down to whether Defendants are presenting a new theory of obviousness by combining previously disclosed references for a different purpose, thus creating a new theory. The Court concludes they have not. A review of the Crowley Report reveals that the references to Noro and the FDA Regulations are described as background and located in the "State-of-the-Art" section of Dr. Crowley's Report (*see* ¶¶ 111, 113-15, 141, 143, and 146). While it is true that the State-of-the-Art section is incorporated by reference into Ground 3, (*see* ¶ 274), footnote 42 of the Crowley Report makes clear that Dr. Crowley is only relying on "Noro [and] FDA Regulations solely for scientific background, motivation, and reasonable expectation of success." (Crowley Report, ¶ 151 n.42).

This Court finds no new theory of invalidity has been presented, and that the references are permissibly used. Specifically, the Court is satisfied that Plaintiff was on notice of both Noro and the FDA Regulations, and that Defendants' Invalidity Contentions included the position that a POSA would have been motivated to reduce sodium content. (*See* ECF No. 244 at 12-15 (citing portions of Defendants' Invalidity Contentions)). Thus, Defendants' reliance on Noro and the FDA Regulations amounts to Dr. Crowley's use of permissible background, a motivation to combine, and, at most, further specification of "a disclosed theory," and not "an impermissibly substituted [] new theory altogether." *Celgene*, 2021 WL 3701700, at *2. The Court therefore declines to strike this portion of the Crowley Report.

B. Dr. Crowley's Alleged New Theory Reliant on Palma[20]

Plaintiff contends Dr. Crowley introduces a new theory of obviousness. Specifically, Plaintiff contends that Dr. Crowley opines that "a POSA would arrive at a mixed oxybate salt composition (rather than a composition of only magnesium oxybate or potassium oxybate) because a reference identified as Palma, which concerns colonoscopy prep drugs, teaches that high doses of magnesium and potassium could 'cause gastrointestinal disturbances.'" (ECF No. 241 at 16).

Defendants acknowledge that the "Palma" reference is not cited in their Invalidity Contentions or included in their accompanying chart. (*See* ECF No. 244 at 6-7). However, Defendants counter that their invalidity theory regarding a mixed oxybate salt composition was fully disclosed as part of its Invalidity Contentions, and that the reference to "Palma" is reduced to a footnote, wherein Palma serves as "scientific knowledge" and background in "further support of Defendants' previously disclosed invalidity allegations." (ECF No. 244 at 17).

Defendants have the better of the argument. Defendants' Invalidity Conventions disclose their theory of invalidity, which appears as part of Grounds 1 and 2 in the Crowley Report. Palma is only tangentially mentioned. Specifically, in noting that "high doses of magnesium and potassium could . . . cause gastrointestinal disturbances," (Crowley Report, ¶ 144), Dr. Crowley cites Palma as support for his observation that "many colonoscopy drugs use combinations of sodium, potassium, and magnesium." (*Id.* ¶ 144 n.41). The context of the Crowley Report's reference to Palma confirms it is a mere anecdotal aside and a background reference, not an attempt to support a new theory with a previously undisclosed reference. Indeed, Palma is not referenced again in the Crowley Report, other than in footnote 42, which, in fact, affirmatively

[20] Crowley Report, ¶¶ 144, 253, 275, and 292-93.

states that Palma is being used for background purposes only. (*See* Crowley Report, ¶ 151 n.42). Thus, the Court agrees with Defendants that the reference to Palma is merely permissible background being offered to support a previously disclosed theory, and thus, declines to strike any aspect of the Crowley Report on this basis. *See Celgene*, 2021 WL 3701700, at *1.

C. Dr. Crowley's Alleged New Solubility Theory[21]

Plaintiff does not dispute that Defendants' Invalidity Contentions contain a theory of solubility. Nevertheless, it contends that Dr. Crowley's Report expands or alters the theory by relying, at least in part, on two new references, the "United States Pharmacopeia ("USP")" and "Page." (*See* ECF No. 241 at 17; *see also* ECF No. 247 at 11). In response, Defendants dispute that there is any new theory. Defendants contend that their solubility theory was disclosed in Invalidity Contentions based on, among other references, the Cook Publication, and that Plaintiff responded to this theory in its responsive Validity Contentions (*see* ECF No. 244 at 18-20). Defendants further contend that USP and Page are merely background references that do not support any theory of invalidity. (*Id.*) This Court agrees.

As Defendants explain, their solubility theory is no surprise and was discussed extensively in their Invalidity Contentions and Plaintiff's responsive Validity Contentions. (*See* ECF No. 244 at 18-20). The references to USP and Page do not change the equation. Rather, USP and Page are referenced, respectively, in footnotes and stand for seemingly uncontroversial factual propositions and background and do not serve as references supporting a new or undisclosed theory of invalidity directed to a particular claim limitation. (*See* Crowley Report, ¶ 134 n. 38; Crowley ¶ 136 n.39). Moreover, as with Palma, Noro, and the FDA Regulations discussed above, Dr. Crowley affirmatively represents that USP and Page are being used for

[21] Crowley Report, ¶¶ 134-139, 147-151, 177, and 276.

background purposes only. (*See* Crowley ¶ 151 n.42). Thus, this Court agrees that these references are purely background information and are permissibly included in the Crowley Report. *See, e.g.*, *Celgene*, 2021 WL 3701700, at *1 (citing *Genetech, Inc. v. Trustees of Univ. of Penn.*, 2012 WL 424985, at *3 (N.D. Cal. Feb. 8, 2012)). Accordingly, the Court finds no basis to strike.

D. Dr. Dyar's Alleged New Sodium Reduction Theory and References[22]

Plaintiff contends that the Dyar Report shifts the sands of Defendants' invalidity theories by arguing, for the first time, that a POSA would have found the pharmacokinetic limitations of the '373 patent obvious because a POSA would "know that sodium impacts the pharmacokinetics of certain drugs and thus would expect the claimed reduction in sodium in an oxybate composition to lead to a commensurate reduction in any food effect." (ECF No. 241 at 12-13).

According to Plaintiff, Defendants' Invalidity Contentions submit that the claimed pharmacokinetic effects would have been obvious "under *only* the inherency doctrine." (*Id.* (emphasis in original); *see also id.* at 3-4). Yet, Plaintiff contends that Defendants have twice tried to change their theory. Plaintiff asserts that Defendants realized the flaw in their original inherency argument upon the retention of new counsel and tried to rectify it by filing a motion to amend their answer to include an inequitable conduct defense. (*Id.*) However, District Judge Chesler denied their motion to amend and thus, Plaintiff contends, Defendants have pivoted to another option: attempting to modify their theory in the Dyar Report to focus on sodium and obviousness, supporting the theory with two completely new references, "Azizi" and "Darbar." (*See id*.)

[22] Dyar Report, ¶¶ 215-221, 299, 330-32, 353, 355, 360-61, 405, 435-36, 455, 457, 462, and 464.

In response, Defendants acknowledge that Azizi and Darbar are not cited in their Invalidity Contentions. Nevertheless, Defendants contend that their "position has always been that a POSA would be motivated to use the lower-salt formulations of the '922 patent given what was known about sodium at the time of the invention." (ECF No. 244 at 27). In support, Defendants contend that Azizi and Darbar are merely cited as supplemental motivations to combine or as complimentary proof in support of a previously disclosed theory. (*Id.* at 28).

Defendants' explanations do not hold up. In short, the Court finds that the Dyar Report contains a new sodium reduction theory supported by the references to Azizi and Darbar, and this theory was not disclosed in Defendants' Invalidity Contentions. Connecting the dots from the patent's claims to Defendant's Invalidity Contentions to the Dyar Report illustrates the point.

The relevant claim limitation from the '373 patent states, in part, "a reduced food effect as measured by C_{max} as compared to an equal dose of Xyrem®." (ECF No. 241 at 4).

In addressing that limitation, Defendants' Invalidity Contentions clearly state that this claim limitation is an "inherent" characteristic of the administration of the '922 patent. (*See* Declaration of Nicholas A. LoCastro, Esq., Ex. 6 (Lupin's Amended Invalidity Contentions) at 29 (claim limitation is "an inherent characteristic of the administration of the '922 patent composition") and Ex. 8 at Appendix 43, p. 4 (Teva's Invalidity Chart) ("The recited C_{max} values are inherent properties following administration"); ECF No. 241-1)).

However, the Dyar Report says something materially different. The Dyar Report states, in relevant part:

> **215.** [T]he teachings of the '922 patent that the reduced sodium GHB mixed salt composition had a reduced food effect compared to a composition made only from sodium GHB would not be surprising to the POSA. Rather, this expectation would have been consistent with a POSA's knowledge that the pharmacokinetics of drugs can be significantly influenced by the presence of sodium. As discussed above, the POSA knew that the administered meal and Xyrem® itself both

introduced high amounts of sodium to a patent. In the context of other drugs, two prior art studies highlighted the impact of sodium content on their pharmacokinetics.

216. For example, Azizi et al., "Effect of Contrasted Sodium Diets on the Pharmacokinetics and Pharmacodynamic Effects of Renin–Angiotensin System Blockers," HYPERTENSION (2013) (LUPIN_XYWAV_EXPERTS_0000025-000031) investigated how dietary sodium affects the pharmacokinetics and pharmacodynamic responses of various renin-angiotensin system (RAS) blockers in healthy male subjects. Azizi at p. 1239. Azizi showed that a high-sodium diet (SR) led to a substantial decrease in the bioavailability of both candesartan cilexetil and atenolol. Azizi at 1243 ("We found that a high-sodium diet was associated with a ≈30% decrease in exposure to a single oral dose of 8 mg candesartan cilexetil or of 50 mg atenolol in healthy male subjects, as shown by the AUCs and C_{max} values obtained, which were lower than those for SD conditions."). For candesartan cilexetil, the area under the curve (AUC0–∞) for plasma concentration was 0.74 (90% CI, 0.66–0.82) during SR compared to SD, indicating a reduction in bioavailability. Azizi at Abstract. Similarly, atenolol exhibited a 31% reduction in bioavailability with an AUC0–∞ ratio of 0.69 (90% CI, 0.54–0.88) during SR. Azizi at Abstract. These findings suggest that sodium intake can significantly alter the absorption and systemic availability of these drugs. Azizi at 1244.

217. Likewise, Darbar et al., "Modulation by Dietary Salt of Verapamil Disposition in Humans" CIRCULATION (1998) (LUPIN_XYWAV_EXPERTS_000032-000038) demonstrates that dietary sodium significantly influences the pharmacokinetics of verapamil, a drug that undergoes extensive first-pass metabolism. Darbar at Abstract. The POSA would be aware that Xyrem® also undergoes significant first-pass metabolism. Xyrem® label at 4 ("Sodium oxybate undergoes significant presystemic (hepatic first-pass) metabolism"). 218. Darbar showed that plasma concentrations of verapamil were significantly lower during the high-salt diet phase. Darbar at Abstract, p. 2704.

. . .

220. *[T]he POSA knew that sodium content impacts the pharmacokinetics of certain drugs. Azizi et al. showed that a high-sodium diet decreases the bioavailability of candesartan cilexetil and atenolol, while Darbar found that high dietary salt intake reduces the plasma concentrations and efficacy of verapamil.*

221. *Therefore, a smaller difference in Cmax between fed and fasted states for a single dose of reduced sodium GHB salt(s) compared to an equal dose of immediate release liquid solution would have been obvious and reasonably expected by the POSA.*

(Dyar Report, ¶¶ 215-17, 220-21) (italics added)).

In short, this aspect of the Dyar Report does not present the inherency theory disclosed in Defendants' Invalidity Contentions. Rather, the Dyar Report presents an obviousness theory directed to the reduced food effect claim limitation in the '373 patent, contending that a POSA would have found it obvious that a formulation with less sodium would have exhibited the claimed food effect. (*Id.*) Moreover, Azizi and Darbar are plainly being utilized as substantive references to support the new theory; they are not merely complimentary sources or background. (*See, e.g.*, Dyar Report, ¶¶ 216-17, 220-21). Thus, this Court finds that the Dyar Report contains a new theory of invalidity based on obviousness. (*See id*.) The question thus turns to whether this new theory should be excluded.

Plaintiff contends the challenged paragraphs in Dyar Report should be automatically and reflexively excluded because Defendants have not moved to amend their Invalidity Contentions to include the theory (or references) as required by Local Patent Rule 3.7, let alone established good cause for any such amendment. (*See* ECF No. 241 at 13; ECF No. 247 at 4-5). As previously addressed, there is support among some courts for this approach. *See, e.g.*, *Janssen Pharms., Inc.*, 2025 U.S. App. LEXIS 7190, at *9-10; *Celgene*, 2021 WL 3701700, at *2; *Merck*, 2014 WL 997532, at *7. And if this Court were to adopt this approach, it cannot be disputed that Defendants have not moved to amend or even attempted to establish good cause pursuant to Rule 3.7. Accordingly, such noncompliance with Rule 3.7 would independently warrant striking the new theory. However, even if this Court were to adopt the more liberal *Pennypack* factors approach, this Court would still find exclusion is warranted.

Here, neither side analyzes the *Pennypack* factors in particularly great detail. Still, in general terms, Plaintiff claims that allowing new theories and references in the case would be

unfairly prejudicial because fact discovery is closed, and Defendants have had years to prepare an invalidity defense. (ECF No. 241 at 17-20). Specifically, Plaintiff continues that allowing Defendants to expand the case at this late stage "would severely prejudice [Plaintiff] and its experts by requiring them to respond to Defendants' new positions without the benefit of fact discovery as to those positions and in far less time than would otherwise be appropriate." (*Id.*) Plaintiff also contends that Defendants are impermissibly attempting to work around Judge Chesler's denial of their motion to amend to include an inequitable conduct defense. (*Id.*)

In response, Defendants argue that Plaintiff's claims of prejudice are "baseless," and that is no basis to strike any aspect of the Reports under the *Pennypack* framework. (ECF No. 244 at 29). Further, Defendants contend that Plaintiff's arguments regarding discovery are "hypothetical," in that Plaintiff fails to explain in any detail what fact discovery it would pursue. (*Id.* at 29-30).

As previously noted, the decision on whether to exclude evidence under the *Pennypack* factors turns on: (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence. *Id.* at 904-05. "The importance of the evidence is often the most important factor." *Z.F. Meritor, LLC v. Eaton Corp.*, 696 F.2d 254, 298 (3d Cir. 2012). The Court is convinced that on balance the *Pennypack* factors support exclusion in this case. *See Meyers*, 559 F.2d 904-05.

First, there is surprise, as this Court has already determined that the theory and references

are new and were not disclosed in Defendants' Invalidity Contentions.

Second, the Court considers whether there is prejudice to Plaintiff and the ability to cure it. *See id.* at 904-05. Here, Plaintiff convincingly shows that it would suffer prejudice if required to address a new theory, post-fact discovery and in the middle of expert discovery. To that end, the Court finds there is insufficient time to reopen fact discovery to allow further exploration of this new theory and then restart expert discovery. This is particularly so given Defendants' complete failure to explain why this new theory (and references) could not have been added earlier in the case through a proper motion to amend invalidity contentions.

Third, allowing the new theory would disrupt the orderly progress of the case. Indeed, as Plaintiff points out, District Judge Chesler previously declined to allow Defendants to pursue an inequitable conduct counterclaim premised, in part, on a theory that an inventor had withheld prior art references from the USPTO during prosecution of the '373 patent that would have allegedly shown that a POSA would have reasonably expected the claimed pharmacokinetics of the '373 patent due to the inclusion of a magnesium salt. (*See* ECF No. 200 at 19-20). While the denial of Defendants' motion to amend was based primarily on futility, Judge Chesler did find that Defendants did not act with sufficient diligence in seeking to alter their theory of invalidity in the case. (*See* ECF No. 200 at 23). Thus, the Court agrees with Plaintiff that allowing Defendants to recast their invalidity position to rely on sodium (as opposed to magnesium) would lead to an unfair result.

Fourth, the Court finds, on this record, bad faith has not been shown.

Finally, Defendants completely fail to address the fifth—and often the most prominent *Pennypack* factor—that is, the importance of the evidence to be excluded. *See Z.F. Meritor*, 696 F.2d at 298. Indeed, Defendants' opposition brief is devoid of any discussion of the importance

of this theory or the consequences of its exclusion. Moreover, the sodium reduction theory at issue is plainly not Defendants' only theory of invalidity, as the Dyar Report has four additional theories of invalidity directed to the '373 patent. (*See* ECF No. 244 at 7-8). Considering Defendants' failure to explain the importance of the evidence and given that they still have several theories of invalidity they can pursue, the Court finds that the evidence has not been shown to be important. *See, e.g.*, *Astellas,* 2022 U.S. App. LEXIS 35933, at *17-18 ("[Plaintiff] has not shown that the excluded evidence here is critical or of sufficient importance to outweigh the other factors. The excluded evidence was merely an alternative theory of infringement, not the sole theory of infringement."). Thus, the most important *Pennypack* factor weighs in favor of exclusion.

On balance, the first, second, third, and fifth *Pennypack* factors weigh in favor of exclusion. Accordingly, the Court finds on the record presented, exclusion of the new references and theory is warranted. As such, the Court grants Plaintiff's request to strike these disputed paragraphs in the Dyar Report.[23]

E. Dr. Dyar's Alleged New Inherency Theory[24]

This dispute focuses on the claim limitation in the '373 patent reciting "a reduced food effect as measured by C_{max} as compared to an equal dose of [Xxyrem]." (ECF No. 241 at 4). The parties agree that Defendants' Invalidity Contentions addressed this claim limitation[25] and that the following paragraph in the Dyar Report is permissible based on that disclosure:

> **223.** As explained throughout this report, the '922 patent discloses using a reduced sodium mixed salt GHB pharmaceutical composition within the meaning

[23] Dyar Report, ¶¶ 215-221, 299, 330-32, 353, 355, 360-61, 405, 435-36, 455, 457, 462, and 464.

[24] Dyar Report, ¶¶ 224-31, 335, 348, 363, 439, 451, 466, 492, 503-04.

[25] Defendants' Invalidity Contentions addressed this claim limitation by stating, in part, "the pharmacokinetics are a natural property of that composition and/or are an inherent benefit or advantage of the composition taught in the '922 patent." (Walsh Decl., Ex. 16 at 29).

> of the claims. Supra at ¶¶81- 83, 135-139, 165-167; infra at ¶¶232-237. And as explained above, the '922 patent discloses a head-to-head comparison of the reduced sodium mixed salt GHB composition with Xyrem®. See, e.g., Table 8; supra at ¶¶194-203. The reduction in C_{max} when the two formulations are compared under the conditions and meaning of Claim 1 is necessarily present.

(Dyar Report, ¶ 223; *see* ECF No. 241 at 4; ECF No. 244 at 21; ECF No. 247 at 7).

However, Plaintiff contends that in responsive Validity Contentions, it argued that the clinical data shows that not *every* patient administered the compositions of the '922 patent will necessarily exhibit the claimed pharmacokinetic parameters, and thus, the pharmacokinetic claim limitation of the '373 patent is not inherent in the compositions of the '922 patent. (ECF No. 241 at 4).

The parties dispute whether the Dyar Report attempts to counter Plaintiff's Validity Position by shifting its inherency theory, focusing on the following paragraph:

> **226**. To the extent Plaintiff (or its expert) attempts to point to data from a patient cohort where there may be data at the edges of the normal distribution (hereinafter referred to as "outliers") where the claimed food effect reduction is not observed for a particular sample set or patient, this would not save the claim. For the purposes of these claims, the pharmacokinetic parameters (including C_{max} and AUC) would still be necessarily present even if Plaintiff was able to point to some *outliers* because "'C_{max}' refers to the **average** of the maximum plasma concentration (in oxybate mg/L or ug/mL) achieved in individual patients." 35:19-22 (the '373 patent defining C_{max}).

(Dyar Report, ¶ 226) (bold emphasis in original; italics added).

Plaintiff argues that the Dyar Report's attempt to define C_{max} as referring to "the average of the maximum plasma concentration . . . achieved in individual patients," is an attempt to respond to Plaintiff's Validity Contentions and rescue Defendants' inherency argument in the event there are "outlier" patients that do not necessarily exhibit the claimed pharmacokinetic limitations. (*See* ECF No. 241 at 10). Plaintiff contends these disputed sections of the Dyar Report should be stricken because Defendants are attempting to attach a particular meaning to

C_{max} that was not raised during the *Markman* process and, is in fact, contrary to the parties' representation in their Joint Claim Construction and Prehearing Statement that the claim limitation containing C_{max} carried its plain and ordinary meaning. (*Id.*, citing Joint Claim Construction and Prehearing Statement at ECF No. 138)). According to Plaintiff, if it had been made aware of Defendants' intent to define C_{max} to include "averages," they would have pursued the question further in *Markman* and/or discovery. (*See* ECF No. 241 at 18, ECF No. 247 at 8).[26]

Defendants counter that paragraph 226 in the Dyar Report is merely expanding on the theory expressed in their Invalidity Contentions and in paragraph 223 and is not a new theory at all. Instead, Defendants contend that Dr. Dyar's Report is merely elaborating on *why* the reduction in C_{max} is present, based on how the '373 patent *itself* defines "C_{max}." (ECF No. 244 at 23 (citing the '373 patent at 35:19-22 ("C_{max} refers to the average of the maximum plasma concentration (in oxybate mg/L or ug/mL) achieved in individual patients."))). As it relates to the parties' claim construction discussions, Defendants contend that they never agreed to any definition of C_{max} and that the parties' Joint Claim Construction and Prehearing Statement merely references C_{max} within the context of a lengthier limitation, where that lengthier limitation carries its plain and ordinary meaning. (*See* ECF No. 244 at 24). Defendants further argue that the patent's definition of C_{max} controls, and that Defendants could not have stipulated otherwise during the *Markman* process as a matter of law, as the inventor's "lexicography governs." (*See id.* at 22, 25). Thus, Defendants contend the Dyar Report does not contain any new theory, and Plaintiff cannot dispute the meaning of C_{max}, as it is the "express definition in its own patent." (*Id.*)

[26] There have been no formal claim construction proceedings in this case, as the parties have not requested the Court construe any terms in the patents-in-suit. (*See* ECF Nos. 76, 114, 138).

On reply, Plaintiff contends that there is "no lexicography for the term C_{max}." (ECF No. 247 at 5). Rather, Plaintiff argues that the "Definitions" section of the '373 patent does not list C_{max}; the definition Defendants rely on is limited to the tables and figures found in a specific example in the patent; and that the '373 patent defines C_{max} differently, at different times. (ECF No. 247 at 6).

The Court rejects Plaintiff's position for several reasons.

First, Defendants have indisputably advanced an inherency theory, arguing that the reduction in C_{max} is necessarily present in the composition of the '922 patent. (*See* Dyar Report, ¶ 223). The Court finds that paragraph 226 is reasonably construed to be an extension or further articulation of that disclosed theory, not a new theory altogether. *See, e,g.*, *Celgene*, 2021 WL 3701700, at *13. In short, Defendants contend their inherency argument should succeed regardless of whether there are outlier patients, whereas Plaintiff disagrees. This is a legal dispute, not a disclosure dispute. As such, the Court does not find a new theory has been asserted in the Dyar Report.

Second, to the extent this theory is more than a mere extension or further articulation (which the Court concludes it is not), Plaintiff would be well-positioned to address this issue in its responsive expert report and in expert depositions. Indeed, while Plaintiff posits several hypothetical questions it would pursue on this subject in discovery, (*see* ECF No. 241 at 18), these questions appear to be more appropriate for expert discovery.

Third, to the extent the parties believe that this issue truly requires *Markman* proceedings, either side is free to submit a request to the District Judge to conduct limited claim construction proceedings on the meaning of the term "C_{max}" in the '373 patent. In short, the Court finds no basis to strike this portion of the Dyar Report.

IV. CONCLUSION

For the reasons set forth above, Plaintiff's motion to strike, (ECF No. 240), is **GRANTED IN PART AND DENIED IN PART**. Specifically, the Court **grants** Plaintiff's request to strike the following paragraphs in the Dyar Report: 215-221, 299, 330-32, 353, 355, 360-61, 405, 435-36, 455, 457, 462, and 464. The remainder of Plaintiff's motion is **denied**. An appropriate order will be entered.

SO ORDERED.

s/Jessica S. Allen
Hon. Jessica S. Allen
United States Magistrate Judge

cc: Hon. Stanley R. Chesler, U.S.D.J.

Dated: January 15, 2026