NOT FOR PUBLICATION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** **(REDACTED)**

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 Defendants' motion to strike three (3) paragraphs in the opening expert report served by Plaintiff's infringement expert, Dr. Richard K. Bogan. Defendants contend the report presents a new, previously undisclosed theory of infringement. (*See* ECF Nos. 242, 248). Plaintiff opposes the motion. (ECF No. 245). No oral argument was heard. *See* Fed. R. Civ. P. 78. For the reasons set forth below, and for good cause shown, Defendants' motion is **DENIED**.

I. RELEVANT 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). Plaintiff served Infringement Contentions on Lupin on June 19, 2023, and on Teva on December 29, 2023. (*See* ECF No. 243 at 2; *see also* ECF Nos. 81, 116). Following the close of fact discovery, the parties timely served their opening expert reports on April 21, 2025. (*See* ECF No. 217).[2]

On May 1, 2025, the Undersigned held a Case Management Conference, wherein Defendants informed the Court that they had issues with the substance of Plaintiff's opening expert reports. (*See* Transcript of Case Management Conference, dated May 1, 2025 ("Tr."), 10:20-14:4; ECF No. 235). The Undersigned directed the parties to informally address the issue and then submit a status letter on or before May 9, 2025. (*See id.*)

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 file any motions to strike opening expert reports by June 20, 2025, and held the balance of expert discovery in abeyance pending the outcome of the motions. (*See* ECF No. 239).

On June 20, 2025, Defendants filed the present motion to strike, contending Dr. Bogan's Report contains a new theory of infringement related to the "reduced food effect" limitation in Claim 1 of U.S. Patent No. 11,426,373 ("the '373 patent"). (ECF No. 242-43).

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[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] By letter dated April 24, 2025, Plaintiff advised the Court that "it had identified new theories, prior art, and prior art combinations in Defendants' opening expert reports that were not previously disclosed in their invalidity contentions." (ECF No. 229). This is the subject of Plaintiff's motion to strike portions of these reports, (ECF No. 240), which is being addressed in a separate opinion and order.

B. Current Dispute

The Bogan Report exceeds three hundred (300) paragraphs and renders opinions bearing on several patents at issue in the case. (*See* Declaration of Liza M. Walsh, Esq., ("Walsh Decl.") Ex. C (Bogan Report to Teva) & Ex. D (Bogan Report to Lupin); ECF No. 243-1).[3] Yet, the parties' agree that their current dispute is limited to a single limitation, in a single claim, in a single patent (the '373 patent), and three paragraphs in Dr. Bogan's Report—i.e., paragraphs 332, 333, and 334 (at times, "the disputed paragraphs"). For context, each is addressed below.

C. Relevant Patent At Issue

Plaintiff contends the '373 patent claims discoveries made during clinical testing of Xywav®. (ECF No. 245 at 2-3). According to Plaintiff, during the development of Xywav®, its 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 different. (*Id.*) 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 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—in other words, Xwyav® showed a reduced food effect as compared to Xyrem®. (*Id.*) According to Plaintiff, the claims of the '373 patent relate to methods of treating patients based on that discovery. (*Id.*)

D. The Disputed Claim & Plaintiff's Infringement Contentions

Claim 1 of the '373 patent (with the "reduced food effect" limitation in bold) reads, in

[3] The Bogan Reports served on Teva and Lupin "are substantially identical, differing only in that they cite Teva- and Lupin specific documents, respectively." (ECF No. 243 at 3 n.1). For brevity and efficiency, the Court refers to both reports collectively as "Dr. Bogan's Report" or the "Bogan Report."

relevant part:

> 1. A method of reducing food effect due to administration of gamma-hydroxybutyrate (GHB) in a patient having cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy, comprising: … ***wherein the pharmaceutical composition of GHB has reduced food effect as measured by C_{max} compared to an equal dose of immediate release liquid solution of Na.GHB, ….***

(ECF No. 243 at 1-2) (emphasis in original).

Plaintiff's Infringement Contentions address this limitation with the following description and citation to documents:

> The claimed pharmaceutical composition, when administered as instructed by [Defendants'] accompanying labeling (within four hours after eating), will, in at least some patients, have a reduced food effect as measured by C_{max} compared to an equal dose of immediate release liquid solution of NaGHB. *See, e.g.*, TEVA_XWAV_00000027-103; TEVA_XWAV_00004932-4997; TEVA_XWAV_00000265-300; TEVA_XWAV_00005054-5089; JPIL0040913-1454; and JPIL0066557-7166.

(Wash Decl., Ex. A at 612).[4]

E. Dr. Bogan's Report

The disputed paragraphs in Dr. Bogan's Report addressing Claim 1 read:

> **332.** Example 2 of the '373 patent describes pharmacokinetic testing where a mixture of sodium, potassium, calcium, and magnesium oxybates called "Formulation O" was compared to Xyrem. See Ex. 10, '373 patent at 35:1-39:3. The mixed salt formulations tested in the pharmacokinetic studies were a single dose "equivalent to 4.5 g sodium oxybate." Ex. 10, '373 patent at 35:14-15. In particular, the '373 patent states: Formulation "O" was tested for bioequivalence relative to Xyrem® (Formulation "X", commercial sodium oxybate solution of the same molar concentration and comparable pH as "O") and in the fasted as well as fed state. The study was compliant with the FDA guidance for food effect studies ("Guidance for Industry: Food-Effect bioavailability and Fed Bioequivalence Studies", FDA December 2002), incorporated herein by reference in its entirety. (Ex. 10, '373 patent at 36:10-19.) The results of the bioequivalence studies are presented in Table 4 and Table 7 of the '373 patent, reproduced below:

[4] Plaintiff's Infringement Contentions are the same for both Defendants, other than the citation to each Defendants' respective documents. For the sake of simplicity, the Court recites only Plaintiff's contentions served on Teva.

TABLE 4

Conditions and Results in Study 13-010 Using 240 mL Liquid Volume

Treatment	Number of Patients	Vol (mL)	Cmax (mg/L)	Cmax ratio	AUC (mg•h/L)	AUC ratio	% equivalent Na	K	Ca	Mg
O, fasted	34	240	102.3	76%	238.7	89%	8	23	48	21
O, fed	36	240	77.7	58%	216.0	81%	8	23	48	21
X, fasted	32	240	134.6	100%	268.1	100%	100	0	0	0
X, fed	36	240	84.9	63%	233.0	87%	100	0	0	0

(Ex. 10, '373 patent at 36:25-37.)

TABLE 7

Results of Study JZP258-101, n = 33 patients

Treatment	Vol (mL)	Cmax (mg/L)	Cmax ratio	AUC Mg•h/L)	AUC ratio	% equivalent Na	K	Ca	Mg
O, fasted	60	93.0	77%	238	95%	8	23	48	21
O, fasted	240	92.7	74%	233	90%	8	23	48	21
O, fed	60	63.0	52%	202	80%	8	23	48	21
X, fasted	60	120.5	100%	251	100%	100	0	0	0
X, fasted	240	125.9	100%	258	100%	100	0	0	0
X, fed	60	68.6	57%	206	82%	100	0	0	0

(Ex. 10, '373 patent at 37:56-38:9.)

The '373 patent states that "[t]he results indicate that formulation 'O' has a reduced food effect compared to Xyrem®." (Ex. 10, '373 patent at 38:16- 18.) As can be seen in Table 4 and Table 7, the difference for C_{max} between the fed and fasted conditions for Formulation O is smaller than the difference for C_{max} between the fed and fasted conditions for Xyrem. This shows, in my opinion, that Formulation O has a reduced food effect compared to Xyrem based on a smaller difference in C_{max} between fed and fasted states for a single dose of sodium, potassium, calcium, and magnesium oxybates compared to an equal dose of Xyrem which is an immediate release liquid solution of sodium oxybate.

333. I understand from my review of the deposition transcript of one of the inventors of the '373 patent, Clark Allphin, that "Formulation O" referred to in Example 2 of the '373 patent is the same salt mixture as Xywav. Specifically, Mr. Allphin identified "Mixture H" from U.S. Patent

> No. 8,591,922 ("the '922 patent") as containing the salt mixture for Xywav. (Ex. 39, Allphin Tr. at 41:24-42:6 ("Q. Can you take a look in the ['922] patent, and let me know where the Xywav formulation is disclosed? A. The Xywav salt mixture is mixture H.").) Mixture H from the '922 patent contains, expressed as % molar equivalents, 8% Na.GHB, 23% K.GHB, 21% Mg.(GHB)2, and 48% Ca.(GHB)2. (Ex. 45, '922 patent at 29:30-45.) The '373 patent describes Formulation O as containing "as (equivalent %) 8% sodium, 23% potassium, 48% calcium, and 21% magnesium oxybate." (Ex. 10, '373 patent at 35:50-36:1.) Therefore, the salt mixture in Formulation O of the '373 patent is the same as the salt mixture in Xywav.
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> **334.** The package inserts for Lupin's ANDA Product and Xywav [redacted] state that their products contain [redacted] Na.GHB, [redacted] K.GHB, [redacted] Mg.(GHB)2, and [redacted] Ca.(GHB)2 per each millimeter (mL) of oral solution. (See, e.g., Ex. 28, at LUPIN-XYWAV_0042988; Ex. 12, at JPIL0179621.) Therefore, Lupin's ANDA Product and Xywav [redacted] in my opinion, Lupin's ANDA Product would also have a reduced food effect compared to Xyrem based on a smaller difference in C_{max} between fed and fasted states for a single dose of sodium, potassium, calcium, and magnesium oxybates compared to an equal dose of Xyrem. Consequently, in my opinion, Lupin's ANDA Product meets this claim element.

(Walsh Decl., Ex. C (Bogan Report to Lupin) at ¶¶ 332-334) (bold emphasis added).

F. The Parties' Arguments

Defendants contend that the disputed paragraphs present a new "ten-step infringement theory" for the "reduced food effect limitation" in Claim 1 of the '373 patent that was absent from Plaintiff's Infringement Contentions. (*See* ECF No. 243 at 3). According to Defendants, Plaintiff's Infringement Contentions "consisted of conclusory allegations and cited documents without explaining how the accused products allegedly satisfied each claim limitation," and "constituted nothing more than a bare assertion of infringement." (*Id.* at 2). Thus, Defendants contend, the new ten-step theory contained in the disputed paragraphs amounts to "a fundamentally new approach [relying on] undisclosed documents, [inventor] testimony, and

technical rationales . . . that bore no resemblance to anything in [Plaintiff's] infringement contentions." (*Id.* at 3). Defendants purport to extract from the disputed paragraphs ten analytical steps and argue that each step was not previously disclosed, given the alleged "boilerplate" nature of Plaintiff's Infringement Contentions. (*Id.* at 3-5; *see also* ECF No. 248 at 2-7). According to Defendants, the Local Patent Rules and Federal Rule of Civil Procedure 37(c)(1) govern Plaintiff's failure to previously disclose this new infringement theory, which must be excluded as untimely and prejudicial based on the Third Circuit's multi-factor test for analyzing a request to exclude evidence set forth in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1977) (at times, "*Pennypack*"). (ECF No. 243 at 6-8; ECF No. 248 at 11-12).

Plaintiff counters that Dr. Bogan's Report does not contain any new theory of infringement. (ECF No. 245 at 1, 2-4). Plaintiff contends that the disputed paragraphs rely on the same data and documents cited in its Infringement Contentions and that the inventor testimony relied upon is directly related to the previously disclosed evidence. (*Id.* at 1, 6-8). Plaintiff denies that there is a "ten-step" theory of infringement presented, but rather, contends that the disputed paragraphs are consistent with its Infringement Contentions. (*Id.* at 8-9). Plaintiff further argues that Defendants' motion is, at its core, a fundamentally misguided and untimely attack on the adequacy of Plaintiff's Infringement Contentions, lodged nearly two years after they were first served. (*Id.* at 11). Accordingly, Plaintiff contends that, by waiting to raise alleged deficiencies in Plaintiff's Infringement Contentions, Defendants have waived any deficiency argument, and thus, by extension, that anything in Dr. Bogan's Report is new. (*Id.* at 11-12). Putting that aside, Plaintiff contends that Defendants have, in fact, been aware of the supposedly new theory of infringement since the beginning of the case, as they conducted

discovery on the issue. (*Id.* at 10-11). Finally, while Plaintiff disputes that Rule 37(c)(1) and the *Pennypack* factors apply, it contends, in all events, there is no prejudice that would warrant striking the disputed paragraphs in Dr. Bogan's Report. (*Id.* at 15).

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).[5] 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 quotations omitted).

Pursuant to Local Patent Rule 3.1, a patent holder must serve an alleged infringer a "Disclosure of Asserted Claims and Infringement Contentions" within 14 days of the initial scheduling conference. *Id.* The infringement contentions must contain, among other things: "(1) each claim of each patent in suit that is allegedly infringed; (2) identification of defendant's "Accused Instrumentality"; (3) a chart identifying where each limitation of each asserted claim is found in each "Accused Instrumentality"; (4) whether the alleged infringement is literal or under the doctrine of equivalents; (5) the priority date to which each asserted claim allegedly is entitled; and (6) the basis for any willful infringement claims." *Elan Pharma Intern. Ltd. v. Lupin Ltd.*, 2010 WL 1372316, at *3 (D.N.J. March 31, 2010); *see also Voxpath RS. LLC v. LG Elecs. U.S.A., Inc.*, 2012 WL 5818143, at *2 (D.N.J. Nov. 14, 2012).

"[A]ll courts agree that the degree of specificity under Local Rule 3.1 must be sufficient to provide reasonable notice to the defendant why the plaintiff believes it has a 'reasonable

[5] 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).

chance of proving infringement.'" *Shared Memory Graphics LLC v. Apple, Inc.*, 812 F. Supp. 2d 1022, 1025 (N.D. Cal. 2010) (quoting *View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000)). However, "[p]arties . . . need not 'prove up' their theories by providing evidence beyond the material they have at the time they make their contentions." *Apple v. Samsung Electronics, Co.*, 2013 WL 3246094, at *3 (N.D. Cal. June 26, 2013); *see also AntiCancer, Inc. v. Pfizer, Inc.*, 769 F.3d 1323, 1338 (Fed. Cir. 2014) (a patentee's infringement contentions "do not need to include proof or direct evidence of infringement"). "Infringement contentions serve two purposes: they act as substitutes for interrogatories and as a method of disclosure for the parties' theories of their case, thereby shaping discovery and trial issues." *Curia*, 2025 WL 1627251, at *6 (D.N.J. Feb. 18, 2025) (citing *Indus.Tech. Rsch. Inst. v. LG Elecs.*, 2015 WL 12819052, at *3 (D.N.J. Mar. 30, 2015)). These requirements "serve an important function—to narrow and focus the issues and theories that must be pursued during the litigation." *Curia*, 2025 WL 1627251, at *6 (citing *Golden v. United States*, 156 Fed. Cl. 623, 632 (Fed. Cl. 2021), *aff'd*, 2022 WL 4103287 (Fed. Cir. 2022)).

If a party develops new theories of infringement after serving its contentions, Local Patent Rule 3.7 allows for amendment of contentions, but "only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7; *see also 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 in patent cases, and that parties should not embed new theories 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.").

Plaintiff submits that the appropriate standard is governed by Local Patent Rule 3.7, which requires a party to move to amend and establish good cause. According to Plaintiff, nothing in the Bogan Report is new, and therefore, there is no basis for it to have filed a motion to amend or establish good cause. Nevertheless, Plaintiff contends that, if an expert's report contains new theories, the proper remedy is to strike those portions of the report for violating the Local Patent Rules. (*See* ECF No. 245 at 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[6] to determine whether exclusion of a new theory is proper. (*See* ECF No. 243 at 6). 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

[6] 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).

importance of the excluded evidence. *Id.* at 904-05.

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 that the Bogan Report contains a newly disclosed theory does this Court need 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 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

The parties' arguments break down into two parts: (1) the timeliness of Defendants' motion to strike, and (2) whether Dr. Bogan's Report, in fact, presents a new theory of infringement, and if so, whether the new theory should be excluded. Each is taken in turn.

A. Timeliness

Ordinarily, on a motion to strike such as this, the dispositive question is whether the contentions disclosed what is in dispute in the expert's report. *See, e.g.*, *Finjan, Inc. v. Blue Coat Sys. Inc.*, 2015 WL 3640694, at *2 (N.D. Cal. June 11, 2015) ("The dispositive inquiry in a motion to strike is thus whether the allegedly undisclosed "theory" is in fact a new theory . . . .") (citing *Oracle Am., Inc. v. Google, Inc.*, 2011 WL 4479305, at *3 (N.D. Cal. Sept. 26, 2011)). However, Plaintiff raises the threshold issue of timeliness, which the Court turns to first.

As noted, Plaintiff's Infringement Contentions were served in June and December 2023, respectively. Defendants' motion focuses heavily on the substance of these Contentions, contending they are perfunctory, conclusory, and deficient. *See, e.g.*, ECF No. 243 at 2 ("With respect to "reduced food effect" limitation specifically, [Plaintiff's] contentions constituted nothing more than a bare assertion of infringement"); *id.* at 3 ("The Contentions did not provide any analysis, explanation, or rationale connecting the cited materials to the specific claim language"). Indeed, Defendants' current motion to strike an expert report could easily be confused with a motion challenging the specificity of an infringement contention. *See id.* at 3 ("[T]his sidesteps the notice and disclosure requirements that are foundational to the purpose of infringement contentions" . . . [and] "[the] contentions are "tantamount to simply saying, Defendants' proposed ANDA Products infringe because they infringe."); *see also* ECF No. 248 at 1 (referring to "barebones contentions"). In other words, Defendants contend that Plaintiff's Infringement Contentions on this limitation in Claim 1 of the '373 patent did not effectively provide them with notice of *any* meaningful theory of infringement.

However, if this deficiency is true, leaving Defendants to "guess which infringement theories Plaintiff may strategically chose to present at trial," (*id.* at 1), then Defendants were

aware of this deficiency in June and December 2023, respectively, when Plaintiff served its Contentions. Yet, the record confirms that Defendants did not raise the purported deficiency with Plaintiff—or the Court—for more than eighteen (18) months when Plaintiff served Dr. Bogan's Report in April 2025. Instead, apparently, Defendants accepted the Contentions, engaged in fulsome fact discovery for over a year, allowed discovery to close, and then raised the issue in a motion to strike Plaintiff's opening expert report. The Court is troubled by this delay.

Plaintiff contends that Defendants' failure to timely raise this issue amounts to a waiver of their right to complain about the adequacy of Plaintiff's Contentions and, correspondingly, Dr. Bogan's Report. In support of its position, Plaintiff relies on *Evolve Biosystems, Inc. v. Abbott Labs*, 2024 WL 4215804 (N.D. Ill. Aug. 16, 2024), and *Sonos*, 2023 WL 2918751. The Court finds both cases instructive in that they support finding waiver in the face of lengthy inaction relating to allegedly deficient contentions.

In *Sonos*, the parties cross-moved to strike allegedly new theories disclosed in expert reports. *Id.* at *1, 4-5. As it related to one issue in dispute, the court noted that while the plaintiff had "some colorable arguments" regarding the deficiency of the defendant's contentions, plaintiff should have made these arguments when the issue was first raised in connection with prior motion practice months earlier. *Id.* at *4. The *Sonos* court concluded that, instead, plaintiff "seems to have sat on its hands waiting to strike expert report language . . . strategically chos[ing] not to initiate motion practice on this issue." *Id.* Based on the delay and the lack of prejudice involved, the court declined to strike the allegedly new material. *Id.* at *5.

Likewise, in *Evolve*, the defendant alleged, among other things, that the plaintiff raised new theories of infringement in an expert report and sought to strike the new theories based on the allegation that previously served infringement contentions were deficient. *See* 2024 WL

4215804, at *5. The *Evolve* court found that the defendant had an obligation to raise the issue of an alleged deficiency in infringement contentions prior to expert reports by way of "a joint status report and/or [] a motion," and that "[i]t is not clear why defendant chose instead to sit back and do nothing . . . ." *Id.* at *7. Accordingly, the *Evolve* court found that the defendant had improperly delayed raising an issue with plaintiffs' infringement contentions, and "[w]hether it was a conscious litigation strategy or a decision now regretted, parties must live with the consequences of the strategic decision . . . ." *Id.* at *7-8.

Here, Defendants could have and should have raised issues concerning the sufficiency of Plaintiff's Infringement Contentions with Plaintiff (and if unsuccessful with the Court), months ago and certainly long before opening expert reports were served. *See, e.g.*, *Fenner Invs. Ltd. v. Hewelett-Packard Co.*, 2010 WL 786606, at *3 (E.D. Tex. Feb. 26, 2010) ("If Defendants were unclear as to the scope of the contentions, it was their responsibility to work with Plaintiff, informally or through motion practice, to clarify the issue"). They did not. Crucially, Defendants do *not* contend that Plaintiff's Contentions were adequate and disclosed a theory of infringement, but that Dr. Bogan's Report now contains a new theory. That would be a more typical motion to strike. Rather, Defendants primarily argue that Plaintiff's Infringement Contentions have been deficient all along. The time to raise deficiencies in contentions passed long ago. *See Sonos,* 2023 WL 2918751, at *4. Moreover, if this Court were to accept Defendants' position, it would lead to a series of unanswered questions. If Plaintiff's Contentions were conclusory and bare boned and thus deficient when served, how did Defendants know Plaintiff's theory of infringement or that Dr. Bogan's Report contained a new theory? What did Defendants believe Plaintiff's Infringement Contention on this claim meant? Without understanding Plaintiff's theories of infringement, how did Defendants effectively

frame and proceed with discovery especially without previously raising this issue? Defendants do not answer these questions in their motion papers.

This Court cannot condone Defendants' course of action. To do so would be unjust. *See Celgene*, 2021 WL 3701700, at *2. Accordingly, this Court finds that Defendants' failure to timely raise this issue without any explanation weighs against striking the disputed paragraphs. *See Sonos*, 2023 WL 2918751, at *4-5. However, in all events, as is explained below, even if the Court were to find Defendants timely raised this issue, the Court still finds that Defendants have not shown that Dr. Bogan's Report contains a new theory of infringement.

B. Whether The Disputed Paragraphs Contain a New Theory of Infringement

"Expert infringement reports may not introduce theories not previously set forth in infringement contentions." *Sol IP v. AT&T Mobility, LLC*, 2020 WL 10045985, at *2 (E.D. Tex. Apr. 23, 2020) (internal quotations omitted). "The scope of infringement contentions and expert reports are not, however, coextensive." *Id.* "For example, infringement contentions need not disclose specific evidence, nor do they require a plaintiff to prove its infringement case, whereas expert reports must include a complete statement of the expert's opinions, the basis and reasons for them, and any data or other information considered when forming them." *Id.* (quotations omitted). "The inquiry is 'whether the allegedly undisclosed theory is in fact a new theory or . . . instead the identification of additional evidentiary proof . . . .'" *Id.* (quoting *KlausTech, Inc. v. Google LLC*, 2018 WL 5109383, at *3 (N.D. Cal. Sept. 14, 2018)); *Finjan, Inc.*, 2015 WL 3640694, at *2.

Dr. Bogan's Report opines in paragraphs 332 through 334 "that Xywav® exhibits the claimed food effect . . . and that because [Defendants] each seek FDA approval for a product [redacted] those products will therefore also exhibit

the claimed food effect." (ECF No. 245 at 3; *see also* ECF No. 243 at 5; ECF No. 248 at 7). Now compare Dr. Bogan's opinion to Plaintiff's Contentions, which state in relevant part, that "the claimed pharmaceutical composition, when administered as instructed by Defendants' labeling will, in at least some patients, have a reduced food effect as measured by C_{max} compared to an equal dose of immediate release liquid solution of NaGHB." (Walsh Decl., Ex. A at 612).

While not terribly explanative, what Plaintiff's Contention effectively translates to is this: Xywav® exhibits the claimed food effect, [redacted] and, as a result, Defendants' product will have [redacted] reduced food effect. (*See* ECF No. 245 at 15-16). Further, Plaintiff's Contentions are supported by two sets of documents: the package inserts that accompany Defendants' products, and clinical study reports for two studies that Plaintiff carried out during the development of Xywav®.[7] (*See* ECF No. 245 at 3). According to Plaintiff, these two sets of documents referenced in their Infringement Contentions show that [redacted] would exhibit the reduced food effect and support the theory in Dr. Bogan's Report. (*Id.* at 10).

The question is whether the theory in Dr. Bogan's Report is present in Plaintiff's Infringement Contentions. The Court concludes that it is, and that there is no new theory of infringement in Dr. Bogan's Report. Specifically, Plaintiff's Infringement Contentions identify the Xywav® salt ratio; identify the package inserts that Plaintiff intends to rely on to show that Defendants' [redacted] and reference the clinical data (in the form of the study reports) that Plaintiff intends to rely on to show that [redacted] would exhibit the claimed reduced food effect. (*See* Walsh Decl., Ex. A at 612). This is in

[7] "JPIL0040913-1454" is a clinical study report for a study designated "13-010." (*See* Declaration of Nicholas A. LoCastro, Esq. ("LoCastro Decl."), Ex. A; ECF No. 245-1)). "JPIL0066557-7116" is a clinical study report for a study designated "JZP258-101." (*See* LoCastro Decl., Ex. B) (at times, the "study reports").

substance the same as what appears in Dr. Bogan's Report in the disputed paragraphs.

Nevertheless, Defendants contend Dr. Bogan's Report has a new theory of infringement because the Report relies on several things not specifically referenced in Plaintiff's Infringement Contentions, primarily: (1) data from the '373 patent, including reference to "Formulation O"; (2) deposition testimony from an inventor of the '373 patent, Dr. Clark Allphin, elicited near the close of fact discovery; and (3) reference to "Mixture H" from the '922 patent and the '922 patent itself. (*See* ECF No. 243 at 3-5). Plaintiff counters that such information is either explanatory, permissible expansion of a disclosed theory, or was otherwise referenced or disclosed in materials that were cited in its Infringement Contentions. (ECF No. 245 at 6-9). This Court finds that Plaintiff has the better end of this argument.

First, as Plaintiff notes, Plaintiff is not required to prove infringement or provide commentary or analysis in its contentions, nor is Plaintiff limited to only using evidence in its expert reports that was originally in its Infringement Contentions. *See, e.g.*, *Curia*, 2025 WL 1627251, at *11 ("Plaintiff need not disclose specific evidence to prove its infringement case in preliminary infringement contentions."). Thus, the Court is not troubled by Dr. Bogan's reliance on Dr. Allphin's deposition testimony in general. Defendants do not cite authority suggesting that an expert cannot rely on deposition testimony in rendering his or her opinion, and the relevant authority suggests otherwise. *See, e.g.*, *Sol IP*, 2020 WL 10045985, at *2. Furthermore, as Plaintiff notes, a contrary rule could require amendment of contentions after fact discovery in every case, a result not contemplated by the Local Patent Rules. Finally, Defendants have not shown that Dr. Allphin's testimony is being used to alter Plaintiff's theory of infringement. Rather, as Plaintiff contends, it appears Dr. Allphin's testimony is merely being used to support a previously disclosed theory.

Second, Plaintiff explains that the data in Tables 4 and 7 in the '373 patent and Formulation O, on which Dr. Bogan relied, is the same data as contained in the clinical studies cited in Plaintiff's infringement contentions—i.e., Study 13-010 and Study JZP258-101. (*See* ECF No. 245 at 4-6). Moreover, as Plaintiff points out, Defendants already took discovery that touched upon issues in the disputed paragraphs in the Bogan Report when they deposed Dr. Cuiping Chen, co-inventor of the '373 patent. Specifically, Dr. Chen testified regarding, among other things, the data and studies referenced in the disputed paragraphs, including Tables 4 and 7 of the '373 patent, as well as conclusions one could draw from the data. (*See* LoCastro Decl., ¶ 6 & Ex. E at 70:15-71:6, 75:12-76:5, 76:15-77:9). At bottom, Dr. Bogan is using the same data disclosed in Plaintiff's Contentions but from a different source, i.e., the '373 patent, as opposed to the clinical studies themselves. The use of the same data from a separate source for the same purpose does not turn a previously disclosed theory of infringement into a new one.

Third, as it relates to the '922 patent and Formulation H, again, the Bogan Report may be fairly read to simply repeat Dr. Allphin's deposition testimony regarding Mixture H and the fact that Plaintiff's position is that "*Mixture H, formulation O, and Xywav® are all the same.*" (ECF No. 245 at 7) (emphasis added). Defendants appear to have been aware of Plaintiff's position, having acknowledged, albeit at other times, that the Patent Examiner had "noted out that 'Composition H' disclosed in the '922 patent 'has the same ratios of salts as instant Formulation O.'" (ECF No. 245 at 7 (citing and quoting ECF No. 241-1, Ex. 8, Appendix 43 at 7-8 (Teva's Invalidity Contentions))). That puts Dr. Bogan's reference to Formulation H and the '922 patent within the scope of permissible complimentary proof and does not reflect a new opinion. *See Sol IP*, 2020 WL 10045985, at *2.

For all the above reasons, the Court finds that the disputed paragraphs in Dr. Bogan's

Report do not present a new "ten-step infringement theory" for the "reduced food effect limitation" in Claim 1 of the '373 patent that was absent from Plaintiff's Infringement Contentions. Having found that the Bogan Report does not contain a newly disclosed theory, and thus, there is no basis to strike the disputed paragraphs, this Court need not determine the proper legal standard for exclusion. *See Celgene*, 2021 WL 3701700, at *2; *Finjan, Inc.*, 2015 WL 3640694, at *2 ("The dispositive inquiry in a motion to strike is thus whether the allegedly undisclosed 'theory' is in fact a new theory.").

IV. CONCLUSION

For the reasons set forth above, Defendants' motion to strike, (ECF No. 242), is **DENIED.** An appropriate order will be entered.

SO ORDERED.

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

Dated: January 15, 2026

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