IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AYTU BIOPHARMA, INC., NEOS THERAPEUTICS, INC., AND NEOS THERAPEUTICS, LP, **Plaintiffs,** **v.** **GRANULES PHARMACEUTICALS, INC.,** **Defendant.**	**Court No. 1:24-cv-01356-JCG** **ANDA Case**

ORDER

Before the Court is a discovery dispute in an action filed by Plaintiffs Aytu Biopharma, Inc., Neos Therapeutics, Inc., and Neos Therapeutics, LP (collectively, "Plaintiffs") against Granules Pharmaceuticals, Inc. ("Defendant" or "Granules") for patent infringement under 35 U.S.C. § 271, et seq. Compl. (D.I. 1).

On April 9, the Parties notified the Court of a discovery dispute and filed 3-page letter briefs that outlined the issues in dispute and the Parties' respective positions. Pls.' Mot. Strike Portions Opening Expert Report S. Craig Dyar, Ph.D. ("Pls.' Mot. Strike") (D.I. 70); Pls.' Letter Br. Supp. Mot. Strike Dyar Report ("Pls.' Letter") (D.I. 71, 74); Def.'s Letter Brief Opp'n Pls.' Mot. Strike Dyar Report ("Def.'s Letter") (D.I. 73, 75). A Discovery Conference was held before

the Court on April 27, 2026. Oral Order (Apr. 16, 2026) (D.I. 66). For the following reasons, Plaintiffs' Motion to Strike is granted in part and denied in part.

LEGAL STANDARD

District courts have broad discretion in deciding discovery matters. See generally Accent Packaging, Inc. v. Leggett & Platt, Inc., 707 F.3d 1318, 1329 (Fed. Cir. 2013) (acknowledging the court's discretion in denying additional discovery); Florsheim Shoe Co. v. United States, 744 F.2d 787, 797 (Fed. Cir. 1984) (stating that "[q]uestions of the scope and conduct of discovery are, of course, committed to the discretion of the trial court.").

Under Federal Rule of Civil Procedure 16(b)(4), "[a] schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). Rule 16(b)(4) "focuses on the moving party's burden to show due diligence." Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 84 (3d Cir. 2010). If the movant satisfies the good cause requirement of Rule 16, leave to amend should be granted unless there is a reason to deny leave, such as bad faith, prejudice to the non-moving party, or futility of the claims. Foman v. Davis, 371 U.S. 178, 182 (1962).

DISCUSSION

Plaintiffs argue that Defendant's opening expert report (the "Dyar Report") includes prior art references and an invalidity theory that were not disclosed in

Defendant's initial invalidity contentions, supplemental invalidity contentions, or final election of asserted prior art. Pls.' Letter. Plaintiffs request the Court to strike the prior art references and invalidity theory because they are amendments made in violation of the Scheduling Order and Rule 16.

Paragraph 11 of the Scheduling Order states in relevant part:

> The addition or substitution of asserted claims or prior art and the amendment of the Noninfringement Contentions, Invalidity Contentions, Infringement Contentions, Preliminary Disclosure of Asserted Claims, and Preliminary Disclosure of Asserted Prior Art may be made only by order of the Court upon a timely showing of good cause. [. . .] The duty to supplement discovery responses does not excuse the need to obtain leave of the Court to add or substitute asserted claims or prior art or to amend contentions.

Sched. Order (Feb. 10, 2025) at ¶ 11, (D.I. 17).

I. Prior Art Disclosure

Plaintiffs argue that the Dyar Report introduces five new prior art references and relies on them substantively to advance opinions regarding alleged motivation to combine and a reasonable expectation of success. Pls.' Letter at 1–2; Pls.' Letter at Ex. A (the "Dyar Report"). Plaintiffs aver that these prior art references were not disclosed by the April 4, 2025 deadline set forth in the Scheduling Order, despite the availability of the references at that time. Id. at 2.

Defendant argues that the Dyar Report's obviousness analysis "discusses, at discrete points, references supporting a [person of ordinary skill in the art]'s knowledge and motivation to combine." Def.'s Letter at 1–2 (citing contested

portions of the Dyar Report). Defendant avers that striking the references would hamper Dr. Dyar's ability to present background information, provide a tutorial on the claimed technology, or answer questions from the bench during trial. Id. at 3; Disc. Conf. Trans. at 12:10–13:18.

"Courts have frequently declined to strike undisclosed references (let alone disclosed references) from expert reports, when those references are used only as "background" material." British Telecommunications PLC v. IAC/InterActiveCorp, No. 18-366-WCB, 2020 WL 3047989, at *6 (D. Del. June 8, 2020) (citing TQ Delta, LLC v. ADTRAN, Inc., No. CV 14-954, 2019 WL 4346530, at *3 (D. Del. Sept. 12, 2019); Pavo Sols. LLC v. Kingston Tech. Co., No. 814-CV-01352, 2019 WL 8138163, at *11 (C.D. Cal. Nov. 20, 2019); Ziilabs Inc., Ltd. v. Samsung Elecs. Co., No. 2:14-CV-203, 2015 WL 7303352, at *2 (E.D. Tex. Aug. 25, 2015); Fujifilm Corp. v. Motorola Mobility LLC, No. 12-CV-03587, 2015 WL 757575, at *30 (N.D. Cal. Feb. 20, 2015); Verinata Health, Inc. v. Sequenom, Inc., No. C 12-00865 SI, 2014 WL 4100638, at *8 n.7 (N.D. Cal. Aug. 20, 2014)).

"'[T]he line between when a reference is used as background material, and when it is used as an anticipation or obviousness reference, can be difficult to draw.'" Id. (quoting Finjan, Inc. v. Sophos, Inc., No. 14-CV-1197, 2016 WL 2988834, at *12 (N.D. Cal. May 24, 2016)).

Paragraph 7(b) of the Scheduling Order states that the disclosure of prior art shall note whether "each item of prior art anticipates each asserted claim or renders it obvious." Sched. Order. at ¶ 7(b). The section states that if obviousness is alleged, a party shall provide "an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness[.]" Id. The language of the Scheduling Order focuses on particular prior art that, either alone or in combination with other references, invalidates the asserted claims of the patents at issue. The Scheduling Order does not expressly, or by implication, require the production of all evidence that may be relevant in any way to the issue of obviousness, such as background evidence that speaks to the state of the art at the time of the invention.

The Court has reviewed the contested portions of the Dyar report and determines that the additional references are offered primarily for the limited purpose of providing background information, describing the state of the art, and the knowledge of a person of ordinary skill in the art. Insofar as these paragraphs discuss such background information, the Court concludes that paragraphs 146, 152, 161, 163, 169, 175, 183, 196, 202, and 210 of the Dyar Report are offered for legitimate purposes and not to evade the requirements of the Scheduling Order.

The Court observes, and Defendant admits, that some of the contested paragraphs of the Dyar Report discuss the disputed references in relation to

obviousness arguments regarding motivation to combine. See e.g., Dyar Report at ¶¶ 161, 163, 175, 183, 202, 210; see also Def.'s Letter at 1–2.

The United States Court of Appeals for the Federal Circuit has emphasized repeatedly that to succeed in establishing obviousness, a challenger must show motivation to combine. See Belden Inc. v. Berk-Tek LLC, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("[O]bviousness concerns whether a skilled artisan not only could have made but would have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention.") (emphasis omitted); Virtek Vision Int'l ULC v. Assembly Guidance Sys., Inc., 97 F.4th 882, 887 (Fed. Cir. 2024) ("[T]here must exist a motivation to combine various prior art references in order for a skilled artisan to make the claimed invention.").

Defendant's use of references that were undisclosed previously to advance arguments and opinions addressing motivation to combine transforms the use of the disputed references beyond sources of background material, and into obviousness references. For example, paragraph 175 of the Dyar Report opens with a permissible statement regarding the knowledge of a person of ordinary skill in the art. Dyar Report at ¶ 175. Dr. Dyar then extrapolates that the prior art would create an expectation of success in combining the teachings of prior art to arrive at the claimed pharmaceutical composition. To the extent that such an argument refers back to the disputed references, it must be stricken as a violation

of paragraphs 11 and 7(b) of the Scheduling Order, and Rule 16(b).

The Court will not permit Defendant to use these references to argue obviousness or motivation to combine references. The Court will permit these references only to the extent that they are included in the Dyar Report for a proper purpose, rather than for a purpose that would have required prior disclosure or judicial consent for leave to amend under the Scheduling Order.

II. Invalidity Theory

Plaintiffs also request that the Court strike portions of the Dyar report that discuss whether Claim 7 of each asserted patent is invalid due to alleged limited support for a chewable composition. Pls.' Letter at 3. Plaintiffs aver that such discussion amounts to the introduction of a new and previously undisclosed invalidity theory. Id. Defendant acknowledges that chewable composition was not specifically addressed in its initial or supplemental contentions, but argues that its supplemental contentions disclosed its written description and enablement defenses with sufficient detail to put Plaintiffs on notice of the possibility that chewable composition arguments could be advanced. Def.'s Letter at 2; Disc. Conf. Trans. at 15:32–17:37. Regarding the written description, Defendant provided:

> Claim 1 is invalid under 35 U.S.C. § 112(a) for lack of written description. A person of ordinary skill in the art would not understand from the specification which ion exchange resins could be used to form complexes with dextro- and levoamphetamines, since Amberlite IRP-69 (a strongly acidic cation exchange resin) was the only ion-exchange resin actually evaluated. Thus, the inventors of the '491 patent were

not in possession of the full scope of the claimed subject matter.

Id. (citing supplemental invalidity contentions). Defendant contends that although "Dr. Dyar does not literally follow this position . . . Plaintiffs were on notice that Granules asserted a written description defense and had contended the disclosure of control release polymers was insufficient." Id. Concerning enablement, Defendant provided:

> Claim 1 is invalid under 35 U.S.C. § 112(a) for lack of enablement. The specification provides illustrative examples of only one ion-exchange resin out of the hundreds that fall within the scope of the claims, and it does not disclose any examples of controlled-release coatings applied to such drug ion-exchange resin complexes. As a result, the '491 patent fails to teach a POSA how to achieve a mixture of dextro- and levoamphetamines complexed with ion-exchange resin particles across the full range of claimed drug–resin complexes and controlled-release coatings without undue experimentation. … enablement requires that the specification enable the full scope of the claimed invention, not merely isolated embodiments. Thus, claim 1 is invalid under 35 U.S.C. § 112.

Id. (citing supplemental invalidity contentions).

A party is entitled to use an opening expert report to expand on an infringement theory, provided it did not raise the infringement theory for the first time in its opening expert report. TQ Delta, LLC v. ADTRAN, Inc., No. 14-954-RGA, 2021 WL 33633637, at *2 (D. Del. Aug. 17, 2021). Having reviewed the contested sections of the Dyar Report that discuss Claim 7 of the asserted patents, the Court concludes that Defendant's previous disclosures regarding ion-exchange polymers and controlled release coatings were not sufficient to put Plaintiffs on

notice of Defendant's position regarding chewable composition or to allow Plaintiffs to inquire further about that specific pharmaceutical composition during fact discovery, had they wished to. Nor has Defendant persuaded the Court that this pharmaceutical composition is sufficiently related to the types of compositions it did assert explicitly, such that it was disclosed and Plaintiffs had notice. The Court agrees with Plaintiffs that the Dyar Report's arguments regarding chewable composition violate the Court's Scheduling Order, as they inserted a new invalidity theory into the case several months after Defendant had provided its required disclosures and Defendant did not seek leave from the Court to amend. The Court concludes that the disclosure was untimely and must be stricken.

Defendant requests leave to amend its invalidity contentions to reflect this theory if the Court strikes it. Def.'s Letter at 3. However, the arguments regarding chewable composition rely on the patent specifications, which have been available and unchanged at all relevant times. Defendant cannot satisfy its burden to show it conducted due diligence, and the Court concludes that it has not been presented with good cause to warrant providing Defendant with leave to amend. See Fed. R. Civ. P. 16(b)(4); Race Tires Am., Inc., 614 F.3d at 84.

CONCLUSION

Upon consideration of the Parties' representations during the April 27, 2026 Discovery Conference, Plaintiffs' Motion to Strike (D.I. 70), Plaintiffs' Letter,

Defendant's Letter, and all other papers and proceedings in this action, it is hereby

ORDERED that Plaintiffs' Motion to Strike (D.I. 70) is granted in part and denied in part; and it is further

ORDERED that Defendant may rely on the new prior art references only as background material and shall not use the references to advance its obviousness arguments; and it is further

ORDERED that the Dyar Report's arguments regarding chewable composition are stricken; and it is further

ORDERED that Defendant shall provide Plaintiffs with a corrected copy of the Dyar Report on or before May 8, 2026.

IT IS SO ORDERED this 1st day of May, 2026.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

* Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.