

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. FALK PHARMA GMBH,
Petitioner,

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner.

Case No. IPR2024-01197
Patent No. 8,771,729 B2

**PATENT OWNER'S MOTION TO STRIKE
EXHIBITS 1075-1082, PORTIONS OF
PETITIONER'S REPLY BRIEF AND DR. PARR'S REPLY
DECLARATION**

Pursuant to 37 C.F.R. § 42.23(b), Patent Owner Ellodi Pharmaceuticals, L.P. (“PO”), respectfully moves to strike Exs. 1075-1082, portions of Petitioner’s Reply Brief (Paper 20 (“Reply”) at 7-8) and Dr. Parr’s Reply Declaration (EX1093 (“Reply Dec.”) ¶¶23-35) discussing this new evidence. The Board authorized this motion on August 15, 2025. EX3003.

I. THE BOARD SHOULD STRIKE PETITIONER’S IMPROPER NEW PRIOR ART REFERENCES AND INVALIDITY THEORIES THAT WERE NOT PRESENTED IN THE PETITION

“[T]he expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016); 35 U.S.C. § 312(a)(3). “[E]vidence necessary to make out a *prima facie* case of unpatentability [therefore] may not be introduced for the first time in the reply brief.” *Dexcom, Inc. v. WaveForm Techs., Inc.*, IPR2016-01680, 2018 WL 1137089, at *13 (P.T.A.B. Feb. 28, 2018); *see also Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1286-1287 (Fed. Cir. 2017) (affirming Board’s refusal to consider “new theory of *prima facie* obviousness absent from the petition”).

Petitioner failed to make a *prima facie* case of unpatentability in its Petition, and now attempts to fill in the gaps by improperly introducing new invalidity theories and eight prior art references for the first time in its Reply. Petitioner’s belated attempt to modify its Petition with new prior art violates the statute and

Board rules, and prejudices PO. The Board should strike Petitioner's improper new arguments and evidence under 37 C.F.R. § 42.23(b).

A. Petitioner Advances For The First Time In Its Reply New Prior Art References And Invalidity Theories Because Its Petition Fails To Establish Unpatentability

The challenges claims require disintegration within 60 seconds. In an attempt to meet this limitation, Petitioner originally argued in the Petition that Dohil, in view of the knowledge of a POSA, teaches a rapidly dissolving lozenge. Paper 2 ("Pet.") at 23 ("Dohil's rapidly dissolving lozenge"). The Petition does not establish *prima facie* obviousness because Petitioner did not submit any evidence of lozenges that disintegrates within 60 seconds when tested using the USP <701> Disintegration Test. Indeed, Petitioner's expert, Dr. Parr, testified that he was not aware of any fast-dissolving lozenges and did not believe a search of any rapidly dissolving lozenges in literature was relevant for his expert opinion. EX2011, 63:6-21.

In its Response, PO provided evidence that lozenges dissolve slowly, over time, to provide continuous treatment—not within 60 seconds as claimed. Paper 18 ("POR") at 25-26. Recognizing the deficiency in Dohil and its Petitioned grounds, Petitioner now presents eight new prior art references, Exs. 1075-1082, alleging that "Petitioner is entitled to reply by introducing evidence and arguments demonstrating that the prior art does disclose rapidly-dissolving lozenges." EX1094, 12:25-13:3; Reply at 7-8; EX1075-EX1082. Dr. Parr now opines on these references, when he

should have done so in his opening declaration. Reply Dec. ¶¶23-35.

These new prior art references, reply argument, and testimony are not mere background references, but rather improperly seek to fill in gaps in the Petition’s *prima facie* case of unpatentability. Petitioner attempts to minimize the implications of its new art, asserting it as “reinforce[ment] by numerous other examples in the prior art.” Reply at 7. But Petitioner *never* provided initial examples in the prior art of fast dissolving lozenges and thus Petitioner’s new art and arguments does not reinforce the petitioned grounds, it remakes them. As the Board has explained, “newly cited prior art references *intended to ‘gap-fill’* by teaching a claim element that was not present in the prior art presented with the petition” is nonetheless improper. Consol. Trial Practice Guide at 74-75 (Nov. 2019) (emphasis added). Moreover, although Petitioner attempts to justify this belated gap-filling as appropriate rebuttal material for allegedly responding to arguments raised in PO’s Response, “‘Respond,’ in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing.” *Id.* at 74.

“[A] reply or sur-reply that raises a new issue or belatedly presents evidence may not be considered.” *Id.* The Federal Circuit has repeatedly held that a petitioner’s argument in its reply that “amount[s] to an entirely new theory of *prima facie* obviousness absent from the petition . . . is foreclosed by statute, [Federal

Circuit] precedent, and Board guidelines.” *Wasica Fin.*, 853 F.3d at 1286; *see also Intelligent Bio-Sys.*, 821 F.3d at 1369-70 (affirming Board’s refusal to consider “new rationale to explain why one of skill in the art would have been motivated to combine” and “a number of non-patent literature references which were not relied upon to support unpatentability in the Petition” (citation omitted)); *Yita LLC v. MacNeil IP LLC*, 69 F.4th 1356, 1367 (Fed. Cir. 2023), *cert. denied*, 144 S. Ct. 499 (2023) (“[Petitioner] waited until its reply to present what in substance is an argument that it would have been obvious to a relevant artisan to modify [the prior art reference] to arrive at the . . . limitation.”); *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-00582, Paper 34 at 30-31 (P.T.A.B. Aug. 5, 2019) (“Petitioner’s new rationale explaining its claim mapping in the Reply is not based on a previous position Petitioner put forth in the Petition; rather, Petitioner posits a rationale about an ordinarily skilled artisan’s perspective where none existed previously.”).

In advancing the eight new prior art references in its Reply, Petitioner provides a POSA’s perspective on rapidly dissolving lozenges and taste-masking drug release for the first time and presents, what in substance, are new arguments that it would have been obvious to a POSA to rely on Dohil. Petitioner’s new theories of *prima facie* obviousness should be stricken under 37 C.F.R. § 42.23(b). *See Yita* 69 F.4th at 1367; *Hulu*, IPR2018-00582, Paper 34 at 30-31; Consol. Trial Practice Guide at 74-75, 80-81; *Lenovo Holding Co., Inc. v. DoDots Licensing Sols. LLC*,

IPR2019-01278, 2020 WL 5413798, at *3 (P.T.A.B. Sept. 9, 2020) (granting motion to strike new evidence and arguments submitted on reply); *Dexcom*, 2018 WL 1137089, at *12-13 (excluding new evidence and portions of Reply brief relying on same).

B. Petitioner's New Prior Art References And Invalidity Theories Prejudice Patent Owner

Striking Petitioner's new arguments and evidence is warranted because their late introduction at the conclusion of this proceeding prejudices PO. The new theories and evidence presented in its Reply were all fully available to Petitioner when it prepared and filed its Petition. Petitioner does not argue in Reply that it newly discovered this art and importantly, Dr. Parr admitted he never searched. EX2011, 63:6-21. Notably, as admitted by Petitioner, the parties' dispute on rapidly dissolving lozenges had similarly occurred in an EPO proceeding, such that Petitioner should have included the references in the Petition if it sought to rely on them for unpatentability. Reply at 9. Petitioner has no plausible justification why it could not have complied with the rules and included all of its unpatentability theories in its Petition at the inception of the proceeding. Remarkably, Petitioner asserts that it "was surprising" that PO raised the same arguments, where Petitioner raises the same art in a different tribunal. EX1094, 24:20-24. There is no surprise here because the prior art fails to render the challenged claims unpatentable. The Federal

Circuit recognized “the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute. While the Board’s requirements are strict ones, they are requirements of which petitioners are aware when they seek to institute an IPR.” *Intelligent Bio-Sys.*, 821 F.3d at 1369.

Because Petitioner presented the new grounds and evidence for the first time after PO’s Response, and as briefing is concluding, PO does not have a full or fair opportunity to respond to these arguments. Indeed, the Board has recognized that the mere opportunity to file a sur-reply does not cure the prejudice. *See, e.g., Renesas Elecs. Corp. v. Lone Star Silicon Innovations*, No. IPR2017-01869, 2019 WL 1373644, at *18 (P.T.A.B. Mar. 25, 2019) (“the filing of a sur-reply does not cure or excuse a reply brief that exceeds the [permitted] scope”). Under 35 U.S.C. § 312(a)(3), all grounds and supporting evidence must be submitted in the Petition to prevent the Petition from becoming a moving target during the proceeding.

Moreover, by responding to Petitioner’s improper new arguments and evidence, PO would be inevitably prejudiced, as (1) PO must use the limited word count for its sur-reply to address the existing arguments as well as the improperly advanced new arguments and evidence; (2) PO is not afforded an expert declaration in its sur-reply to support its position against the new arguments and evidence; and (3) PO must use the limited time afforded during its oral argument to address the existing arguments as well as the improperly advanced new arguments and evidence.

Such prejudice should be avoided by striking Petitioner’s improper new arguments and evidence, as the Board has recognized. Consol. Trial Practice Guide at 81 (Nov. 2019) (“where addressing this new theory during oral hearing would prejudice the opposing party, striking the portion of the brief containing that theory may be appropriate”).

II. CONCLUSION

PO respectfully requests that the Board strike Exs. 1075-1082, portions of Petitioner’s Reply Brief (Paper 20) and Dr. Parr’s Reply Declaration (EX1093) discussing this new evidence.

Date: August 29, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Sanya Sukduang, hereby certify that on August 29, 2025, the foregoing **PATENT OWNER’S MOTION TO STRIKE EXHIBITS 1075-1082 AND PORTIONS OF PETITIONER’S REPLY BRIEF AND PARR REPLY DECLARATION** were served electronically via email on the following counsel of record for Petitioner as follows:

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