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On behalf of **Dr. Falk Pharma GmbH**

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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

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
MOTION TO STRIKE**

Patent Owner seeks the exceptional remedy of striking portions of Petitioner’s Reply, along with Exhibits 1075-1082 and Petitioner’s expert declaration. *See* Paper 26 (“Motion”). That exceptional remedy is not warranted here. The Reply appropriately responds to arguments raised in Patent Owner’s Response. The Motion should be denied.

I. The Reply appropriately responds to Patent Owner’s Response

Patent Owner wrongly asserts that the Petitioner’s Reply contains a “new ground” or “new theory” of unpatentability that was not raised in the Petition. *See* Motion at 1, 6. The grounds of unpatentability raised in the Petition include obviousness based on the Dohil prior art reference, including Dohil’s disclosure of a rapidly dissolving lozenge or tablet. *See, e.g.*, Paper 2 (“Petition”) at 18-26. Patent Owner admits that the Petition argued that “Dohil, in view of the knowledge of a POSA, teaches a rapidly dissolving lozenge.” Motion at 2 (citing Petition at 23). Petitioner’s Reply did not change legal grounds or theories. Petitioner’s Reply remains consistent with the Petition in asserting that the challenged claims would have been obvious over Dohil. *See, e.g.*, Paper 20 (“Reply”) at 2-21.

Patent Owner admits that its Response argued that Dohil’s rapidly dissolving lozenges must disintegrate slowly. *See* Motion at 2 (“[i]n its Response, PO provided evidence that lozenges dissolve slowly”). Indeed, the Patent Owner’s Response repeatedly argued that a lozenge—by definition—must dissolve slowly, and that the

prior art does not disclose rapidly dissolving lozenges. *See* Paper 18 (“POR”) at 13, 14, 20, 25-27, 30, 36. Patent Owner submitted evidence in the form of its expert’s testimony that he was “not aware of any fast or quick dissolving lozenges” in the prior art. EX2007 ¶83; POR at 14.

The Federal Circuit has “regularly held [that] the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.” *Apple Inc. v. Andrea Elec. Corp.*, 949 F.3d 697, 706-07 (Fed. Cir. 2020). Patent Owner should have expected that Petitioner’s Reply would provide argument and evidence definitively demonstrating that Patent Owner’s representation as to the state of the prior art regarding lozenges was incorrect because rapidly dissolving lozenges *were* known in the prior art. Reply at 7-8. Petitioner’s arguments in reply are responsive to the incorrect depiction of the state of the prior art regarding lozenges provided in Patent Owner’s Response and are therefore appropriate subject matter for Petitioner’s Reply. *See* 37 C.F.R. § 42.23(b) (providing that a reply may respond to arguments raised in the patent owner response); *Apple Inc.*, 949 F.3d at 706-07 (vacating PTAB obviousness decision that refused to consider petitioner arguments and evidence where the “reply squarely responds to [the] Patent Owner Response”).

During the oral hearing on Patent Owner’s request for authorization to file the Motion, the Board questioned Patent Owner as to why Petitioner’s arguments and

evidence were “not proper evidence of what a generally skilled artisan” would understand in view of Patent Owner’s Response arguing that “lozenges generally are not fast-dissolving.” EX1094 at 20:1-17. The Board further expressed questions and concerns over Patent Owner’s proposed motion, *id.* at 25:17-20, and cautioned Patent Owner that it should not proceed with filing the motion unless it could “clearly explain in its motion why it believes such exceptional remedy to be justified in this case.” EX3003 at 1. Patent Owner’s Motion fails to address the questions, concerns, and caution from the Board.

Instead, Patent Owner’s Motion seeks to unjustifiably limit the record available for the Board’s consideration. The Board, however, “is capable of identifying new issues or belatedly presented evidence when weighing the evidence at the close of trial ... [thus] striking the entirety or a portion of a party’s brief is an exceptional remedy that the Board expects will be granted rarely.” Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) at 80. The Board should reject Patent Owner’s attempt to avoid the merits of Petitioner’s Reply arguments and evidence via the exceptional—and clearly unwarranted—remedy sought via its Motion.

Patent Owner asserts that Petitioner should have submitted Exhibits 1075-1082 in its Petition in view of Patent Owner’s previously failed argument to the EPO that lozenges must dissolve slowly. *See* Motion at 5. The Board has previously

explained that “it would be difficult if not impossible for a petitioner to anticipate every argument it could have made in a petition.” *Micron Technology, Inc. v. Lone Star Silicon Innovations LLC et al*, IPR2017-01563, Paper 29, at 32-33 (PTAB 2018). The EPO so definitively rejected Patent Owner’s argument that it is surprising Patent Owner would re-raise it here seeking a different outcome. *See* Petition at 12-14; EX1004 ¶¶26.2-4.

Regardless, “[t]he standard is not whether Petitioner could have raised the arguments or evidence in the Petition, but whether they respond to arguments raised by Patent Owner.” *Grunenthal GmbH v. Antecip Bioventures II LLC*, PGR2018-00092, Paper 24, at 3 (PTAB 2020). Here, Petitioner’s Reply directly responds to Patent Owner’s Response, which is standard reply content and the very purpose of a petitioner reply. Patent Owner’s Motion should be denied.

II. There is no prejudice to Patent Owner

Patent Owner did not (and cannot) show that the arguments and evidence in Petitioner’s Reply are unfairly prejudicial. Patent Owner had the last word on the topic of lozenges in its Corrected Sur-Reply. *See* Paper 28 (“Corrected Sur-Reply”) at 1-14. Unlike the old cases cited by Patent Owner that predate when patent owners were authorized to file a sur-reply as a matter of right, here Patent Owner provided the Board with its position on rapidly dissolving lozenges in its Corrected Sur-Reply, effectively mooted any supposed prejudice.

Further, there is no prejudice because Patent Owner had a full and fair opportunity to depose Petitioner's expert, Dr. Parr, regarding the arguments and exhibits it seeks to strike. Patent Owner did not lack for time during the deposition, as it only used a fraction of the 7 hours available. *See* EX2018 at 72:9-13 (Ellodi's counsel "ha[d] no further questions" for Dr. Parr and adjourned the deposition after approximately 3 hours on the record). Patent Owner had ample time to inquire about Petitioner's arguments and exhibits during the deposition, but chose not to do so.

Patent Owner raises a supposed concern of having to allot time during oral argument to discuss rapidly dissolving lozenges. *See* Motion at 6. This concern is unavailing. Patent Owner can seek permission for any amount of time for its oral argument in its forthcoming Request for Oral Hearing that is due on September 15, 2025. Patent Owner will not have to address arguments on rapidly dissolving lozenges for the first time during the upcoming oral argument because it already submitted its response in its Corrected Sur-Reply.

Patent Owner additionally asserts prejudice because its expert was unable to submit a responsive declaration with its Corrected Sur-Reply. If the lack of an expert declaration with a sur-reply was a legitimate source of prejudice, then it would apply to all patent owners because no responsive expert declaration is authorized under the default rules. *See* 37 C.F.R. § 42.23(b). Here, no amount of expert testimony would change the fact that Patent Owner's depiction of the state of the prior art as lacking

rapidly dissolving lozenges was definitively incorrect. There “is a difference between evidence that brings unfair prejudice and evidence that is damning.” *United States v. Burt*, 495 F.3d 733, 740 (7th Cir. 2007). Patent Owner’s incorrect presentation of the state of the prior art on rapidly dissolving lozenges resulted in irreparable damage to Patent Owner’s credibility in this proceeding, but Petitioner’s decisive rebuttal of Patent Owner’s inaccurate portrayal of the prior art is not unfairly prejudicial.

III. Patent Owner’s cited cases are inapplicable

Patent Owner cites several cases in its Motion, none of which apply to the present situation. Patent Owner ignores the numerous other decisions that reject patent owner motions seeking the exceptional remedy of striking petitioner arguments that respond to issues raised in a patent owner response. *See, e.g., Grunenthal*, PGR2018-00092, Paper 24, at 1 (denying motion to strike where petitioner directly rebutted patent owner’s position and properly provided supporting evidence with its reply); *TCL Indus. Holdings Co. Ltd. v. ParkerVision, Inc.*, IPR2021-00985, Paper 25, at 10 (PTAB 2022) (denying motion to strike where petitioner’s reply “responds to the arguments asserted in [patent owner’s] response”); *Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554, Paper 40, at 36 (PTAB 2020) (denying motion to strike where “Petitioner’s arguments on Reply may be considered properly responsive to Patent Owner’s

arguments [and] any surprise or prejudice to Patent Owner... is mitigated in this case because Patent Owner substantively responded to those arguments in its Sur-Reply.”).

Patent Owner relies on several cases where the petitioner changed its legal grounds, presented a new theory of unpatentability, or filled gaps in the petition. *See* Motion at 1, 4-6 (citing *Intelligent Bio-Sys.*, *Dexcom*, *Wasica Fin.*, *Hulu*, and *Renesais Elecs.*). None of those situations apply here. Dohil expressly and undeniably discloses a rapidly dissolving lozenge, which was discussed in the Petition. *See, e.g.*, Petition at 23 (quoting EX1002 ¶[0032] (“[t]he lozenge or other similar tablet, capsule, or other solid, would dissolve rapidly in the mouth or esophagus”))). Like the Petition, Petitioner’s Reply is based on Dohil rendering the challenged claims obvious. *See* Petition at 18-26; Reply at 2-21. There is no new ground or theory in the Reply, and there is no gap in the Petition or Dohil.

Patent Owner relies on other cases where a petitioner’s reply arguments were not responsive to arguments raised in the patent owner response. *See* Motion at 4-5 (citing *Yita* and *Lenovo*). Here, Patent Owner admits that it raised the issue of whether rapidly dissolving lozenges were known in the prior art in its Response. *See* Motion at 2; POR at 13, 14, 20, 25-27, 30, 36. Petitioner appropriately replied.

IV. Conclusion

The Board should deny Patent Owner’s motion to strike.

IPR Petition – Patent No. 8,771,729
Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.

Dated: September 12, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
**PETITIONER’S OPPOSITION TO PATENT OWNER’S MOTION TO
STRIKE** was served by email on the Patent Owner at the following email addresses:

ssukduang@cooley.com; jcousin@cooley.com;

jdavies@cooley.com; iagarwal@cooley.com

Dated: September 12, 2025

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