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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 REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

The Petition presents four compelling grounds of obviousness. Rather than address the merits of these grounds, Patent Owner seeks a procedural pass to avoid scrutiny of its claims under the Board's two-step *Advanced Bionics* §325(d) test. Neither step applies here for reasons discussed in the Petition and in this reply.

Patent Owner's Preliminary Response (POPR) ironically reinforces unpatentability by presenting detailed charts aligning the prior art with the challenged claims. *See* POPR 12-17, 22-27, 37-44. The Board should institute trial.

I. *Advanced Bionics* Step 1 Does Not Apply

The Petition is based on four references: Dohil, Grother, the FDA Guidance, and Venkatesh. Dohil, Grother, and the FDA Guidance were not made of record during prosecution of the '729 patent. The Petition relies on Venkatesh only for certain dependent claims. *Advanced Bionics* step 1 does not apply. Petition 69-70.

Patent Owner incorrectly argues that Dohil is substantially the same as the Phillips reference (EX2003). Dohil contains material disclosure absent from Phillips, which Patent Owner seeks to summarily dismiss. Patent Owner argued during prosecution that Phillips "provides no reason to have a rapid disintegration time." POPR 9; EX1031 31-32. In contrast, Dohil teaches that its orally disintegrating composition would "dissolve rapidly in the mouth or esophagus." EX1002 ¶[0032]; Petition 23-25. Dohil contains the precise disclosure that Patent Owner asserted was missing from Phillips. Dohil's teaching suggests the

disintegration time claimed by the '729 patent, especially in view of the POSA's knowledge of the FDA's Guidance that such compositions should disintegrate within 30 seconds using the USP <701> Disintegration Test. EX1005 2-3; Petition 23-25.

Patent Owner admits that Dohil is the closest prior art. POPR 30; EX1038 ¶8.7 (admitting "D1," Dohil, "is a suitable choice as the closest prior art"); EX1004 ¶36.1. The EPO determined that a Phillips equivalent, "D14a" (WO2009064457) "is not prima facie more relevant than evidence already in the proceedings" and "does not mention at all orally dispersing dosage formulations, which is the technology at the core of the present invention." EX1004 ¶20.3. The EPO already determined that Dohil is not substantially the same as, or cumulative to, Phillips.

Patent Owner asserts that the FDA Guidance, Grother, and Venkatesh are cumulative to Venkatesh 2009 (EX2002). This assertion is incorrect as the FDA Guidance provides agency recommendations on the desirable disintegration time and testing parameters for orally disintegrating compositions. EX1005 1-3. The FDA Guidance evidences the widespread general knowledge of the POSA and provides a strong motivation to formulate orally disintegrating compositions according to its authoritative guidance that is not equivalent to the lesser-known Venkatesh 2009 reference. EX1030 ¶¶119-120; Petition 23-25; *Teva Pharms. USA, Inc. v. Corcept Ther., Inc.*, PGR2019-00048, Paper 19 at 26 (PTAB 2019) (FDA Guidance supports what was routine in the art).

Grother also contains material disclosure absent from Venkatesh 2009. During prosecution, Patent Owner argued that Venkatesh 2009 does not disclose a corticosteroid deposited topically in the upper gastrointestinal tract, which led to the Examiner removing rejections based on Venkatesh 2009. POPR 22, 28-29; EX1031 71-76, 41-42. Importantly, the Examiner overlooked that independent claim 27 does not require deposition in the upper gastrointestinal tract. EX1001 20:16-22. Patent Owner's argument should not have led to an allowance over Venkatesh 2009. More importantly, Grother teaches that its orally disintegrating composition should contain budesonide or fluticasone as corticosteroids, EX1008 18:15-18, and that the composition is "designed to release the active ingredient rapidly in the oral cavity." EX1008 3:18-20; Petition 36-39, 41. Grother therefore contains the disclosure that Patent Owner asserted was missing from Venkatesh 2009. Patent Owner argues that Grother does not recognize the difference between systemic and topical corticosteroids, POPR at 35-36, 44, but ignores that a POSA would have known that Grother's budesonide and fluticasone are topical corticosteroids. Petition 36-39, 51.

The Examiner also relied on Venkatesh 2009 as a primary reference against all pending claims, whereas the Petition relies on Venkatesh as a secondary reference only for certain dependent claims. The Petition combines Venkatesh with Dohil and Grother as primary references, which are different combinations than what was presented during prosecution and favors institution. *See Resideo Techs., Inc. v.*

Central Security Group, IPR2021-01355, Paper 12 at 14 (PTAB 2022) (instituting where a previously considered reference “is combined with different references and argued in different ways compared to what was made to the Examiner”).

II. *Advanced Bionics* Step 2 Compels Institution

As discussed above, the Examiner was not aware of Dohil during prosecution and therefore overlooked its teaching of an orally disintegrating composition that dissolves rapidly in the mouth, which evidences the claimed disintegration time the Examiner believed was missing from Phillips when the claims were allowed. This constitutes an error material to patentability. *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9, n.9 (“[a]n example of material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims”) (PTAB 2020). Patent Owner admits that the EPO held all of the corresponding European claims obvious over Dohil. POPR 30. The EPO decision is “instructive” for purposes of institution. *See Novartis Pharms. Corp. v. Shilpa Pharma, Inc.*, IPR2022-00886, Paper 13 at 28-29 (PTAB 2022). Patent Owner fails to identify any material differences or errors in the EPO’s obviousness determination discussed in the Petition. Petition 12-14.

Patent Owner asserts that the Board should exercise 325(d) discretion because Dohil 2009 (EX2001) was cited in later-examined child applications. POPR 19-20.

Patent Owner fails to identify anything from the prosecution of the child applications indicating that the Examiner accounted for Dohil's teachings of rapid, orally disintegrating compositions or the knowledge of the POSA reflected in the FDA Guidance that such compositions should disintegrate within 30 seconds. These teachings bear directly on the limitation that the Examiner erroneously believed was missing from the prior art and favors institution. Petition 70-71; *Eli Lilly & Co. v. Teva Pharms. Int'l. GmbH*, IPR2022-00738, Paper 9 at 11-12 (PTAB 2022).

As discussed above, Grother discloses an orally disintegrating composition that deposits a corticosteroid topically in the upper gastrointestinal tract, which is the exact disclosure Patent Owner asserted was missing from the prior art that led the Examiner to err in allowing the claims. *See Agrofresh Sols., Inc. v. Lytone Enter., Inc.*, IPR2021-00451, Paper 11 at 14-15 (PTAB 2021) (instituting where there "appear[ed] to have been an error material to patentability because [the Examiner's allowance] was made without the benefit of the teachings of these additional references"). As discussed above, the Examiner also overlooked that independent claim 27 does not require deposition in the upper gastrointestinal tract and should not have been allowed over Venkatesh 2009.

In sum, the Examiner did not have the benefit of Dohil, the FDA Guidance, Grother, the declaration of Dr. Parr, or the EPO decision. All of this additional evidence was presented in the Petition and warrants instituting trial on obviousness.

Dated: November 26, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
**PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY
RESPONSE** was served by email on the Patent Owner at the following email
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