

Filed January 13, 2026

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

By: Nathanael R. Luman (Reg. No. 63,160)
Eric S. Furman (Reg. No. 45,664)
Phillip J. Minnick (Reg. No. 81,223)
KNOBBE, MARTENS, OLSON & BEAR, LLP
3579 Valley Centre Drive, Suite 300
San Diego, CA 92130
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxFalkPharma@knobbe.com

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.

PGR2025-00086
Patent No. 12,290,598

**PETITIONER'S SUR-REPLY TO PATENT OWNER'S
DISCRETIONARY DENIAL BRIEF**

TABLE OF CONTENTS

Page No.

I.	<i>ADVANCED BIONICS</i> AND 35 U.S.C. § 325(D) DO NOT APPLY	1
II.	PATENT OWNER’S UNAUTHORIZED COC REQUEST SHOULD BE DENIED	2
III.	ANY GRANTED COC WOULD NOT APPLY TO THIS PGR	3

TABLE OF AUTHORITIES

Page No(s).

<i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (PTAB 2020).....	1
<i>Askeladden LLC v. Encoditech, LLC,</i> IPR2017-00452, Paper 7 (PTAB 2017).....	4
<i>Edwards Lifesciences Corp. v. Evalve, Inc.,</i> IPR2019-01285, Paper 19 (PTAB 2020).....	2, 4
<i>Emerson Electric Co. v. Sipco, LLC,</i> IPR2016-00984, Paper 52 (PTAB 2020).....	3, 4
<i>Inguran, LLC v. Premium Genetics (UK) Ltd.,</i> PGR2015-00017, Paper 8 (PTAB 2015).....	4

OTHER AUTHORITIES

AIA § 3.....	4
35 U.S.C. § 112.....	1, 3
35 U.S.C. § 255.....	3
35 U.S.C. § 325.....	1
37 C.F.R. § 42.3.....	2
MPEP § 1481.....	3

I. *Advanced Bionics* and 35 U.S.C. § 325(d) Do Not Apply

Patent Owner (PO) wrongly asserts that Petitioner’s discretionary denial opposition is “too late” and “should have been made within the Petition.” Paper 13 (Discretionary Denial Reply, “DDR”) at 1. PO apparently failed to read the Director’s instruction that “[t]he petition should not address discretionary issues.” www.uspto.gov/patents/ptab/interim-director-discretionary-process, Section III.A.

PO wrongly asserts that this Petition does not present new arguments or demonstrate examiner error because the Examiner considered the IPR2024-01197 institution decision, the ’069/’828/’407 patent IPR petitions, and other materials from U.S./European cases. DDR 1-3. Grounds 1-4 of the Petition raise new § 112 challenges that were not previously presented as explained in Petitioner’s Discretionary Denial Opposition (“DDO,” Paper 9) at 9-13. PO does not dispute the newness of Grounds 1-4. It also does not dispute that Grounds 5-6 raise new challenges based on Perrett as prior art. Kararli and USP <1216> in Grounds 7-12 are newly presented. *Id.* 10-12. *Advanced Bionics* Part 1 and § 325(d) do not apply.

PO does not dispute that the Examiner erred in allowing the claims due to lack of support and enablement for claiming “4-48 N.” Indeed, PO admits “4-48 N” is unsupported, EX2001 1-2, and thus cannot dispute Examiner error. Therefore, *Advanced Bionics* Part 2 and § 325(d) do not apply for these additional reasons.

PO concedes that it will disclaim all claims from the ’069/’828/’407 patent

IPRs, which will result in adverse judgments against PO. DDR 2 n.1. PO's attempt to spin its requested adverse judgments as somehow positively furthering its own "resource purposes," *id.*, is callously apathetic to the significant resources expended by Petitioner in policing PO's thicket of unpatentable patents across six IPRs/PGR.

II. Patent Owner's Unauthorized COC Request Should Be Denied

The Board ordered PO to inform the Director of any judicial or administrative matter that would affect this proceeding, "includ[ing] requests for certificate of correction." Paper 3 at 2; 37 C.F.R. § 42.3(a). PO expresses no remorse for its open defiance of the Board's order by filing its unauthorized COC request. PO doesn't deny that it sought to evade accountability in this PTAB proceeding or that it intentionally withheld this PGR Petition from the COC Branch.

PO audaciously seeks to blaze a path for all future patent owners to willfully disobey Board orders and file COCs without authorization based on misinterpreting *Edwards*. DDR 3. The *Edwards* panel did not endorse patent owner's unauthorized COC request. Rather, that panel determined it lacked jurisdiction to disturb the unauthorized COC after it had been issued by the Director via the COC Branch. *Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01285, Paper 19 at 7-8 (PTAB 2020). Here, the Director has jurisdiction over PO's unauthorized COC request and this PGR. He should deny PO's unauthorized COC request, not reward it.

PO wrongly asserts that Petitioner "cites no authority" why the unauthorized

COC request should be denied. DDR 3. Petitioner cited 35 U.S.C. § 255 and MPEP § 1481. DDO 5-6. A COC may only issue for “a mistake of a clerical or typographical nature, or of minor character.” 35 U.S.C. § 255. A mistake is not minor if “the requested change would materially affect the scope or meaning of the patent.” MPEP § 1481. Here, PO seeks to materially affect the scope of the claims by changing the claimed hardness from “4-48 N” to “8-48 N.” EX2001 1-2. According to PO this change would convert the claims from presently violating § 112 to supposedly complying with § 112, DDB 6, which must materially change the claim scope and therefore cannot be of the minor character required for a COC.

PO wrongly asserts that Petitioner does not dispute that the claimed hardness range is a typographical error that is correctable via COC. DDR 4. The ’598 specification discloses an ODT with a hardness of 8-48 N in Example 1, EX1001 17:40-18:23, and it includes an alternative (and ambiguous) reference to ODTs that “exhibit sufficient hardness” values for packaging, transportation, and distribution, *id.* 16:43-48. PO told the PTO *five* times that it sought to patent “4-48 N.” EX1096 151, 154, 156, 157. The Examiner understood that PO sought to patent “4-48 N.” *Id.* 16. There is no intent to patent 8-48 N that is clearly manifest in the record.

III. Any Granted COC Would Not Apply To This PGR

PO wrongly asserts Petitioner did not provide authority against retroactive application of COCs in PTAB cases. DDR 3-4. Petitioner provided *Emerson*, which

explains that COCs should not apply retroactively based on at least Congressional intent to only apply COCs prospectively and to avoid moving targets. DDO 7-8.

PO wrongly asserts that *Emerson* only analyzed a COC filed after a final written decision. DDR 4. The *Emerson* patent owner also filed an unauthorized COC after the petition was filed, and the Board stayed that COC request until the proceeding was instituted. *Emerson*, IPR2016-00984, Paper 52 at 6-7 (PTAB 2020).

PO relies on *Edwards* and *Askeladden* where COCs were retroactively applied. DDR 3-4. Those cases involved clerical errors that were readily apparent in the record and therefore correctable via COC, which is not the case here.

PO wrongly asserts that Petitioner did not provide support for PGR eligibility should the Director grant its unauthorized COC request. DDR 4. Petitioner explained that, by statute, the AIA applies when a patent “contains or contained at any time” a claim having an effective date after 03/16/2013. DDO 4 (citing AIA § 3(n)(1) and *Inguran*). PO admits that the patent presently contains a claim lacking support, which confirms PGR eligibility. *Id.*; Petition 18-20. Further, Grounds 3-6 and 7-12 cannot be mooted by PO’s COC. Ground 3 demonstrates lack of enablement because the specification provides no guidance on how hardness should be determined in making the claimed ODTs. Petition 34-37. PO’s COC cannot fill the void in its specification. Because PO’s COC cannot moot Ground 3, Perrett is prior art such that Grounds 5-6 cannot be mooted, and neither can Grounds 7-12.

PGR Petition – Patent No. 12,290,598

Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 13, 2026

/Nathanael R. Luman/

Nathanael R. Luman (Reg. No. 63,160)

Eric S. Furman (Reg. No. 45,664)

Phillip J. Minnick (Reg. No. 81,223)

Counsel for Petitioner

Dr. Falk Pharma GmbH

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
**PETITIONER’S SUR-REPLY TO PATENT OWNER’S DISCRETIONARY
DENIAL BRIEF** was served by email on the Patent Owner at the following email
addresses:

Sanya Sukduang
ssukduang@cooley.com

Jonathan Cousin
jcousin@cooley.com

Isha Agarwal
iagarwal@cooley.com

Ellodi_IPR@cooley.com

Dated: January 13, 2026

/Nathanael R. Luman/

Nathanael R. Luman (Reg. No.63,160)
KNOBBE MARTENS OLSON & BEAR, LLP

Counsel for Petitioner
Dr. Falk Pharma GmbH