

Case No. PGR2025-00086

Patent No. 12,290,598

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. PGR2025-00086

Patent No. 12,290,598

**PATENT OWNER'S AUTHORIZED REPLY IN SUPPORT OF ITS
REQUEST FOR DISCRETIONARY DENIAL**

I. INSTITUTION IS NOT PROPER UNDER § 325(D)

Petitioner's response to PO's request for a discretionary denial should be rejected because its arguments come too late. Petitioner's material error arguments should have been made within the Petition itself. (Paper 9, 12–15); *see Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8–9 (P.T.A.B. Feb. 13, 2020) (Petitioner bears the burden “to make a showing of material error” under § 325); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (P.T.A.B. Dec. 15, 2017). Indeed, the six Becton factors “should be read broadly . . . to apply to any situation in which a petition relies on the same or substantially the same art or arguments previously presented to the Office[.]” *Advanced Bionics*, IPR2019-01469, Paper 6 at 10. That is exactly the case here, as set forth within PO's Discretionary Denial Brief (“PODDB”). (Paper 6, 7–17.)

Further, Petitioner's untimely arguments regarding the institution decisions for the '069/'828/'407 patents are misleading. (Paper 9, 14–15.) As explained in the PODDB, the Examiner considered the institution decision for IPR2024-01197 regarding the '729 patent, and the petitions for the '069/'828/'407 patents, all of which relied on the same art and arguments in the current Petition. (Paper 6, 3–4.) Thus, the Examiner had the benefit of the institution decision analyzing the prior art and still issued the '598 patent.

Petitioner also raises the adverse judgment in IPR2024-01197, but acknowledges that the '598 patent requires a different and distinct limitation of hardness and friability not in the '729 patent. (Paper 9, 14–15.) Petitioner only points to the terminal disclaimers PO filed during prosecution of the '598 patent as evidence that the claims are not patentably distinct from the '729/'069/'828/'407 patents. (Paper 9, 15.)¹ As explained in the PODDB, this is not enough, as a terminal disclaimer is not an admission on the merits of the rejection of double patenting. (Paper 6, 20 (citing *Quad Env't Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991)).)

Finally, Petitioner takes issue with the number of references PO submitted during prosecution of the '598 patent. (Paper 9, 15.) A vast majority of the submitted references come from proceedings brought by Petitioner in Europe and the United States challenging related patents, as well as the associated exhibits, as is required of an applicant. 37 C.F.R. § 1.56; EX1096, 302–340, 141–145, 51–55, 43. Thus, contrary to Petitioner's assertion, the Examiner had the benefit of not only the petitions and Dr. Parr's declarations in related petitions, which overlap with the art

¹ Patent Owner disclaimed the '729 patent for resource purposes. Patent Owner also intends on disclaiming all claims in the related IPR proceedings for the '069/'828/'407/'061 patents for resource purposes.

and arguments presented here, but also all of Petitioner's arguments made in Europe and the outcome of the proceedings there. The '598 patent still issued.

II. GRANTING THE COC WOULD APPLY TO THE '598 PATENT AND CONSERVE RESOURCES

Petitioner states that the Certification of Correction ("CoC") PO requested prior to any institution decision should not be granted and PO must file a motion to amend, but cites no authority supporting this argument. (Paper 9, 6.) Petitioner cites *Election Systems*, where the CoC was requested *after* the Board instituted trial and issued during the pending proceedings. *Election Sys. & Software, LLC v. Hart Intercivic, Inc.*, PGR2020-00031, Paper 18 at 2–3 (P.T.A.B. Feb. 5, 2021). The Board declined to apply the CoC retroactively in the PGR after institution because the petition had been instituted on the original claims, not the corrected claims. *Id.* at 9. Here, PO properly requested the CoC as soon as it became aware of the inadvertent typo in the claims and before the Director or the Board have reached a decision on institution. *Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01285, Paper 19 at 6–8 (P.T.A.B. Jan. 9, 2020) (rejecting petitioner's argument that, after a petition is filed, patent owner must receive Board authorization before submitting a request for CoC). The Director can grant the request prior to any decision on institution, which would result in a more efficient use of the Board's resources.

Petitioner also argues that a grant of the CoC request would not apply retroactively to the '598 patent, but does not cite any supporting authority. (Paper 9,

7.) Instead, Petitioner points to *Emerson*, which analyzed whether the correction applied retroactively *after* the Board issued its final written decision. *Emerson Elec. Co. v. SIPCO, LLC*, IPR2016-00984, Paper 52 at 18 (P.T.A.B. Jan. 24, 2020). Here, the Board has yet to make a decision on institution, let alone a final written decision, and the '598 patent is not subject to trial at this time. Correcting the inadvertent typo in the claims prior to any institution decision will moot a number of Petitioner's grounds and therefore conserve the Board's resources and increase judicial efficiency. Importantly, Petitioner does not dispute that the claimed hardness range of "4-48 N" is an inadvertent typo introduced during the prosecution of the '598 patent. It is in the interest of both the public and the parties that the corrected claims be the subject of the PGR proceeding going forward. *Askeladden L.L.C. v. Encoditech, LLC*, IPR2017-00452, Paper 7 at 3–4 (P.T.A.B March 31, 2017).

Finally, Petitioner's argument that the '598 patent will still be eligible for PGR even after the Director grants the CoC is unsupported. (Paper 9, 4.) Petitioner cites no authority supporting this argument, but instead relies on decisions addressing statutory disclaimers. (*Id.*) For these reasons, the request for CoC should be granted and the Petition discretionarily denied.

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Respectfully submitted,

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CERTIFICATION OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e)(4)(i) *et seq.*, a complete copy of the attached **PATENT OWNER'S REPLY IN SUPPORT OF REQUEST FOR DISCRETIONARY DENIAL** is being served via electronic email on the Petitioner by serving Petitioner's counsel of record as follows:

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