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 SURREPLY

I. THE PROSECUTION HISTORY DEMONSTRATES THAT THE COC SHOULD BE GRANTED, MOOTING GROUNDS 1–2

PO properly requested a Certificate of Correction ("CoC") once the minor and inadvertent typo in the claims was brought to its attention. *See Edwards Lifesciences Corp. v. Evalve, Inc.*, IPR2019-01285, Paper 19 at 6–8 (P.T.A.B. Jan. 9, 2020). As the request for CoC explains, during prosecution, PO amended the claims to recite the hardness limitation to overcome a statutory double patenting rejection. EX2001, 1. The prosecution history demonstrates that PO specifically pointed to Example 1 for support. EX1096, 156. The only disclosure of a hardness value in the '598 patent is "8-48 N" in Example 1. EX1001, 18:6-17. It is therefore clear that PO intended to recite a hardness of "8-48 N."

Petitioner points to the fact that in its amendment, PO refers to "4-48 N" five times. Paper 15, 1. While PO acknowledges that it inadvertently repeated the typographical error, this does not negate the fact that PO relied only on Example 1 for support, which expressly discloses a hardness of "8-48 N." EX1096, 156; EX1001, 18:6-17. Petitioner also points to only one other reference in the specification to hardness. Paper 15, 2 (citing EX1001, 16:43-48). This is a red herring. This section does ***not*** disclose any hardness values. PO did not cite to this section, and instead cited Example 1, which discloses the hardness range of "8-48 N" that PO clearly intended to claim. EX1096, 156; *see* MPEP § 1481 ("clerical or

typographical mistake…is manifest from the contents of the file of the patent sought to be corrected."). The fact that the Examiner also did not notice PO's unintentional error is not evidence that PO intended to claim "4-48 N." (i.e., because PO never argued implicit disclosure of "4-48 N.") Paper 15, 2; EX1096, 16. To the contrary, it indicates that this typo is a relatable and minor mistake that should be corrected by a CoC. Taking into consideration the fact that Example 1 is the ***only*** disclosure of hardness values in the specification and PO expressly relied on Example 1 to support the claim amendments, common sense dictates that PO's intention was to claim "8-48 N."

Petitioner cites to MPEP § 1481 to support its argument that PO's CoC should be denied because the correction would "materially affect the scope of the claims[.]" Paper 15, 1. Petitioner misrepresents MPEP § 1481. As MPEP § 1481 states, a request for a CoC to ***broaden*** a claim to correct an error is not a mistake of "minor character" because it would "be issuing a patent on a claim that had never been examined[.]" MPEP § 1481. Narrowing a claim, as PO seeks to do here, however, does not present the same issues as broadening a claim. "8-48 N" falls within "4-48 N," and therefore "8-48 N" was necessarily examined. Narrowing a claim limitation that was already examined cannot materially affect claim scope, otherwise any typographical error related to a claim term would be considered material and not correctable by a CoC. Petitioner does not cite to any precedent precluding PO from

correcting its error and narrowing the scope of the claims. Instead, Petitioner misinterprets MPEP § 1481 for the sole purpose of continuing to needlessly assert Grounds 1–2, whereas the CoC would narrow the scope of the issues in this proceeding.

Finally, Petitioner's assertion that the CoC would not apply retroactively to this PGR is wrong. Paper 15, 2. No trial has been instituted, and the Board has repeatedly and consistently given effect to a CoC that issued after the filing of a petition, where the correction eliminated a proposed ground of invalidity. *See, e.g.*, *Parsons Xtreme Golf, LLC v. Taylor Made Golf Co.*, IPR2018-00657, Paper 14 at 11 (P.T.A.B. Aug. 14, 2018); *Edwards*, IPR2019-01285, Paper 19 at 6–8; *SPTS Techs., Ltd. v. Plasma-Therm LLC*, IPR2018-00618, Paper 24 at 14–15 (P.T.A.B. Aug. 26, 2019). Petitioner's reliance on *Emerson* is inapposite, as there the Board declined to apply the correction 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 can lift the stay on the request for CoC and allow the Director to consider and issue the correction prior to a decision on institution. *Askeladden L.L.C. v. Encoditech, LLC*, IPR2017-00452, Paper 7 at 3–4 (P.T.A.B March 31, 2017) (finding that "[s]hould trial be instituted, it is in the interest of the parties and the public that the corrected claim be the subject of our final written decision.").

II. PETITIONER HAS NOT SHOWN A LIKELIHOOD OF SUCCEEDING ON THE MERITS FOR GROUNDS 3–4

"A patent need not teach, and preferably omits, what is well known in the art." *Spectra–Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987). Hardness testing was well-known and routine in the field by 2009, as demonstrated by the Petition and Petitioner's exhibits. *See* EX1104; EX1106. For example, USP <1217> provides guidance for testing hardness, and Petitioner admits that a POSA would have followed the USP's recommendations. EX1104, 677-678; Pet., 57-58, 76-77. Thus, a POSA would have known the appropriate process and calibration for testing hardness, so these parameters need not be described in the patent.

PO's EX2032 illustrates that while hardness values can vary among different hardness testers, the variation is not substantial. EX2032, 112-115; EX2007, ¶85. Petitioner's citations to the variability disclosed in EX2032 further bolsters the fact that a POSA would be well-aware of such variability, but Petitioner ignores the fact that a POSA would also be well-aware of how to test for hardness and know to ensure proper calibration and consistency for accurate results. EX1104, 677. Thus, there would be no undue experimentation to arrive at the claimed invention. Rather, a POSA reading the specification and the claims would know that the claimed range of 8-48 N would account for any variation between testers. EX2007, ¶85.

III. GROUNDS 5–6 ARE MOOTED BY THE COC

As explained above and in PO's Preliminary Response ("POPR"), the CoC will correct PO's typographical error and the '598 patent should be evaluated based on the corrected claims. Paper 8, 25–26. Thus, the '598 patent is entitled to a priority date of October 1, 2009 and Perrett cannot be prior art to the '598 patent.

IV. PETITIONER REPEATS THE SAME ART AND ARGUMENTS IN GROUNDS 7–12 AS IN IPR2024-01197

PO disclaimed the '729 patent and requested adverse judgment in IPR2024-01197 for resource purposes. PO's statutory disclaimer is not indicative of its acquiescence to Petitioner's arguments. *See SoftView LLC v. Apple Inc.*, 108 F.4th 1366, 1374–1375 (Fed. Cir. 2024) (finding that the application of estoppel after adverse judgment does not apply to already issued claims). Further, it is Petitioner who continues to relitigate the same art across multiple proceedings, not PO. *Compare* IPR2024-01197 (asserting obviousness in Grounds 1–4 over Dohil, Grother, FDA Guidance, and Venkatesh988) *with* this Petition (asserting obviousness in Grounds 7–12 over Dohil, Grother, FDA Guidance, and Venkatesh988).

As explained in the POPR, neither Kararli nor USP <1216> fill in gaps in the prior art, and the Board should deny institution on Grounds 7-12. Paper 8, 46–48, 65-67.

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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 SURREPLY** is being served via electronic email on the Petitioner by serving Petitioner's counsel of record as follows:

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