

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

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

V.

PGR2025-00086
Patent No. 12,290,598

PETITIONER’S REPLY TO PATENT OWNER’S PRELIMINARY RESPONSE

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OTHER AUTHORITIES

35 U.S.C. § 112	1, 2
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I. Grounds 1-2 Are Not Mooted By PO's Unauthorized COC Request

Ground 1 demonstrates lack of written description for the claimed hardness of “4-48 N.” Petition 24-28. Patent Owner (PO) admits this hardness is an “error” that lacks support. EX2001 1-2; POPR 17. Ground 2 demonstrates lack of enablement for the claimed “4-48 N” hardness, which PO does not dispute. POPR 19-20.

PO wrongly asserts that Grounds 1-2 are moot based on its unauthorized COC request to amend the scope of the claims to “8-48 N.” POPR 19-20. First, the Director should deny PO's COC request. 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. POPR 19-20. For § 112 to apply differently to the amended claim, the amendment must materially change the claim scope, which cannot be of the minor character required for a COC. MPEP § 1481.

PO consistently told the PTO—at least *five* times—that it sought to patent a hardness range of “4-48 N,” and PO never sought claims with a different hardness range. EX1096 151, 154, 156, 157. PO asserts that its requested amendment is clerical/typographical because Example 1 discloses a hardness of 8-48 N. POPR 19-

20. PO fails to address the alternative (and ambiguous) reference in its specification to ODTs that “exhibit sufficient hardness” values for packaging, transportation, and distribution. EX1001 16:43-48. The Examiner understood that PO sought to patent a hardness of “4-48 N.” EX1096 16. Thus, PO has not demonstrated that its supposed intent to patent 8-48 N is clearly manifest in the record.

Second, even if the Director were to grant PO’s COC request (which he should not), the amended claims would not apply retroactively to this PGR. *Emerson Elec. Co. v. SIPCO, LLC*, IPR2016-00984, Paper 52 at 6, 17-24 (PTAB 2020). This prevents the Board and the parties from litigating “a moving target.” *Id.* 22. Further, equitable considerations require PO to bear all the consequences of its negligence in patenting claims that violate § 112; not Petitioner or any other third-party as would be the case if the COC were to apply retroactively here. *Id.* 23-24.

II. Grounds 3-4 Cannot Be Mooted By PO’s Unauthorized COC Request

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 does not (and cannot) fill the void in its specification.

PO asserts that no guidance is required because measurements between automated/electronic hardness testers supposedly deviate by only 10%. POPR 10, 21-24. PO’s assertion is belied by its own exhibits and expert.

PO’s EX2033 concedes that comparing hardness values from different

automated testers is a “**particularly difficult**” task. EX2033 1.¹ It explains that each tester has its own “tester-specific” factors that “influence any tablet hardness measurement.” *Id.* 2. “Measured hardness values **may differ significantly** depending on the measuring principle used” and “[r]esults can also be higher/lower if different settings for speed or linear force increase are being used.” *Id.* 4.

PO’s EX2032 evaluates 16 automated hardness testers and reports that there is “**a highly significant difference between the 16 testers**,” EX2032 112, and the accuracy of hardness values **within any single tester** is “mostly” within $\pm 10\%$, which is a range of 20%. EX2032 109. Figure 4 shows the hardness measured between the S2E3, S6D4, S8M2, and Er28 testers varied **by nearly $\pm 15\%$ (a 30% range)**. *Id.* 114. Automated/electronic testers “do not produce uniform results for the same tablet due to operator variation, lack of calibration, spring fatigue, and manufacturer variation.” EX1107 928; EX1095 ¶¶133-135.

PO’s EX2032 demonstrates the difficulty in predicting and determining hardness values. In Table 4, MCC50 tablets were expected to have a hardness of 50 N, yet the hardness measured on the Er28 tester was 44.6 N (which **would** fall within the claimed range of 4-48 N), but other testers such as PH2 measured the hardness for the same MCC50 tablets as 53.1 N (which **would not** fall within the claimed range). EX2032 113 (Table 4).

¹ All emphases added unless otherwise noted.

PO's expert admits that "the composition of the tablet and the process used to make the tablet contribute to hardness." EX2007 ¶147. PO's specification fails to provide any guidance on tablet composition and processing to make ODTs having the full scope of the claimed hardness range. PO relies exclusively on Example 1 for supposed enablement, POPR 19, but this example cannot enable the full scope of the claims. Example 1 discloses an ODT containing **4 mg** of fluticasone, ***crospovidone XL-10*** as a disintegrant, and ***mannitol*** as an excipient; and the tablet was made via ***a specific wet-granulation process*** including a "pressure of about 1.25 bar and at a spray rate of 30-50 mL/min and an outlet temperature of >70° C," and ***a compression tableting process***. EX1001 17:40-18:23. In contrast, claim 1 broadly encompasses **0.5-6 mg** of fluticasone ***or budesonide, any disintegrant, and any unrecited excipients*** in an ODT ***made by any process***. *Id.* 18:50-61. A POSA would have to experiment with numerous tablet compositions, tableting processes, and testing parameters to empirically arrive at ODTs having the full scope of the claimed hardness range. Petition 34-37; EX1095 ¶¶133-144. This amount of experimentation is undue in view of the single example in the specification and its failure to provide any guidance on how hardness should be determined. *Id.*

PO's COC does not (and cannot) moot Ground 4 on indefiniteness. A POSA cannot be reasonably certain of the claimed ODT scope due to the highly statistically significant differences across hardness tester measurements. Petition 38-40.

III. Grounds 5-6 & 7-12 Cannot Be Mooted By PO's COC Request

As discussed above, PO's COC does not (and cannot) moot Ground 3 on lack of enablement. Thus, the '598 patent can only be entitled to a filing date of 01/05/2022. Petition 18-20, 41-51. Perrett issued on 07/08/2014 and is prior art such that Grounds 5-6 cannot be mooted, and neither can Grounds 7-12 be mooted.

IV. Grounds 7-12: The POPR Seeks To Relitigate Issues From IPR2024-01197

In IPR2024-01197, PO requested and received adverse judgment against its '729 patent. EX1118 3. PO seeks to relitigate the same issues by repeating—often verbatim—significant portions of its IPR2024-01197 POR in this POPR. *E.g., compare this POPR 41-46 with IPR2024-01197, Paper 18 (POR) at 23-27; compare this POPR 63-65 & 71-74 with IPR2024-01197, Paper 18 at 41-46.*

The only substantive difference between the '729 and '598 claims is the hardness/friability limitation. Here, Grounds 7-12 include Kararli and USP <1216> that demonstrate the desirability of ODTs with hardness/friability within the claimed range so the tablet has sufficient mechanical integrity for packaging, transportation, and patient handling. Petition 57-59, 75-77, 21. Grounds 7-12 warrant institution.

PO fails to show a nexus between its purported unexpected results from EX2002/EX2006 and the claims. POPR 76-78; *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1330-31 (Fed. Cir. 2017). There is no nexus because PO fails to show that EX2002/EX2006 disclose at least the disintegration limitation 1[iv].

Respectfully submitted,

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Dated: January 13, 2026

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
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