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. IPR2025-00056
U.S. Patent No. 11,260,061

PATENT OWNER'S SURREPLY

I. The Board Should Exercise its Discretion Under § 325(d)

The Office already considered Petitioner's primary reference (Perrett) and the key issue – adsorption – and found the claims patentable. There is no need for the Board to waste resources on rehashing the same art and arguments. The March 26, 2025 Interim Process for PTAB Workload Management Memorandum ("Interim Process") is designed to prevent institution of such petitions where Petitioner presents no new art or evidence, relies heavily on its expert declaration, and Petitioner's arguments are tenuous at best. *See* Interim Process, 2 (bullets 2-4, 6).

As explained in PO's Preliminary Response, the Examiner initially rejected the claims over Ramalho and Perrett. POPR, 9-11. Petitioner makes the exact same arguments as the Examiner that Perrett teaches adsorption of the corticosteroid onto a carrier. POPR, 10. None of Petitioner's arguments indicate any material error during prosecution. With regard to Perrett, the Examiner, like Petitioner, argued that Example 1 resulted in adsorption of the corticosteroid onto a carrier. Ex. 1056, 160-162. In response, PO correctly argued – based on the discussion of Perrett in the '061 specification – that Perrett's process did not adsorb the corticosteroid to a carrier, and instead resulted in agglomerated particles, which causes problems with content uniformity and efficacy. Ex. 1056, 111-112. As described in the specification, adsorption of the corticosteroid onto a carrier prevents this agglomeration and enhances the efficacy of corticosteroid in treating inflamed esophageal tissue. Ex.

1001, 3:23-38, 10:59-67. Contrary to Petitioner's assertion, PO is not required to claim the results of the adsorption, i.e. the prevention of agglomeration. Petitioner's Reply, 3-4. Rather, PO's arguments regarding preventing agglomeration, and improving content uniformity and efficacy are relevant to patentability because there is a nexus to the claim: adsorption of the corticosteroid to the carrier.

Further, Petitioner continues to ignore the fact that Perrett is cited to in the specification of the '061 patent to explain the precise problem in Perrett that the '061 patent overcomes. Petitioner has provided no actual evidence that Perrett's process resulted in adsorption, and instead relies on the opinion of Dr. Parr to assert that the mixing in Perrett necessarily results in adsorption. Pet., 21-23 (citing Ex. 1070, ¶¶ 131-147). The purpose of § 325(d) is to protect the Board from wasting resources on issues it has already decided and to protect patent owners from defending their patents against serial attacks using the same prior art and same arguments the Office already addressed. To institute would be a waste of the Board's time and resources. *See SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 365 (2018); *Chevron Oronite Co. v. Infineum USA L.P.*, IPR2018-00923, Paper 9 at 10-11 (P.T.A.B. Nov. 7, 2018) (Informative); *Deeper, UAB v. Vexilar, Inc.*, IPR2018-01310, Paper 7 at 41-43 (P.T.A.B. Jan. 24, 2019).

Because Petitioner cannot show that the Examiner materially erred in allowing the claims, Petitioner focuses on the EPO proceedings. Petitioner's Reply,

1-2. Petitioner seems to imply that "another forum" or "new judicial precedent" in the Interim Process applies to foreign forums and decisions. Petitioner's Reply, 1 (citing Interim Process at 2 (bullets 1-2)). But the EPO proceeding is not US precedent and is not binding on the Board. Further, the Federal Circuit has repeatedly cautioned against reliance on foreign proceedings, given that "the theories and laws of patentability vary from country to country, as do examination practices." *Heidelberger Druckmaschinen AG v. Hantscho Com. Prods., Inc.*, 21 F.3d 1068, 1072 n.2 (Fed. Cir. 1994); *Starhome GmbH v. AT&T Mobility LLC*, 743 F.3d 849, 858 (Fed. Cir. 2014); *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1279 (Fed. Cir. 2011) ("[P]recedent cautions against indiscriminate reliance on the prosecution of corresponding foreign applications."); *see also TI Grp. Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1136 (Fed. Cir. 2004).

Nevertheless, Petitioner has not demonstrated that the EPO decision warrants institution here. The Examiner considered various filings from the opposition proceeding involving EP3041476 during prosecution of the '061 patent, including the grounds for opposition and list of references cited. Ex. 1001, code (56). Thus, the Examiner was aware of the arguments being made at the EPO.

To save its Petition from denial, Petitioner also points to references, Wen and Martin, that are not part of Petitioner's asserted grounds. Petitioner's Reply, 3. As explained in the Preliminary Response, however, neither Wen nor Martin disclose

that adsorption necessarily occurs during mixing as Petitioner contends. POPR, 29, 36-37, 48. Regardless, because Petitioner does not assert Wen or Martin in any of its grounds for obviousness, they cannot be relied upon to bypass § 325(d). *KOA Corp. v. Vishay Dale Elecs.*, *LLC*, IPR2019-00201, Paper 30 at 77 (P.T.A.B. May 7, 2020) ("A reply that raises a new issue or belatedly presents evidence may not be considered.") (citation omitted). Further, Wen (Ex. 1054) was cited in an IDS which the Examiner initialed. Ex. 1056, 64. Thus, at least Wen was considered by the Examiner during prosecution.

In its Reply, Petitioner only makes a conclusory statement that Dohil2009 and Venkatesh disclose some mixing/grinding and relies on an institution decision for an unrelated patent with claims that do not recite the feature at issue – adsorption. Petitioner's Reply, 4. Such conclusory statements are inadequate to demonstrate material error. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness."). Regardless, the Examiner considered cumulative art during prosecution of the '061 patent, and both Dohil2009 and Venkatesh appear on the face of the '061 patent. POPR, 18; Ex. 1001, code (56). Further, as explained in PO's Preliminary Response, Dohil2009 alone, or in combination with Venkatesh, would

not result in the claimed adsorption of the corticosteroid onto a carrier. POPR, 44-54.

I. Plain and Ordinary Meaning Of "Adsorbed"

Petitioner's construction of "adsorbed" is unreasonably broad, not supported by any evidence, and not the view of a POSA. Pet., 18-19; Petitioner's Reply, 5-7. Petitioner again fails to point to any intrinsic evidence supporting its construction. Petitioner's Reply, 5-7. Instead, Petitioner relies on the EPO proceeding and other extrinsic evidence for its construction which is divorced from the plain and ordinary meaning of the term and misconstrues the teachings of the extrinsic evidence on which it relies. Petitioner's Reply, 5-7.

As an initial matter, Petitioner doubles down on its assertion that the plain and ordinary meaning "includes" disposition. Petitioner's Reply, 7. This is improper as it is impossible for PO to know what else Petitioner contends the plain and ordinary meaning of "adsorbed," "includes". Rather, Petitioner appears to be attempting to broaden the definition to be unlimited in scope. Nevertheless, PO will understand Petitioner's construction to be limited to "the reversible disposition of a corticosteroid particle on the surface of a pharmaceutically acceptable carrier."

Petitioner relies on Wen to support its construction, which describes the interactions involved in adsorption. Petitioner's Reply, 6. While Wen describes adsorption as including van der Waals force, hydrogen bonding or electrostatic

force, (Ex. 1054, 34), noticeably absent is any reference to "disposition." Relying on an illustration, Petitioner asserts particles in Wen are adsorbed "by depicting drug particles disposed and distributed over the carrier surface." Petitioner's Reply, 6 (citing Ex. 1054, Fig. 1). Nowhere does Wen state that these particles are merely disposed on the carriers. Rather, the drug particles are adsorbed onto a carrier and thus retained on the surface of the carrier by the forces described in Wen. Ex. 1054, 34.

Petitioner also takes issue with PO's reliance on a nontechnical dictionary definition for "dispose" and "adsorb." Petitioner's Reply, 6. This is an odd argument since Wen does not use the term "dispose," and a POSA would need to consult the nontechnical definition of terms like "dispose" or "disposition," which Petitioner does not indicate is a technical term of art. Regardless, Petitioner's own technical dictionary defines "adsorption" as having "surface retention" which is consistent with PO's definition. Pet., 19; Ex. 1060, 41. Thus, as explained in PO's Preliminary Response, a POSA would understand adsorption to require surface retention or adhesion, and not merely be disposed onto a carrier. POPR, 27-28.

Finally, Perrett's and the '061 patent's disclosure of a corticosteroid "disposed on the surface of the adhesive agent" was already considered by the Examiner and is a separate embodiment from the invention claimed in the '061 patent. The prosecution history of the '071 patent further illustrates the distinction between

"disposed on the surface of the adhesive agent" and "adsorbed onto a carrier." Ex. 1068. The '061 patent claims priority to the '071 patent and thus, the prosecution history of each patent in a family of patents is relevant to construing the claims of all patents in that family. *See, e.g.*, *NTP, Inc. v. Rsch. in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) ("Because [the] patents all derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents."). In particular, original claim 4 of the '071 patent claimed a pharmaceutical composition "wherein the pharmaceutically acceptable carrier for adsorption of the corticosteroid is selected from" a group of carriers that do not include an adhesive agent. Ex. 1068, 114. Original claim 24 further comprised an adhesive agent. Ex. 1068, 117. Thus, the adhesive agent is not considered an acceptable carrier for adsorption. As such, the '061 patent does not simply use a different word as Petitioner contends, but rather means something different by the term "adsorbed." Petitioner's Reply, 3.

As described in the Preliminary Response, PO's construction is supported by the intrinsic evidence and bolstered by a POSA's understanding of the term "adsorption." POPR, 25-27. The Board should therefore adopt PO's construction and reject Petitioner's construction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify, pursuant to 37 C.F.R. Section 42.6, that a complete copy of the attached **PATENT OWNER'S SURREPLY** is being served via electronic mail the 7th day of May 2025, on Petitioner by serving the Petitioner's counsel of record in this proceeding as follows:

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