

Filed: April 23, 2025

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

By: Nathanael Luman (Reg. No. 63,160)
Eric S. Furman (Reg. No. 45,664)
Jared C. Bunker (Reg. No. 58,474)
KNOBBE, MARTENS, OLSON & BEAR, LLP
3579 Valley Centre Drive, Suite 300
San Diego, CA 92130
Ph: 949-760-0404
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

Case No. IPR2025-00056
Patent No. 11,260,061

**PETITIONER'S REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

I. The Board Should Not Apply 35 U.S.C. § 325(d)

Patent Owner (PO) seeks to avoid scrutiny of its claims under the Board's two-step *Advanced Bionics* §325(d) test. The Board previously rejected PO's §325(d) arguments in the related matter of *Dr. Falk Pharma v. Ellodi*, IPR2024-01197, Paper 10 at 24-42 (PTAB 2025). It should do the same here.

PO only disputes whether Perrett, Dohil2009, and Venkatesh disclose active ingredients *adsorbed* onto the surface of a carrier. Under *Advanced Bionics* Step 2,¹ the Board should institute trial because the Examiner did not have the benefit of (1) the EPO decision that Perrett discloses the claimed adsorption (EX1062), (2) the encyclopedia (Wen, EX1054) and textbook (Martin, EX1055) explaining that adsorption occurs during mixing, (3) the expert declaration of Dr. Parr (EX1070), or (4) this IPR Petition. PO also made misleading statements during examination. These circumstances led the Office to materially err in allowing the claims.

PO admits that the EPO “found Perrett to disclose” the adsorbed claim limitation. POPR 39. PO fails to identify any errors in the EPO's decision. The EPO rendered its decision *after* the U.S. Examiner allowed the claims. EX1056 3-6; EX1062 17-19, 23. The Examiner did not have the benefit of the EPO's well-reasoned decision, which is relevant to institution. *See* March 26, 2025 Interim Process for PTAB Workload Management Memorandum at 2 (bullet points 1 & 2).

¹ The parties agree that *Advanced Bionics* Step 1 applies in this proceeding.

Contrary to the EPO decision, PO asserted during prosecution of the '061 patent and grandparent U.S. 10,471,071 that it is *impossible* for Perrett to teach or suggest the “adsorbed” limitation. EX1068 75 (“Perrett does not, and cannot, teach or suggest a corticosteroid adsorbed onto a pharmaceutically acceptable carrier.”); *id.* 73-76; EX1056 111-12. The U.S. Examiner withdrew obviousness rejections in view of PO’s assertion, which it repeats here. EX1068 57; EX1056 46; POPR 34. This assertion is wrong and led to Office error for numerous reasons.

First, the '061 patent concedes that adsorption occurs via mixing. EX1001 10:5-8; EX2001 ¶47 (admitting adsorption via blending). Perrett discloses such mixing/blending. Petition 21-24. PO admits Perrett was expected to “have resulted in adsorption.” POPR 37. Yet PO asserts there was no actual adsorption when Perrett mixed for 3-5 minutes because 10 ± 1 minutes is needed for adsorption. *Id.* 34-35 (citing EX1001 Examples 2-3). This time difference is inconsequential. At most it is a matter of degree. The EPO determined that adsorption “covers different degrees and mechanisms of adsorption” and rejected PO’s position that adsorption can only be obtained with the specific mixing times from the '061 specification. EX1062 15-16. At least some adsorption occurs via Perrett’s mixing. *Id.* 18; EX1070 ¶¶132-147.

Second, the '061 specification concedes that some of Perrett’s corticosteroid “may not” be readily exposed to tissues because the drug particles “may” be present in granules. EX1001 3:19-23. “May not” is permissive language that fairly indicates

some of Perrett's corticosteroid may be readily exposed to tissues because the drug particles are also present on the surface of the granules. The EPO found that Perrett discloses corticosteroid surface adsorption and "[t]here can be adsorption onto the surface and simultaneously or subsequently also agglomeration." EX1062 15.

Third, the Examiner did not appear to consider Perrett's claim that "the corticosteroid is disposed over the surface of an excipient." EX1057, Claims 19, 22, ¶[0063]. The Examiner appears to have overlooked that PO merely used different language (here, "adsorbed") to reclaim the same subject matter it previously claimed in Perrett and erroneously asserted was missing from the prior art to improperly extend its patent estate and restrict competition. EX1070 ¶145; Petition 75-77.

Fourth, the Examiner did not have the benefit of Wen or Martin, which teach adsorption occurs via mixing. EX1054 35 ("During mixing... adsorption generally plays a role when the average particle size is $\leq 400 \mu\text{m}$."); EX1055 383; Petition 21. The '061 patent admits Perrett's corticosteroid was "micronized" to small particle sizes. EX1001 3:19-23; EX1057 ¶¶[0066]-[0067] (e.g., "1-300 μm "). Perrett's micronized drug particles adsorb onto the carrier during mixing. Petition 21-24.

Also, PO misleadingly asserted during prosecution that it allegedly solved an unrecognized problem of Perrett "consist[ing] of agglomerated corticosteroid granules that are not uniformly dispersed." EX1068 75; EX1056 111. It reasserts that allegation here. POPR 1-3, 13. PO's assertion is misleading because none of the

claims recite anything about preventing “agglomeration.” For obviousness, “[w]hat matters is the objective reach of the claim,” not “the particular motivation nor the avowed purpose of the patentee.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). It was common knowledge that surface adsorption reduces agglomeration and promotes content uniformity. *Wen* (an encyclopedia) teaches that “adsorbing small drug particles onto the surface of large excipients” was a known solution for achieving content uniformity (EX1054 34) and was “very beneficial.” *Id.* 35.

Dohil2009 was merely cited in an IDS, and Venkatesh was only cited in an IDS and the specification. This “weighs strongly” in favor of institution. *SolarEdge Techs. Ltd. v. SMA Solar Tech.*, IPR2020-00021, Paper 8 at 10-12 (PTAB 2020). Dohil2009 and Venkatesh disclose mixing/grinding micronized active ingredient with a pharmaceutical carrier that leads to adsorption. Petition 42-45, 58. This adsorption is the exact disclosure PO asserted was missing from the prior art that led the Examiner to err in allowing the claims. EX1056 46, 111-12; EX1068 57, 73-76.

PO argues Dohil2009 does not render obvious ODTs that dissolve within 60 seconds via USP <701>. POPR 45. The Patent Office already rejected this argument in IPR2024-01197, Paper 10 at 37-42 (PTAB 2025). PO asserts that Dohil2009’s disclosure of ODTs and grinding is “limited” and “sparse.” POPR 44, 47. But Dohil2009 is “considered for everything that it teaches, not simply [its] preferred embodiment.” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012).

PO concedes that Venkatesh discloses milled drug particles that are blended with a binder and granulated with diluents. POPR 38. This leads to adsorption according to the '061 patent (EX1001 10:5-8; Petition 58), which the Examiner appears to have overlooked. The Office therefore erred in allowing the '061 patent.

II. Construction of “adsorbed onto a pharmaceutically acceptable carrier”

The parties dispute the meaning of “adsorbed.” PO seeks an overly narrow construction of this term to avoid its own Perrett reference, which should be rejected.

The EPO determined that adsorbed is “broad and covers different degrees and mechanisms of adsorption,” including Perrett. EX1062 15-18; Petition 13-15. PO had a full and fair opportunity to litigate this issue at the EPO. PO seeks to relitigate this issue by asking the Board to reach the opposite conclusion and upset principles favoring “interjurisdictional uniformity” and international comity. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-91 (1996); *Cochran Consulting, Inc. v. Uwatec USA, Inc.*, 102 F.3d 1224, 1229 (Fed. Cir. 1996) (comity).

Petitioner’s construction encompasses the “disposed on the surface” embodiment from the '061 patent specification. EX1001 8:63-65. PO’s construction seeks to exclude this embodiment and disregards the “strong presumption against a claim construction that excludes a disclosed embodiment.” *Nobel Biocare Serv. v. Intradent USA*, 903 F.3d 1365, 1381 (Fed. Cir. 2018). PO seeks to rewrite its claim with a new negative limitation excluding its “disposed” embodiment, which would

be error. *Omega Eng'g v. Raytek*, 334 F.3d 1314, 1322-23, 1333 (Fed. Cir. 2003).

Petitioner agrees with PO that “adsorption” includes adhesion, *but disagrees* that adsorption excludes disposition of corticosteroid particles on the carrier. Petitioner provides Wen (a pharmaceutical encyclopedia), which includes a technical description of adsorption. EX1054 34. Wen explains that forces involved in adsorption broadly include “van der Waals force, hydrogen bonding or electrostatic force in physical adsorption, and covalent chemical bonds in chemical adsorption” and adsorption is “involved in nearly every aspect of pharmaceutical development.” EX1054 34. PO agrees that adsorption is based on these forces. POPR 26-27. Wen illustrates adsorption by depicting drug particles disposed and distributed over the carrier surface. EX1054, Fig. 1; EX1070 ¶¶121-122, 145.

In contrast, PO relies on a nontechnical dictionary definition of “dispose” to assert that disposition means “arrangement.” POPR 27. The dictionary actually defines “dispose” broadly as “to place, distribute, or arrange.” EX2002 361. PO relies on the same dictionary to assert that “adsorption” must be limited to “adhesion.” POPR 26-29; EX2002 18. The dictionary does not state that “disposition” of drug particles on a carrier is excluded from “adsorption,” and it would be improper to interpret “adsorption” so narrowly in view of the broader technical description and depiction of adsorption in Wen.

PO nonsensically asserts that Perrett’s and the ’061 patent’s disclosure of

corticosteroid “disposed on the surface of the adhesive agent” cannot be adsorption because the corticosteroid is allegedly disposed on an excipient to promote adhesion to a *biological surface* instead of to a *carrier*. POPR 28-29; EX1057 ¶[0063]; EX1001 8:63-65. PO ignores that surface disposition of the corticosteroid on the excipient promotes adhesion to biological surfaces such that the excipient carries the corticosteroid to the biological surface. The corticosteroid is therefore adsorbed on the surface of the adhesive agent excipient, which is a carrier. EX1070 ¶145.

Martin explains that physical adsorption “is reversible.” EX1055 380. Petitioner’s construction acknowledges this reversibility. PO’s does not.

PO asserts that Petitioner’s construction is “unclear” because it “*includes*” disposition on the carrier surface. POPR 27. Petitioner’s construction resolves the controversy as to adsorption encompassing the ’061 patent’s disclosure of corticosteroid “disposed on the surface” of an excipient and is appropriate because terms need only be construed “to the extent necessary to resolve the controversy.” *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

Finally, the EPO found Perrett discloses adsorption because a POSA understood its mixing process will “lead to at least some adhesion” of drug to carrier. EX1062 18; Petition 45. Perrett, Dohil2009, and Venkatesh disclose and render obvious mixing processes that the ’061 patent teaches lead to adsorption even under PO’s narrow “adhesion” construction. EX1001 10:5-8; Petition 21-24, 42-45, 58.

Dated: April 23, 2025

Respectfully submitted,

By: /Nathanael R. Luman/

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

Attorney for Petitioner,
Dr. Falk Pharma GmbH

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
**PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY
RESPONSE** was served by email on the Patent Owner at the following email
addresses:

ssukduang@cooley.com; jcousin@cooley.com;

jdavies@cooley.com; iagarwal@cooley.com; Ellodi_IPR@cooley.com

Dated: April 23, 2025

By: /Nathanael R. Luman/

Nathanael Luman (Reg. No. 63,160)

KNOBBE MARTENS OLSON & BEAR, LLP