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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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DR. FALK PHARMA GMBH,
Petitioner,

v.

ELLODI PHARMACEUTICALS, L.P.,
Patent Owner.

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PGR2025-00086
Patent No. 12,290,598

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# PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL

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*Resideo Techs., Inc. v. Ubiquitous Connectivity, LP*,
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*ResMed Inc. v. New York Univ.*,
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*SimpleAir, Inc. v. Google LLC*,
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*Toyota Motor Corp. v. Autoconnect Holdings LLC*,
PGR2025-00041, Paper 9 (Dir. Stewart, Sept. 8, 2025).....17

## TABLE OF AUTHORITIES
## (*cont'd*)

**Page No(s).**

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IPR023-00172, Paper 12 (PTAB 2023).....12

## OTHER AUTHORITIES

AIA § 3.....4

35 U.S.C. § 102.....2, 10, 13

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35 U.S.C. § 255.....5, 6, 7, 8

35 U.S.C. § 325.....1, 8, 9

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37 C.F.R. § 42.23 .....19

37 C.F.R. § 42.221 .....6

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# LIST OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 1001 | U.S. Patent No. 12,290,598 to Perrett et al. |
| 1002 | U.S. Publication No. 20070111978 to Dohil et al. |
| 1003 | RESERVED |
| 1004 | The Opposition Division of the European Patent Office decision revoking EP2484822B1 with auxiliary requested claims |
| 1005 | "Guidance for Industry: Orally Disintegrating Tablets," U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2008. |
| 1006 | RESERVED |
| 1007 | "DRAFT Guidance for Industry: Orally Disintegrating Tablets," U.S. Food & Drug Administration, Center for Drug Evaluation and Research (CDER), 2007. |
| 1008 | International Publication No. WO2000044351 to Grother et al. |
| 1009 | Svoboda et al., "Oral formulations of budesonide: a novel treatment for inflammatory bowel disease," Drugs of Today, 44:857-863 (2008) at 857. |
| 1010 | Tan et al., "Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets," European Journal of Gastroenterology & Hepatology, 13:425-427 (2001) |
| 1011 | Kolkman et al., "Evaluation of oral budesonide in the treatment of active distal ulcerative colitis," Drugs of Today, 40:589-601 (2004) |
| 1012 | Siewert et al., "Eosinophilic gastroenteritis with severe protein-losing enteropathy: Successful treatment with budesonide," Digestive and Liver Disease, 38:55-59 (2006) |

| Exhibit No. | Description |
|---|---|
| 1013 | Elsing et al., "Budesonide for the treatment of obstructive eosinophilic jejunitis," Z. Gastroenterology, 45:187-189 (2007). |
| 1014 | Aceves et al., "Topical viscous budesonide suspension for treatment of eosinophilic esophagitis," Journal of Allergy and Clinical Immunology 116:705-706 (2005) |
| 1015 | Aceves et al., "Oral Viscous Budesonide: A potential new therapy for eosinophilic esophagitis in children," American Journal of Gastroenterology, 102:1-9 (2007) |
| 1016 | RESERVED |
| 1017 | Danckwerts, "Intraoral Drug Delivery: A Comparative Review," American Journal of Drug Delivery, 1:171-186 (2003). |
| 1018 | Fu et al., "Orally fast disintegrating tablets: developments, technologies, taste-masking and clinical studies," Critical Reviews in Therapeutic Drug Carrier Systems, 21:433-475 (2004) |
| 1019 | Shukla et al., "Mouth Dissolving Tablets I: An overview of formulation technology," Scientia Pharmaceutica, 77:309-326 (2009) (March 6, 2009) |
| 1020 | U.S. Publication No. 20050232988 to Venkatesh et al. ("Venkatesh988") |
| 1021-1024 | RESERVED |
| 1025 | Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 11th edition, eds. Brunton, Lazo, Parker, 2005 |
| 1026 | Budenofalk® Brochure (2005) |
| 1027 | Budenofalk® Advertisement (2007) |
| 1028 | Dr. Falk Pharma Brochure (2008) |
| 1029 | *Curriculum Vitae* of Alan F. Parr, Pharm.D., Ph.D. |

| Exhibit No. | Description |
|---|---|
| 1030 | RESERVED |
| 1031 | Prosecution history excerpts from U.S. Application No.12/896,005 |
| 1032 | RESERVED |
| 1033 | Teitelbaum et al., Eosinophilic esophagitis in children: Immunopathological analysis and response to fluticasone propionate," Gastroenterology 122:1216-1225 (2002) |
| 1034 | Noel et al., "Clinical and immunopathologic effects of swallowed fluticasone for eosinophilic esophagitis," Clinical Gastroenterology and Hepatology 2:568-575 (2004) |
| 1035 | U.S. Patent No. 7,122,198 to Singh et al. |
| 1036 | U.S. Patent No. 7,229,641 Cherukuri et al. |
| 1037-1039 | RESERVED |
| 1040 | USP Convention 701 Disintegration, Revision Bulletin August 1, 2008 |
| 1041 | Conway, "Solid dosage forms," Chapter 4.1 in Pharmaceutical Manufacturing Handbook: Production and Processes, ed. Gad, pages 235-265 (2008) |
| 1042-1046 | RESERVED |
| 1047 | El-Arini et al., "Evaluation of disintegration testing of different fast dissolving tablets using the texture analyzer," Pharmaceutical Development & Technology, 7:361-371 (2002) |
| 1048-1063 | RESERVED |
| 1064 | Roeder et al., "Safety and efficacy of fluticasone propionate in the topical treatment of skin diseases," Skin Pharmacology Physiology, 18:3-11 (2004) |

| Exhibit No. | Description |
|---|---|
| 1065 | Remedios et al., "Eosinophilic esophagitis in adults: clinical, endoscopic, histologic findings, and response to treatment with fluticasone propionate," Gastrointestinal Endoscopy, 63:3-12 (2006) |
| 1066 | Konikoff et al., "A randomized, double-blind, placebo-controlled trial of fluticasone propionate for pediatric eosinophilic esophagitis," Gastroenterology, 131:1381-1391 (2006) |
| 1067-1094 | RESERVED |
| 1095 | Declaration of Alan F. Parr, Pharm.D., Ph.D. supporting PGR petition of U.S. 12,290,598 |
| 1096 | Prosecution history excerpts from U.S. Application No. 17/569,047, which issued as U.S. 12,290,598 |
| 1097 | U.S. Application No. 17/569,047 as filed on January 5, 2022 ("the '047 Application") |
| 1098 | U.S. Application No. 16/821,464 as filed on March 17, 2020 ("the '464 Application") |
| 1099 | U.S. Application No. 15/816,154 as filed on November 17, 2017 ("the '154 Application") |
| 1100 | U.S. Application No. 15/205,390 as filed on July 8, 2016 ("the '390 Application") |
| 1101 | U.S. Application No. 14/311,732 as filed on June 23, 2014 ("the '732 Application") |
| 1102 | U.S. Application No. 12/896,005 as filed on October 1, 2010 ("the '005 Application") |
| 1103 | U.S. Provisional Application No. 61/247,642 as filed on October 1, 2009 ("the '642 Application") |
| 1104 | The United States Pharmacopeia, USP 31, 2008 ("USP") |

| Exhibit No. | Description |
|---|---|
| 1105 | The European Pharmacopeia, 6.0, 2008 |
| 1106 | Remington: The science and practice of pharmacy, 20th edition, pages 882-884 (2000). |
| 1107 | Lee, "Pharmaceutical Preformulation," in Pharmaceutical Manufacturing Handbook: Production and Processes, pages 881-931 (2008). |
| 1108 | Seitz et al., "Evaluation of the physical properties of compressed tablets I," Journal of Pharmaceutical Sciences, 54:1353-1357 (1965) |
| 1109 | U.S. Patent No. 8,771,729 to Perrett et al. |
| 1110 | International Publication No. WO2002015884 to Kararli et al. ("Kararli") |
| 1111 | International Publication No. WO2009006516 to Venkatesh et al. ("Venkatesh516") |
| 1112 | International Publication No. WO2010127345 to Venkatesh et al. ("Venkatesh345") |
| 1113 | International Publication No. WO2010127346 to Venkatesh et al. ("Venkatesh346") |
| 1114-1116 | RESERVED |
| 1117 | Petitioner's Reply Brief, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.,* IPR2024-01197, Paper 20 |
| 1118 | Judgment Granting Request for Adverse Judgment after Institution of Trial, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, IPR2024-01197, Paper 41 (PTAB 2025) |
| 1119 | 2024-10-23 Transcript of Oral Hearing Dismissing Complaint, *Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma*, Case No. 24-cv-01392-PTG (E.D. Va) |

| Exhibit No. | Description |
|---|---|
| 1120 | Judgment Against Ellodi in *Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH*, Case No. 4b O 43/24, Regional Court of Dusseldorf, Germany (Feb. 27, 2025) – Original German Language |
| 1121 | Judgment Against Ellodi in *Ellodi Pharmaceuticals, L.P. v. Dr. Falk Pharma GmbH*, Case No. 4b O 43/24, Regional Court of Dusseldorf, Germany (Feb. 27, 2025) – Certified English Language Translation |
| 1122-1128 | RESERVED |
| 1129 | PTAB email instructing Ellodi Pharmaceuticals that declaration evidence may not be submitted with Patent Owner's Sur-reply, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, IPR2024-01197, EX3003 |
| 1130 | Email exchange between PTAB and Ellodi Pharmaceuticals regarding improper exhibits submitted with Patent Owner's Sur-reply, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P* IPR2024-01197, EX3004 |
| 1131 | Patent Owner's Opposition To Petitioner's Motion For Additional Discovery, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.,* IPR2025-00052, Paper 22 |
| 1132 | Patent Owner's Opposition To Petitioner's Motion For Additional Discovery, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.,* IPR2025-00054, Paper 23 |
| 1133 | Email exchange between PTAB and the Parties regarding additional discovery and false statement in Patent Owner Opposition brief, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, IPR2025-00052 and IPR2025-00054, EX3001 |
| 1134 | Petitioner's email to the Director regarding Patent Owner's unauthorized request for Certificate of Correction, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.*, PGR2025-00086 |
| 1135 | Patent Owner's Response, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.,* IPR2025-00052, Paper 15 |

| Exhibit No. | Description |
|---|---|
| 1136 | Patent Owner's Response, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.,* IPR2025-00054, Paper 16 |
| 1137 | Patent Owner's Response, *Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P.,* IPR2025-00055, Paper 15 |

The Director evaluates the following relevant factors in determining to institute trial: (1) the strength of the unpatentability challenges, (2) *Advanced Bionics* and 35 U.S.C. § 325(d), (3) lack of settled expectations, (4) the PTAB and other forum adjudications from related proceedings, and (5) public health interests. Each of these factors favor institution. The Board should institute trial.

## I. PETITIONER'S UNPATENTABILITY CHALLENGES ARE EXCEPTIONALLY STRONG

This PGR Petition presents the strongest case of § 112 violations that the Director is likely to see. The '598 patent violates § 112(a) because it lacks written description for the claimed hardness range of "4-48 N." Petition 24-28 (Ground 1). Indeed, Patent Owner (PO) openly admits in its unauthorized request for Certificate of Correction (COC) that the claimed hardness range is an "error" that lacks written description support because a hardness range of "8-48 N" is "the only one disclosed" in the specification. EX2001 1-2; PO's Discretionary Denial Brief (DDB) at 5 (admitting "the only hardness value disclosed in the specification is '8-48 N'").

PO does not dispute that it added the unsupported hardness limitation via amendment during prosecution. EX1096 151-156. The '598 patent cannot claim priority to any of PO's applications that were filed before March 16, 2013 because none of those applications provide written description support for the claimed hardness range. Petition 18-20, 25-28. The '598 patent is only entitled to a filing date of January 5, 2022 (the date on which the application that issued as the '598

patent was filed), which is clearly after March 16, 2013, thereby confirming that the '598 patent is eligible for PGR.

PO asserts that it was merely negligent in patenting claims with a hardness of "4-48 N" because it "intended to amend the claim to recite a hardness value of 8-48 N." EX2001 2. Whether PO violated § 112 intentionally or negligently does not matter, as there is no AIA negligence exception for PGR eligibility and unpatentability. Even accepting PO's representation that it lacked intent to violate § 112, PO was at least grossly negligent during prosecution because it repetitively and 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 (claim 1), 154 (claims 33 and 35), 156, 157. The merits of Ground 1 are exceptionally strong in view of PO's admission that the hardness range in its issued claims lack written description support.

Grounds 2-3 are based on PO's violations of § 112(a) for lack of enablement, and Ground 4 is based on PO violating § 112(b) for indefiniteness. PO does not dispute that there is no enablement or definiteness for the "4-48 N" hardness recited in its issued claims. DDB 6. Grounds 2-4 are therefore exceptionally strong as well.

Grounds 5-6 are based on § 102 anticipation and § 103 obviousness over Perrett. In view of PO's admission that the claimed hardness of "4-48 N" is erroneous and lacks written description support, Perrett constitutes prior art to the

'598 patent. Petition 41; *id.* 18-20. PO admits that Perrett "shares the same specification" as the '598 patent and discloses an ODT "containing a topical corticosteroid that is deposited on the esophagus, with a hardness value of 8-48 N and a friability of no more than 0.1%." DDB 10. This disclosure clearly anticipates and renders obvious all claims of the '598 patent. Petition 41-51. These grounds are extremely strong and likely to prevail.

Grounds 7-12 are based on obviousness over prior art that includes Kararli and USP <1216>. Kararli and USP <1216> demonstrate that the POSA was well aware of the common-sense desirability of formulating ODTs with a hardness falling between 4-48 N and a friability of not more than 1% to ensure that the tablet has sufficient mechanical integrity to withstand the rigors of packaging, transportation, and patient handling. Petition 57-59. PO admits that the Examiner believed the prior art did not disclose ODTs having such a hardness or friability. DDB 18. Kararli and USP <1216> therefore provide the disclosures that the Examiner mistakenly believed were missing from the prior art when the claims were erroneously allowed. The combination of references provided in Grounds 7-12 provide strong and compelling evidence of obviousness.

## A. Patent Owner's COC Request Does Not Moot Grounds 1-4 And The '598 Patent Is Eligible For PGR

PO wrongly asserts that Grounds 1-4 are moot because it submitted an unauthorized request for COC seeking to change the scope of the issued claims to

supposedly bring the issued claims into compliance with § 112. DDB 6. As a preliminary matter, the Director appropriately stayed PO's unauthorized COC request. Paper 7. The Director has not yet ruled on PO's requested COC. As discussed below in Section I.B, the Director should deny PO's requested amendment because it does not comply with the statutory requirements for COCs.

Second, even if the Director were to grant PO's COC request (which it should not, *see infra* Section I.B), the COC would not convert the '598 patent from a PGR-eligible AIA patent to a pre-AIA patent. The AIA applies to a challenged patent if it "contains ***or contained at any time***" a claim having an effective filing date after March 16, 2013. AIA § 3(n)(1);[1] *Inguran, LLC v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 8 at 9-11 (PTAB 2015); Petition 18-20. This is true if there exists even a single claim having an effective filing date after March 16, 2013, and it is true even if the claim having an effective filing date after March 16, 2013 is subsequently disclaimed, amended, or corrected. *Unified Patents, LLC f/k/a Unified Patents Inc. v. Pebble Tide LLC*, PGR2020-00011, Paper 12 at 19-20 (PTAB 2020).

As discussed above, PO openly admits that the '598 patent presently contains a claim that violates § 112 because the specification does not describe the claimed hardness of "4-48 N." EX2001 1-2; DDB 5. PO added the unsupported hardness limitation via amendment during prosecution. EX1096 151-156. The specification

[1] All emphases supplied unless otherwise noted.

of the '598 patent does not describe an ODT with a hardness of "4-48 N," and neither do any of PO's priority applications. Petition 25-28. The '598 patent is therefore only entitled to a filing date of January 5, 2022 (the date on which the '598 application was filed). The '598 patent therefore presently contains, and will forever hereafter have contained, a claim with an effective filing date after March 16, 2013. Thus, regardless of whether PO's COC request is ever granted, the patent will have contained a claim having an effective date after March 16, 2013. As a result, the '598 patent is undoubtably PGR eligible. Petition 18-20.

## B. The Director Should Deny Patent Owner's Unauthorized COC Request

The Director has jurisdiction over PO's request for COC. 35 U.S.C. § 255 ("the ***Director*** may… issue a [COC]"). The Director should deny PO's request.

By statute, 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 considered to be of the 'minor' character required for the issuance of a [COC] 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 range 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. DDB 6. For § 112 to apply differently to the amended claim, the amendment must materially change the claim scope. Such a change cannot be

of the minor character required by § 255 because it "would materially affect the scope" of the patent. MPEP § 1481. Instead, the appropriate path for PO to seek to change the '598 patent claim scope is via reissue or motion to amend. MPEP § 1481 ("Usually, any mistake affecting claim scope must be corrected by reissue."); 37 C.F.R. § 42.221 (authorizing a motion to amend in PGR). The PTAB has declined to apply a COC in a PGR because it would "essentially circumvent[] the [Rule 42.221] amendment process that Congress designed" for PGR proceedings. *Election Sys. & Software, LLC v. Hart Intercivic, Inc.*, PGR2020-00031, Paper 18 at 9 (PTAB 2021). Here, the Director should deny PO's COC request.

**C. Patent Owner Wrongly Sought To Evade Accountability In This PGR**

One month after Petitioner filed this PGR petition, PO attempted to evade accountability for its unpatentable claims in this PTAB proceeding by filing a request for COC with the COC Branch. EX2001. PO filed its COC request without seeking the required authorization from the Director and without notifying Petitioner in violation of 37 C.F.R. § 42.3 and Paper 3 (Notice of Filing Date Accorded) at 2. Worse yet, PO withheld relevant information from the COC Branch by failing to inform it that this PGR is pending. PO wrongly sought to deprive the PTAB of its right to exercise its exclusive jurisdiction over the '598 patent and its responsibility to ensure that the patent is consistently managed throughout the Office.

Petitioner notified the Director of PO's unauthorized and improper COC

request on November 18, 2025. EX1134. The PTAB appropriately stayed PO's unauthorized COC request on December 18, 2025. Paper 7; 37 C.F.R. § 42.3.

**D. Any Granted COC Would Not Apply Retroactively To This PGR**

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 proceeding. By statute, COCs apply only to causes of actions arising after a COC issues. 35 U.S.C. § 255 (COCs apply only to "trial of actions for causes thereafter arising"). The PTAB has explained that, even "assum[ing], without deciding," that a PGR is not a "trial of actions" under § 255, the statute "does not contain any affirmative language indicating any intention to retroactively apply" a COC in a PTAB proceeding, and any retroactive application of a COC to a PTAB proceeding "would be inconsistent with the plain language [of § 255], which communicates that Congress contemplated only prospective application of a [COC]." *Emerson Elec. Co. v. SIPCO, LLC,* IPR2016-00984, Paper 52 at 18 (PTAB 2020); *id.* 20 ("the logical and natural reading of § 255 is that… a [COC]… does not receive retroactive application"); *see generally id.* 6, 17-24. This policy prevents the parties and the Board from having to address "a moving target" of claim scope during a PTAB proceeding. *Id.* 22.

In addition, "equitable considerations support giving § 255 only prospective application" because it is not unreasonable "to expect a patentee to check a patent when issued in order to determine whether it contains any errors that require [a

COC]." *Id.* 23 (quoting *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1296 (Fed. Cir. 2000)). Here, PO's gross negligence and lack of diligence in patenting claims that violate § 112 "has potentially negative consequences for the public, who may allocate its affairs based on the patent as issued, unaware of any such error." *Id.* Section 255 indicates that Congress intended for PO to bear all of the consequences of its negligence; not Petitioner or any other third-party as would be the case if the COC were to receive retroactive application. *Id.* 23-24.

## II. *ADVANCED BIONICS* & 35 U.S.C. § 325(d) DO NOT APPLY

The Director addresses § 325(d) by applying the "two-part framework" set forth in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-10 (PTAB 2020) (precedential). The first part of the framework asks whether the same or substantially the same art or arguments were previously presented to the Office. *Id.* 8. The first part involves *Becton Dickinson* (*BD*) factors (a) and (b), which pertain to art evaluated during examination, and factor (d), which pertains to arguments made during examination. *Id.* 10 (discussing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB 2017) (precedential as to § III.C.5, first paragraph)).

If either condition of the first part is met, the Director moves on to part two of the framework by asking "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims." *Id.* 8.

The second part involves *BD* factor (c), which is the extent to which the asserted art was evaluated during examination, and factors (e) and (f), which focus on the petitioner's evidence of Office error and evidence warranting reconsideration of prior art or arguments. *Id.* 10.

Here, PO seeks denial of institution under § 325(d). DDB 7-18. As discussed below, *Advanced Bionics* does not apply to this PGR, and institution is warranted.

## A. ***Advanced Bionics* Part 1 Does Not Apply (*BD* factors (a), (b), (d))**

*Advanced Bionics* Part 1 does not apply to the Petition because it presents new art and arguments in Grounds 1-12.

### 1. Grounds 1-4: § 112 Arguments Are New

Grounds 1-3 are based on lack of written description and enablement under § 112(a). The Examiner did not raise written description or enablement rejections.

Ground 4 is based on indefiniteness for the claimed "hardness of 4-48 N." The Examiner raised an indefiniteness rejection based on lack of antecedent basis for the term "orally ***dispersing*** tablet" in view of the preamble reciting an "orally ***disintegrating*** tablet." EX1096 171-172. However, the Examiner did not raise an indefiniteness rejection for the hardness limitation at issue in Ground 4.

As a result, the arguments raised in Grounds 1-4 do not overlap with arguments raised during examination. Grounds 1-4 are therefore new and were not previously presented. Accordingly, *Advanced Bionics* Part 1 and *BD* factors (a), (b),

and (d) do not apply to these grounds.

**2. Grounds 5-6: § 102 & § 103 Arguments For Perrett Are New**

Grounds 5-6 are based on anticipation and obviousness by Perrett under § 102 and § 103. During prosecution, the Examiner issued a nonstatutory double patenting (NSDP) rejection based on Perrett. EX1096 172-175. This type of double patenting rejection is based on a judicially created doctrine seeking to avoid unjustly extending patent rights at the expense of the public. *Id.*; MPEP § 804. The Examiner did not apply Perrett as prior art in an anticipation or obviousness rejection under § 102 or § 103. There is no indication that the Examiner appreciated that Perrett constitutes prior art to the '598 patent. Perrett issued on July 8, 2014. The '598 patent is only entitled to a priority date of January 5, 2022. Thus, Perrett is prior art under AIA § 102(a)(1). Petition 18-20, 41. The Examiner's NSDP rejection, which was not based on Perrett constituting prior art to the '598 patent, is materially different from (and non-cumulative to) the anticipation and obviousness arguments raised in the Petition that are based on Perrett being prior art to the '598 patent.

As a result, the prior art and arguments raised in Grounds 5-6 do not overlap with prior art and arguments raised during examination. Accordingly, *Advanced Bionics* Part 1 and *BD* factors (a), (b), and (d) do not apply to these grounds.

**3. Grounds 7-12: § 103 Challenges Present New Art And Arguments**

Grounds 7-12 are based on Dohil or Grother in view of ***Kararli***, the FDA

Guidance, and the ***USP <1216> on friability***.[2] Kararli and USP <1216> were not of record during prosecution. The Petition therefore provides different combinations of prior art references than were presented during prosecution.

Further, PO admits that the Examiner believed the prior art did not disclose the hardness and friability claim limitations. DDB 18; EX1096 15-16, 80. The Petition explains that Kararli and the USP disclose the hardness and friability limitations that the Examiner mistakenly believed were missing from the prior art. Petition 57-59. The Petition further explains that a POSA was motivated with a reasonable expectation of success to arrive at the claimed hardness and friability for the purpose of providing a tablet of sufficient mechanical integrity to withstand the rigors of packaging, transportation, and patient handling. *Id*. Grounds 7-12 therefore present non-cumulative new art and arguments that substantively differ from what was considered during examination. Accordingly, *Advanced Bionics* Part 1 and *BD* factors (a), (b), and (d) do not apply. *ResMed Inc. v. New York Univ.*, IPR2022-00990, Paper 16 at 15-16 (PTAB 2022) (first prong of the *Advanced Bionics* framework is not satisfied because "there are no rejections based on the

[2] As set forth in the Petition, Grounds 7-12 further include USP <701> and USP <1217> on disintegration and hardness, respectively, as well as Venkatesh988 and Venkatesh516 for certain dependent claims.

combination of references asserted here."); *Resideo Techs., Inc. v. Ubiquitous Connectivity, LP*, IPR2021-01355, Paper 12 at 14 (PTAB 2022) (instituting where a previously considered reference "is combined with different references and argued in different ways compared to what was made to the Examiner").

## B. ***Advanced Bionics* Part 2 Compels Institution Due to Examiner Error (*BD* factors (c), (e), (f))**

Because Grounds 1-12 present arguments and prior art that are not the same or substantially the same as those considered during examination, there is no need to proceed to *Advanced Bionics* Part 2 (*i.e.,* whether the Office erred in a manner material to the patentability). *Yita LLC v. MacNeil IP LLC*, IPR023-00172, Paper 12 at 47 (PTAB 2023) ("the first prong of the *Advanced Bionics* framework is not satisfied and we need not consider the second prong").

Nevertheless, should the Director proceed to evaluate *Advanced Bionics* Part 2, he should find that institution is warranted due to several material Examiner errors.

### 1. Grounds 1-4: Error For Not Issuing § 112 Rejections

The Examiner made material errors by not issuing § 112 rejections for lack of written description, enablement, and definiteness for the reasons explained in Grounds 1-4 of the Petition. Indeed, PO openly admits the claimed hardness range of "4-48 N" is an "error" that lacks written description support because a hardness range of "8-48 N" is "the only one disclosed" in the specification. EX2001 1-2; DDB 5. The lack of written description support leads to lack of enablement. Petition

28-33. PO does not dispute that the issued claims are indefinite. The Petition therefore warrants institution in view of these material Examiner errors under *Advanced Bionics* Part 2 and *BD* factors (c), (e), and (f).

### 2. Grounds 5-6: Error On Anticipation & Obviousness By Perrett

The Examiner made a material error in not applying Perrett as prior art to the '598 patent, and by not issuing anticipation and obviousness rejections under § 102 or § 103 based on Perrett, for the reasons provided in Grounds 5-6 of the Petition. There is no indication that the Examiner evaluated Perrett as prior art during examination. The Petition should therefore be instituted based on these material Examiner errors under *Advanced Bionics* Part 2 and *BD* factors (c), (e), and (f).

### 3. Grounds 7-12: Error On Hardness/Friability In The Prior Art

As discussed above, the Examiner was not aware of Kararli and USP <1216> during prosecution and therefore overlooked their teachings that the POSA was well aware of the desirability of formulating ODTs with a hardness falling between 4-48 N or a friability of not more than 1% to ensure that the tablet has sufficient mechanical integrity to withstand the rigors of packaging, transportation, and patient handling. Petition 57-59; EX1110 25:23-26:13; EX1104 676; EX1095 ¶¶235-241.

During prosecution, the Examiner mistakenly believed the prior art did not disclose the claimed hardness and friability. EX1096 15-16, 80. Kararli and USP <1216> provide the disclosures that the Examiner believed were missing from the

prior art when the claims were allowed. These references provide compelling evidence of obviousness and demonstrate that the Examiner erred in allowing the claims. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9 n.9 ("[a]n example of material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims"); *Agrofresh Sols., Inc. v. Lytone Enter., Inc*., IPR2021-00451, Paper 11 at 14-15 (PTAB 2021) (instituting where there "appear[ed] to have been an error material to patentability because [the Examiner's allowance] was made without the benefit of the teachings of these additional references").

The Examiner did not have the benefit of this Petition mapping the references to PO's claims and Dr. Parr's accompanying expert declaration explaining the POSA's understanding of the references. Dr. Parr's testimony is supported by objective evidence in view of nearly every paragraph in his declaration citing or quoting prior art that supports his positions.

Further, the '598 patent issued before the PTAB entered final adverse judgment against PO in related IPR2024-01197 involving the '729 patent. The '598 patent also issued before the PTAB's institution decisions for the related '069 patent in IPR2025-00052, the '828 patent in IPR2025-00054, and the '407 patent in IPR2025-00055. The only substantive difference between the cancelled '729 patent claims, the instituted '069/'828/'407 claims, and the '598 claims challenged here is

a new limitation requiring "a hardness of 4-48 N or a friability of not more than 1%." The lack of patentable distinction between these patents is evidenced by the Examiner issuing double patenting rejections and PO filing terminal disclaimers (TDs) over these patents during prosecution of the '598 patent. EX1096 165-167 (TDs over '729 and '407 patents), 115-117 (TDs over '069 and '828 patents). The '598 patent Examiner did not have the benefit of any of these PTAB decisions.

Also, PO submitted over 500 references (over 20 times the typical amount) during prosecution of the '598 patent, and did not identify relevant teachings from the references to the Examiner. *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 6-7 (PTAB 2025) (precedential) (noting typical IDSs include about 25 references). The PTAB has recognized that voluminous IDS submissions may show that the Examiner did not meaningfully consider the submitted art. *Id.* 6-7. Here, the large volume of PO's IDS submissions favors institution. *Id.* Paper 16 at 13-15 (declining discretionary denial where the record lacked evidence of substantive consideration).

In sum, the Examiner did not have the benefit of Kararli or USP <1216>, the declaration of Dr. Parr, the PTAB's final judgment in IPR2024-01197, or the PTAB's institution decisions in the related matters of IPR2025-00052, -00054, -00055, and -00056. All of this additional evidence warrants instituting trial here.

## III. PATENT OWNER HAS NO SETTLED EXPECTATIONS

PO asserts that it is entitled to settled expectations that its patents will not be challenged "dating back to the '729 patent." DDB 19. PO's assertion is absurd. When PO was confronted with the overwhelming case of obviousness against the '729 patent presented by Petitioner in the related proceeding of IPR2024-01197, PO requested and received adverse judgment by disclaiming all claims from the '729 patent. EX1118 3. PO also admitted that IPR2024-01197 and the related proceedings between Petitioner and PO in IPR2025-00052, IPR2025-00054, and IPR2025-00055 all concern "the same [prior] art and arguments." EX1135 10 n.2; EX1136 9 n.2; EX1137 3-4 n.2. Thus, PO should expect its patents challenged in those related proceedings to be cancelled as well.

Also, when PO was confronted with the overwhelming case of obviousness presented by Petitioner in the related proceeding of IPR2025-00056, it elected not to file a Patent Owner Response, thereby effectively conceding unpatentability in that case. Petitioner initiated three opposition proceedings regarding related patents at the European Patent Office, each of which resulted in the revocation of PO's claims. Petition 1-2. In view of the many successful and instituted challenges to PO's patents, the only settled expectations PO could reasonably have developed is that its challenged patents are overly broad and ***un***patentable.

Here, it is ***Petitioner*** that is entitled to settled expectations that this Petition

will be instituted in view of the successful IPR challenge to the patentably indistinct '729 patent and the instituted challenges in the related matters of IPR2025-00052, IPR2025-00054, IPR2025-00055, and IPR2025-00056.

Moreover, the Director has explained that patent owners in PGRs are ***not*** entitled to settled expectations because PGR petitions must be filed close in time to examination and within 9 months of issuance. *Toyota Motor Corp. v. Autoconnect Holdings LLC,* PGR2025-00041, Paper 9 at 2 (Dir. Stewart, Sept. 8, 2025). PGR petitions provide early challenges and "weigh against discretionary denial." *Id.* Accordingly, PO has no settled expectations.

## IV. ADJUDICATIONS BY THE PTAB AND OTHER FORUMS IN RELATED PROCEEDINGS

To date, all decisions in related matters at the PTAB and in other forums have ruled against PO and in favor of Petitioner. These adjudications favor institution.

As discussed above, when PO was confronted with the overwhelming case of obviousness presented by Petitioner in the related proceeding of IPR2024-01197, PO requested and received adverse judgment by disclaiming all claims in the '729 patent. EX1118 3. PO requested adverse judgment after all briefing had been completed and just 5 days before the final oral argument was scheduled.

The '598 patent at issue here is a continuation of the '729 patent. During prosecution, the Examiner rejected the '598 patent application claims for obviousness-type double patenting over the '729 claims. EX1096 172-175. PO did

not dispute the double patenting rejection and instead filed a terminal disclaimer over the '729 patent. *Id*. 165-167. This "terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent." *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018).

The PTAB's adverse judgment adjudication against PO for the patentably indistinct '729 patent claims favors institution because it would promote efficient use of PTAB resources given the overlapping nature of this proceeding and the related '729 patent from IPR2024-01197, as well as the instituted IPRs in the related matters of IPR2025-00052, IPR2025-00054, IPR2025-00055, and IPR2025-00056.

The EPO determined that related European claims were obvious over Dohil. EX1004 ¶¶33-36.9. The Eastern District of Virginia (EDVA) and German courts have also ruled against PO (and for Petitioner).

PO filed a lawsuit in the EDVA, where it wrongly accused Petitioner of breaching a 2022 settlement agreement between the parties based on Petitioner filing the petition in IPR2024-01197. The EDVA dismissed that case because the settlement agreement has a binding forum selection clause that requires all disputes concerning the agreement to be adjudicated in Germany. EX1119 20:1-21:25.

Petitioner filed the same wrongful accusations of breaching the 2022 agreement in the German court of Düsseldorf. The German court determined that

PO's accusations were completely unfounded, and it issued sanctions in the form of attorneys' fees against PO for "culpably breach[ing]" the agreement and "act[ing] at least negligently" by filing suit in Virginia. EX1121 20-22.

Further, PO has developed a pattern of improper and negligent behavior before the PTAB that weighs in favor of instituting this PGR. As mentioned above, in this PGR, PO filed a COC request without seeking the required authorization from the Board, without notifying the COC Branch that a PGR is pending, and without notifying Petitioner in violation of 37 C.F.R. § 42.3 and Paper 3 at 2. Also as mentioned above, PO openly admits that it was at least negligent in patenting claims that lack written description support in the '598 patent. EX2001 1-2; DDB 5.

In IPR2024-01197, PO filed numerous new exhibits with its sur-reply in violation of 37 C.F.R. § 42.23(b), even after the PTAB had instructed PO ***not*** to file new evidence with its sur-reply. EX1129 1. PO later sought permission to expunge the improper exhibits and submit a corrected sur-reply. EX1130. Also in that proceeding, PO took positions regarding taste-masking that were contradictory to its prior statements to the PTO. EX1117 14-17.

In IPR2025-00052 and IPR2025-00054, PO made a false statement to the PTAB in connection with a discovery dispute by stating that it "did not retain or instruct Professor Lee to perform the test outlined in his report." EX1131 2; EX1132 2. PO later admitted that the statement was false. EX1133 2. In connection with

the same discovery dispute, PO failed to conduct a reasonable inquiry into Petitioner's requested discovery into Professor Lee's report and PO failed to timely inform Petitioner that Dr. Lee passed away half-a-decade earlier in 2020, which resulted in the Board and Petitioner needlessly spending time and resources on motion practice. *Id*.

## V. PUBLIC HEALTH INTEREST

Public health interest favors institution here. Petitioner is working with the FDA to allow U.S. patients to receive the benefits of Jorveza®. Petition 1-4. In contrast, PO has no products of its own and a history of using its overly broad patents to seek to preclude Jorveza® from being used by patients. *Id*. The many U.S. patients suffering from eosinophilic esophagitis that would benefit from Jorveza® provides a strong public interest that favors instituting this PGR trial.

## VI. PATENT OWNER FAILS TO ADRESS ANY ADDITIONAL DISCRETIONARY FACTORS

PO fails to assert that any of the additional discretionary considerations enumerated in the Director's March 26, 2025 Memorandum on PTAB Workload Management apply to this proceeding. PO therefore concedes that no other considerations would support discretionary denial here.

## VII. CONCLUSION

The Director should deny PO's Request for Discretionary Denial and allow this PGR to proceed to an institution determination on the merits.

Respectfully submitted,

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## CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL AND EXHIBIT NOS. 1004, 1117-1121, AND 1129-1137** were served by email on the Patent Owner at the following email addresses:

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