

Case No. PGR2025-00086

Patent No. 12,290,598

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 BRIEF IN SUPPORT OF  
DISCRETIONARY DENIAL**

## TABLE OF CONTENTS

|                                                                                                                                                                                       | Page |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| I. INTRODUCTION .....                                                                                                                                                                 | 1    |
| II. PROSECUTION HISTORY OF THE '598 PATENT.....                                                                                                                                       | 2    |
| III. THE '598 PATENT IS INELIGIBLE FOR POST GRANT REVIEW .....                                                                                                                        | 5    |
| IV. GROUNDS 1-4 ARE MOOT.....                                                                                                                                                         | 6    |
| V. PERRETT IS NOT PRIOR ART TO THE '598 PATENT .....                                                                                                                                  | 6    |
| VI. THE DIRECTOR SHOULD EXERCISE DISCRETION AND DENY<br>INSTITUTION UNDER § 325(D).....                                                                                               | 7    |
| 1. <i>Advanced Bionics</i> Part I – Substantially the Same Prior<br>Art and Arguments were Presented to, and Considered<br>by, the Office During Prosecution of the '598 Patent ..... | 9    |
| a. Grounds 5 and 6 Rely on the Same Art and<br>Arguments that were Considered by the Office<br>Without Error.....                                                                     | 9    |
| b. Grounds 7-9 Rely on The Same Art and<br>Arguments that were Considered by the Office<br>Without Error.....                                                                         | 11   |
| c. Grounds 10-12 Rely on The Same Art and<br>Arguments that were Considered by the Office<br>Without Error.....                                                                       | 13   |
| d. Secondary References in Grounds 7-12 Are<br>Cumulative of Art and Arguments that were<br>Considered by the Office Without Error .....                                              | 16   |
| 2. <i>Advanced Bionics</i> Part II – No Material Error.....                                                                                                                           | 18   |
| B. Workload Memo Supports Discretionary Denial.....                                                                                                                                   | 18   |
| 1. The Merits of the Petition are Weak.....                                                                                                                                           | 18   |
| 2. The '598 Patent is Entitled to Settled Expectations.....                                                                                                                           | 19   |
| VII. CONCLUSION.....                                                                                                                                                                  | 20   |

**TABLE OF AUTHORITIES****Page(s)****Cases**

|                                                                                                                                 |               |
|---------------------------------------------------------------------------------------------------------------------------------|---------------|
| <i>Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH,</i><br>IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020)..... | <i>passim</i> |
| <i>Becton, Dickinson &amp; Co. v. B. Braun Melsungen AG,</i><br>IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) .....           | 8             |
| <i>NHK Spring Co. v. Intri-Plex Techs., Inc.,</i><br>IPR2018-00752, Paper 8 .....                                               | 18            |
| <i>Quad Env't Techs. Corp. v. Union Sanitary Dist.,</i><br>946 F.2d 870 (Fed. Cir. 1991) .....                                  | 20            |
| <i>SoftView LLC v. Apple Inc.,</i><br>108 F.4th 1366 (Fed. Cir. 2024) .....                                                     | 20            |
| <i>Tricam Indus., Inc., v. Little Giant Ladder Sys., LLC,</i><br>PGR2021-00044, Paper 10 (P.T.A.B. Aug. 3, 2021) .....          | 5             |

**Statutes**

|                          |               |
|--------------------------|---------------|
| 35 U.S.C. § 325(d) ..... | <i>passim</i> |
| AIA § 6(f)(2)(A) .....   | 5             |

**Other Authorities**

|                            |    |
|----------------------------|----|
| 37 C.F.R. § 42.73(d) ..... | 19 |
|----------------------------|----|

**List of Patent Owner's Exhibits**

| <b>Exhibit<br/>No.</b> | <b>Description</b>                                                   |
|------------------------|----------------------------------------------------------------------|
| <b>2001</b>            | Request for Certificate of Correction for U.S. Patent No. 12,290,598 |

## I. INTRODUCTION

Pursuant to the March 26, 2025 Memorandum titled “Interim Processes for PTAB Workload Management” (“Workload Memo”), Patent Owner Ellodi Pharmaceuticals L.P. (“Patent Owner” or “PO”) respectfully requests that the Director exercise its discretion to deny institution of this post-grant review (“PGR”) filed by Petitioner Dr. Falk Pharma GmbH (“Petitioner”) against U.S. Patent No. 12,290,598 (the “’598 patent”) under 35 U.S.C. § 325(d). The Director should deny institution because the ’598 patent is ineligible for PGR. PGR is only available for patents that have an effective filing date after March 15, 2013. The ’598 patent has a pre-AIA priority date of October 1, 2009, and Petitioner’s sole reason for PGR eligibility hinges on a typographical error for which PO has already filed a Request for Certificate of Correction (EX2001). PO’s correction also renders Petitioner’s § 112 arguments, Grounds 1-4, moot, as the correction obviates Petitioner’s arguments for lack of written description, enablement, and indefiniteness regarding the hardness limitation.

Further, Petitioner relies on references that are either not prior art or have already been presented to and considered by the Office during prosecution of the ’598 patent. In particular, Perrett, asserted in Grounds 5 and 6, is not prior art to the ’598 patent and the Examiner already considered Perrett during prosecution. With respect to Dohil and Grother, the primary references in Grounds 7-9 and 10-12,

respectively, the Examiner reviewed both references, as well as Petitioner's arguments in related *inter partes* review ("IPR") proceedings and accompanying expert reports, and nonetheless allowed the '598 patent. As to the secondary references, Venkatesh988 and the FDA Guidance were considered during prosecution along with Petitioner's arguments in related IPR proceedings, and Kararli and Venkatesh516 do not cure the deficiencies of Dohil or Grother. Revisiting the identical art and arguments here would undermine the efficiency and consistency that § 325(d) and the Workload Memo are intended to protect. The Director should exercise discretion and deny institution.

## **II. PROSECUTION HISTORY OF THE '598 PATENT**

The '598 patent issued from U.S. Application No. 17/569,047 (the "'047 Application"), and claims priority to U.S. Provisional Patent Application No. 61/247,642 (the "'642 Provisional Application"). EX1001, cover. PO filed the '047 Application on January 5, 2022. EX1001, cover. During prosecution, the Examiner rejected the pending claims for non-statutory double patenting over U.S. Patent Nos. 8,771,729 (the "'729 patent" or "Perrett") and 9,486,407 (the "'407 patent"). EX1096, 172-176. PO overcame the rejections by filing a terminal disclaimer to the '729 and '407 patents. EX1096, 165-167. PO stated in its response to the Examiner's rejection that it is not "acquiescing to the merits of the rejection[.]" EX1096, 157. PO also submitted an Information Disclosure Statement ("IDS"), which included

Petitioner's Petition for *Inter Partes* Review of the '729 patent and all exhibits. EX1096, 144.

The Examiner subsequently issued a Notice of Allowance. EX1096, 75-82. In the Notice of Allowance, the Examiner stated that the closest prior art to the claimed invention is Singh (EX1035), but that Singh does not teach a fast dissolving tablet containing 0.5 mg to 6 mg of budesonide that is deposited on the esophagus, a "hardness of [] 4-48 N or the friability of not more than 1%, as recited in instant claim 1." EX1096, 80. The Examiner further concluded that a prior art search "did not uncover a reference that teaches an orally disintegrating tablet comprising" the combination of elements claims, including the hardness and friability limitations. EX1096, 80.

On January 22, 2025, PO submitted a Request for Continued Examination ("RCE") and filed an IDS. EX1096, 50-57. In the IDS, PO submitted papers from related *inter partes* review petitions challenging the claims of four patents related to the '598 patent. EX1096, 50-55. In particular, PO provided PO's Preliminary Response submitted in IPR2024-01197, and petitions in IPR2025-00052 challenging U.S. Patent No. 10,632,069, IPR2025-00054 challenging U.S. Patent No. 11,246,828, and IPR2025-0055 challenging the '407 patent. EX1096, 50-55. The same Petitioner here submitted the petitions in the related IPR proceedings, asserting the same references, including Dohil, Grother, Venkatesh988, and the FDA

Guidance. *See* IPR2024-01197; IPR2025-00052; IPR2025-00054; IPR2025-00055 (collectively, the “related IPRs”). Importantly, in addition to submitting the IPR petitions, PO also submitted Dohil, Grother, Venkatesh988, and the FDA Guidance in IDS filings throughout prosecution prior to allowance and the RCE. EX1096, 43, 50-55, 143, 144, 304. On February 6, 2025, PO filed another IDS, which included the Board’s institution decision in IPR2024-01197, relating to the ’729 patent. EX1096, 43. In IPR2024-01197, the Board instituted review challenging the claims of the ’729 patent on Petitioner’s grounds asserting Dohil, Grother, Venkatesh988, and the FDA Guidance which refers to the USP. IPR2024-01197, Paper 10.

On March 24, 2025, the Examiner subsequently issued another Notice of Allowance. EX1096, 12-18. The Examiner maintained her reasons for allowance, again citing to Singh as the closest prior art and stating that she uncovered no prior art reference that teaches the instant claims. EX1096, 16. The Examiner also acknowledged the January 22, 2025 and February 6, 2025 IDS’s, and found that the filings “did not change the previous determination of patentability since the references do not teach an orally disintegrating tablet comprising” the claimed limitations, including the dosage, hardness, and friability limitations. EX1096, 16. Thus, the Examiner considered the prior art and arguments Petitioner made in IPR2024-01197, IPR2025-00052, IPR2025-00054, and IPR2025-00055.

The ’598 patent issued on May 6, 2025. EX1001, cover. On October 14, 2025,

PO filed a Request for a Certificate of Correction to correct an obvious typographical error. EX2001. Specifically, PO seeks to correct inadvertent errors in the claims that recite a hardness value of “4-48 N” to “8-48 N.” EX2001, 1-2. As explained in PO’s Request, the errors are clerical or typographical in nature, as the only hardness value disclosed in the specification is “8-48 N.” EX2001, 1-2. The Request is currently pending.

### **III. THE ’598 PATENT IS INELIGIBLE FOR POST-GRANT REVIEW**

Petitioner has the burden of establishing eligibility for PGR. *See, e.g., Tricam Indus., Inc., v. Little Giant Ladder Sys., LLC*, PGR2021-00044, Paper 10 at 14 (P.T.A.B. Aug. 3, 2021). A patent is PGR eligible only if it is subject to the Leahy-Smith America Invents Act (“AIA”) and has an effective priority date after March 16, 2013. *See* AIA § 6(f)(2)(A); *id.*, § 3(n)(1). Here, to meet its burden, Petitioner asserts that the ’598 patent lacks written description and enablement support for the claimed “hardness of 4-48 N,” and thus the ’598 patent is not entitled to an effective filing date prior to January 5, 2022. Pet., 18-20. Petitioner is wrong.

The ’598 patent claims priority to the ’642 Provisional Application, filed October 1, 2009. EX1001, cover. As mentioned above, PO submitted a Request for a Certificate of Correction, correcting the typographical error in the claimed “hardness of 4-48 N.” EX2001. PO’s correction to “hardness of 8-48 N” has written description support in the specification. EX1001, 17:40-18:24; EX2001, 1-2.

Further, contrary to Petitioner's assertion, the specification does enable a POSA to make an ODT with a hardness of 8-48 N. Pet., 19. Example 1 of the '598 patent discloses how to make a claimed ODT with a hardness of 8-48 N. EX1001, 17:40-18:24. Because the '598 patent is entitled to its priority date of October 1, 2009, which is prior to March 16, 2013, PGR of the '598 patent is not available.

#### **IV. GROUNDS 1-4 ARE MOOT**

In Grounds 1-4, Petitioner asserts § 112 arguments for lack of written description, lack of enablement, and indefiniteness. Pet., 24-40. Petitioner's § 112 arguments are based on the hardness limitation, which recites a "hardness of 4-48 N." Pet., 24-40. PO has submitted a Request for a Certificate of Correction to correct the limitation to read a "hardness of 8-48 N." EX2001. This obviates Petitioner's § 112 arguments, as there is written description and enablement support in the specification of the '598 patent for a "hardness of 8-48 N," and the claims are not indefinite for this reason. EX1001, 17:40-18:24. Thus, Grounds 1-4 are moot.

#### **V. PERRETT IS NOT PRIOR ART TO THE '598 PATENT**

Petitioner relies on Perrett for anticipation and obviousness, stating that because the '598 patent cannot claim priority to the '642 Provisional Application, Perrett is prior art. Pet., 41. Perrett is the '729 patent that PO filed a terminal disclaimer over. EX1096, 165-167. It is also the first in a chain of continuation patents stemming from the '642 Provisional Application and culminating in the '598

patent. EX1001, cover. As explained above, PO has filed a Request for a Certificate of Correction and, as such, the '598 patent is entitled to an October 1, 2009 priority date. EX2001. Because Perrett was filed after the '642 Provisional Application and published on April 7, 2011, it is after the October 1, 2009 priority date of the '598 patent and does not constitute prior art. EX1109, cover. Therefore, Perrett cannot anticipate the '598 patent, or render it obvious, making both Grounds 5 and 6 moot.

**VI. THE DIRECTOR SHOULD EXERCISE DISCRETION AND DENY INSTITUTION UNDER § 325(D)**

Under 35 U.S.C. § 325(d), the Director “may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). The Board’s *Advanced Bionics* decision provides a two-part framework when determining whether to exercise its discretion under § 325(d): (1) “whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office”; and (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.” *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). This analysis “reflects a commitment to defer to previous

Office evaluations of the evidence of record unless material error is shown.” *Id.* at

9.

The Board also explained that *Becton Dickinson* provides useful factors in applying the *Advanced Bionics* framework. The *Becton Dickinson* factors are:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination;
- (d) the extent of the overlap between the arguments made during examination and the manner in which a petitioner relies on the prior art or a patent owner distinguishes the prior art;
- (e) whether a petitioner has pointed out sufficiently how the Office erred in evaluating the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

*Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017). *Becton* factors (a), (b), and (d) are relevant to the first part of the *Advanced Bionics* framework. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9-10. *Becton* factors (c), (e), and (f) relate to the second part of the *Advanced Bionics* framework. *Id.* at 10-11.

**1. *Advanced Bionics* Part I – Substantially the Same Prior Art and Arguments were Presented to, and Considered by, the Office During Prosecution of the '598 Patent**

As set forth below, the Petition relies on eight different grounds based on three primary references: Perrett, Dohil, and Grother. Pet., 41-87. These references are identical to or substantially the same as (and cumulative of) references that were considered during the prosecution of the '598 patent. Six of the eight grounds rely on secondary references Kararli, the FDA Guidance, and the USP. Pet., 51-66, 68-85. Four of the eight grounds further rely on Venkatesh988 or Venkatesh516. Pet., 61-68, 81-87. These references are also identical to or substantially the same as (and cumulative of) references that were considered during prosecution of the '598 patent. Petitioner's arguments are also cumulative of the arguments the Examiner considered during prosecution of the '598 patent. Despite this overlap, Petitioner makes no attempt to establish that the Examiner "erred in evaluating the art or arguments" previously presented to the Office, as has "generally [been] required" for such cumulative petitions to be instituted under § 325(d). *Advanced Bionics*, IPR2019-01469, Paper 6 at 8. Accordingly, the Director should exercise discretion not to institute PGR.

**a. *Grounds 5 and 6 Rely on the Same Art and Arguments that were Considered by the Office Without Error***

In Grounds 5 and 6, Petitioner relies on Perrett for anticipation and

obviousness. Pet., 41-51. The Director should deny institution because, as explained in Section V, Perrett is not prior art to the '598 patent and moreover Perrett is the '729 patent that was before the Examiner during prosecution.

Like the '598 patent, Perrett claims priority to the '642 Provisional Application. EX1109, cover. As such, Perrett and the '598 patent share the same specification. *Compare* EX1001 *with* EX1109. Perrett 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%. EX1109, Abstract, 17:11-62.

As explained in Section II, during prosecution of the '598 patent, the Examiner rejected the claims for non-statutory double patenting over Perrett. EX1096, 172-175. The Examiner noted that Perrett discloses an ODT that disintegrates within 60 seconds when using the USP <701> Disintegration Test, and comprises about 2 mg to 10 mg of fluticasone. EX1096, 174-175. Similarly, here, Petitioner argues that Perrett discloses an ODT containing 0.5 mg to 6 mg of fluticasone or budesonide, that disintegrates within 60 seconds under the USP <701> Disintegration Test, with a hardness of 4-48 N and friability of no more than <0.1%. Pet., 41-51.

The Examiner has already considered Perrett during prosecution and raised the same arguments as Petitioner on the same individual elements of the claims of the '598 patent. EX1096, 174-175. PO overcame the Examiner's rejection by filing

a terminal disclaimer. EX1096, 165-167. The Examiner subsequently allowed the claims following the filing of the terminal disclaimer. EX1096, 79-82. Thus, substantially the same art and arguments have already been considered and need not be reexamined by the Board, thereby wasting the Board's resources. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 9 (describing § 325(d) as reflecting “a commitment to defer to previous Office evaluations of the evidence”).

**b. Grounds 7-9 Rely on The Same Art and Arguments that were Considered by the Office Without Error**

Grounds 7-9 rely on Dohil. Pet., 51-68. The Examiner considered Dohil during prosecution of the '598 patent and the Director should deny the Petition.

During prosecution of the '598 patent, PO submitted Dohil in an IDS filed on August 11, 2022. EX1096, 304. The Examiner signed the IDS, noting “ALL REFERENCES CONSIDRED EXCEPT WHERE LINED THROUGH. /A.S./.” EX1096, 222. Dohil was not lined through. EX1096, 222. An IDS citation alone is deemed previously presented to, and considered by, the Office. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 7-8.

PO also presented Petitioner's arguments on Dohil to the Examiner. EX1096, 144. Specifically, PO filed an IDS listing the petition filed in IPR2024-01197, including exhibits and the expert declaration in support of the petition. EX1096, 142-144. In IPR2024-01197, Petitioner argued that Dohil discloses an ODT containing a

corticosteroid that deposits a topical corticosteroid on the esophagus. IPR2024-1197, Paper 2, 18-34, 52-57. The Board ultimately instituted review in IPR2024-01197, over PO's preliminary response seeking discretionary denial. IPR2024-01197, Paper 10.

Following the Examiner's Notice of Allowance (EX1096, 79-82), PO filed a Request for Continued Examination so that it could submit the additional papers from IPR2024-01197, as well as Petitioner's petitions for *inter partes* review of related patents. EX1096, 56-57. PO filed two IDS's listing PO's preliminary response and the institution decision in IPR2024-01197, as well as the petitions, exhibits, and supporting expert declarations in IPR2025-00052, IPR2024-00054, and IPR2025-00055. EX1096, 43, 51-55. Petitioner asserts Dohil in its ground for obviousness in these three IPR proceedings as well, making similar arguments to the arguments made in IPR2024-01197. *See* IPR2025-00052, Paper 2 at 20-39; IPR2024-00054, Paper 1, 22-45; IPR2025-00055, Paper 2, 19-33, 53-64. The Examiner signed both IDS filings, noting "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./." EX1096, 27, 29-33. Nothing in either IDS was lined through. EX1096, 27, 29-33. The Examiner also explicitly acknowledged the IDS filings in her Notice of Allowance, finding that they "did not change the previous determination of patentability" since the references did not teach the claimed combination of elements, including the limitations on hardness

and friability. EX1096, 15-16.

Here, Petitioner presents the same arguments based on Dohil as it did in each of the IPRs proceedings presented to the Examiner. In particular, Petitioner relies on Dohil for its disclosure of a lozenge, which Petitioner claims is the equivalent of an ODT, containing budesonide that dissolves in the mouth and deposits the corticosteroid on the esophagus. Pet., 51-61. This is the same argument the Examiner considered during prosecution of the '598 patent, from Petitioner itself, and having the benefit of mapping the claims of related patents to Dohil. *See* IPR2024-1197, Paper 2 at 18-34, 52-58; IPR2025-00052, Paper 2 at 20-39; IPR2024-00054, Paper 1 at 22-45; IPR2025-00055, Paper 2 at 19-33, 53-64. Thus, under § 325(d), there is no reason to disturb the Examiner's conclusion that the '598 patent is allowable over Petitioner's arguments regarding Dohil and discretionary denial is appropriate.

**c. Grounds 10-12 Rely on The Same Art and Arguments that were Considered by the Office Without Error**

Grounds 10-12 rely on Grother. Pet., 68-86. Like Dohil, the Examiner considered Grother, and Petitioner's arguments regarding Grother, during prosecution of the '598 patent, as well as cumulative art.

PO listed Grother in an IDS. EX1096, 142. The Examiner signed the IDS, noting ALL REFERENCES CONSIDRED EXCEPT WHERE LINED THROUGH. /A.S./." EX1096, 98. Grother was not lined through. EX1096, 98. As explained

above, PO filed multiple IDS's listing the petitions, exhibits, and supporting expert declarations in the related IPRs, which the Examiner considered. EX1096, 27, 29-33, 43, 51-55, 142-144. In the related IPRs, Petitioner argued that Grother discloses an ODT formulation that dissolves within 60 or 30 seconds, and can include corticosteroids such as budesonide. *See* IPR2024-01197, Paper 2 at 34-51, 58-68; IPR2025-00052, Paper 2 at 39-60; IPR2024-00054, Paper 1 at 45-65; IPR2025-00055, Paper 2 at 34-53, 64-71. The Examiner did not find Petitioner's arguments persuasive, finding that they did not change the Examiner's determination of patentability. EX1096, 15-16.

Here, Petitioner's arguments based on Grother are the same as those presented to the Examiner during prosecution. *Compare* IPR2024-01197, Paper 2 at 34-51, 58-68 *with* Pet., 68-86. Petitioner relies on Grother in this proceeding for its disclosure of an ODT formulation that dissolves within 60 seconds and can contain budesonide. Pet., 68-81. The Examiner has therefore already considered Grother and these same arguments based on Grother during the prosecution of the '598 patent.

The Examiner also considered similar and cumulative art to Grother during prosecution of the '598 patent. In the Notice of Allowance for the claims of the '598 patent, the Examiner noted that Singh is the closest prior art. EX1096, 16. Singh, also relied on by Petitioner for background (Pet., 17), discloses "fast dissolving tablets." EX1035, 1:20-23, 2:37-49. The tablets disintegrate within one minute.

EX1035, 2:29-36. Singh also discloses groups of drugs that can be used in the tablets, including budesonide. EX1035, 16:56-17:14. The Examiner found that while Singh teaches a fast dissolving composition that dissolves or disperses within one minute, and can include budesonide, it does not teach the tablet containing 0.5 mg to 6 mg of budesonide, deposition of the budesonide in the esophagus, or the hardness or friability limitations. EX1096, 16.

Just like Singh, Grother teaches an ODT formulation with groups of drugs that can be used with the formulation, including budesonide. EX1008, Abstract, 15:19-20, 18:15-18. And, similar to Singh, Grother does not teach its ODTs having the specific dosage 0.5 mg to 6 mg of budesonide as required by claim 1 of the '598 patent. Moreover, just like Singh, Grother does not teach the hardness and friability limitations of the '598 patent. Thus, Grother is the same or substantially the same as Singh, which was cited by the Examiner and addressed in the Notice of Allowance. As such, Grother is not materially different from Singh and discloses substantially the same information already considered by the Office. These references are merely cumulative art. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 18-19.

Petitioner's arguments based on Grother are the same as those considered by the Examiner for the same limitations based on Singh. For example, the Examiner stated that Singh teaches a fast dissolving tablet that dissolves rapidly in the mouth. EX1096, 16. Likewise, Petitioner argues that Grother discloses a fast-dispersing

solid composition that disintegrates in the oral cavity. Pet., 68-69. Thus, the Examiner's conclusion that the '598 patent was allowable over the closest prior art, Singh, is equally applicable to Grother.

**d. Secondary References in Grounds 7-12 Are Cumulative of Art and Arguments that were Considered by the Office Without Error**

Petitioner's additional references, Kararli, Venkatesh988, the FDA Guidance, Venkatesh516, and the USP, do not offer any additional support, and are cumulative at best, adding nothing new to the Office's previous considerations of obviousness. Pet., 51-86.

As an initial matter, Venkatesh988 and the FDA Guidance were presented to the Examiner during the prosecution of the '598 patent, which the Examiner considered. EX1096, 100, 144, 222, 304. As explained above, PO submitted papers from IPR proceedings on related patents in IDS filings during prosecution of the '598 patent. EX1096, 27, 29-33, 43, 51-55, 142-144. In two of those IPRs, Petitioner argued that Venkatesh988 disclosed rapidly dispersing microgranules and the FDA Guidance disclosed that ODTs disintegrate within 30 seconds when based on the USP <701> Disintegration Test. *See* IPR2024-01197, Paper 2 at 52-68; IPR2025-00055, Paper 2 at 53-71. The Examiner considered Petitioner's arguments and determined that the art and arguments in the related IPRs "did not change the previous determination of patentability" and found the claims of the '598 patent

patentable. EX1096, 16. Petitioner here relies on Venkatesh988 and the FDA Guidance for the same arguments as it did in the related IPRs. Pet., 61-65, 81-85. The Examiner therefore already considered identical art and arguments to Venkatesh988 and the FDA Guidance.

Petitioner relies on Kararli for its disclosure of tablet hardness of about 9.8 to 49.1 N. Pet., 52. Petitioner further relies on Venkatesh516 for its disclosure of friability. Pet., 66. As stated in the Notice of Allowance, the Examiner did not uncover a reference that teaches an ODT, with the claimed hardness or friability, comprising 0.5 mg to 6 mg of a corticosteroid that is deposited in the esophagus. Neither Kararli nor Venkatesh516 disclose an ODT containing a corticosteroid. Rather, Kararli discloses an oral formulation of a cyclooxygenase-2 inhibitor and Venkatesh516 discloses ODT compositions of lamotrigine. EX1110, Abstract; EX1111, Abstract. Petitioner merely states, in a conclusive manner, that a POSA would be motivated to combine Kararli and/or Venkatesh516 with Dohil or Grother to achieve the claimed invention. Pet., 58, 66, 76-77, 85. This is not enough, as neither Kararli nor Venkatesh516 address the deficiencies of Dohil and Grother regarding the hardness and friability claim elements as neither reference is directed to the topical deposition of a corticosteroid to treat inflammation of the esophagus.

## **2.     *Advanced Bionics Part II – No Material Error***

Petitioner has not shown that the Office erred in a manner material to the patentability of the Challenged Claims. Where, as here, the same or substantially overlapping disclosures were before the Patent Office and expressly relied on by the Examiner, it is incumbent on the Petitioner to offer a particularized explanation of how the Office erred. Accordingly, the Director should exercise discretion to deny institution under § 325(d).

Petitioner does not present new evidence that warrants reconsideration of the same prior art. Petitioner's expert declaration repeats arguments in the Petition and the expert fails to support his testimony with objective evidence. *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 16-17. Specifically, neither Petitioner nor its expert address the prosecution history or the fact that the teachings of the asserted art are substantially the same as the art already considered. The Examiner found no prior art that discloses the hardness and friability limitations in combination with the claimed ODT containing a corticosteroid deposited on the esophagus, and thus Petitioner cannot show material error by the Office and the Office did not err in allowing the '598 patent claims.

### **B.     Workload Memo Supports Discretionary Denial**

#### **1.     The Merits of the Petition are Weak**

As explained in Section IV, Grounds 1-4 of the Petition are moot as PO's

Request for a Certification of Correction obviates Petitioner's § 112 arguments. Regarding Perrett, as explained in Section V, PO's Request for Certificate of Correction also makes clear that the '598 patent is entitled to a priority date of the '642 Provisional Application. Thus, Grounds 5 and 6 are also moot.

Turning to the remaining Grounds, the Petition fails to properly show how each element of the Challenged Claims is found in the prior art. As explained above, Petitioner offers only conclusory statements that a POSA would find the combinations in the asserted Grounds obvious. For this reason, the Petition is weak and discretionary denial is appropriate.

## **2. The '598 Patent is Entitled to Settled Expectations**

As discussed above, the '598 patent claims priority through a chain of applications, and to the '642 Provisional Application. As described in Section II, PO properly pursued the invention of the '598 patent before the Office. In doing so, PO has developed settled expectations, dating back to the '729 patent, that its patents will not be subject to continued, repetitive challenges by Petitioner raising the same art and arguments. Discretionary denial is appropriate for this reason as well.

Petitioner may argue that because a terminal disclaimer to the '729 patent was submitted for the '598 patent, and the '729 patent has now been disclaimed, PO cannot continue to defend the claims of the '598 patent because the claims are not patentably distinct under 37 C.F.R § 42.73(d). A terminal disclaimer, however, does

not indicate that the claims of the '598 patent are not patentably distinct for purposes of presumption or estoppel. *Quad Env't Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient of 'obviation' into an admission or acquiescence or estoppel on the merits.") (citation omitted); M.P.E.P. § 804.02. Thus, PO is not precluded from defending its rights to the claims of the '598 patent. *See SoftView LLC v. Apple Inc.*, 108 F.4th 1366, 1374-1375 (Fed. Cir. 2024). For this reason, PO also has settled expectations that its patents will not continue to be challenged by Petitioner on the same art, and discretionary denial is appropriate.

## VII. CONCLUSION

Extensive Office resources have already been expended in the review of the same questions the Petitioner raises here. The Examiner's prosecution of the application that led to the '598 patent has already considered the art and arguments raised here. It would be an inefficient use of the Board's resources to ignore the work already done and revisit the same issues. Thus, for the reasons detailed herein, PO respectfully requests that the Director exercise discretion to deny this petition.

Date: November 24, 2025

Respectfully submitted,

Cooley LLP  
ATTN: Patent Group  
1299 Pennsylvania Ave., NW  
Suite 700  
Washington D.C. 20004  
Tel: (202) 776-2982  
Fax: (202) 842-7887

BY: /Sanya Sukduang/  
Sanya Sukduang  
Reg. No. 46,390  
Counsel for Patent Owner

**CERTIFICATION OF SERVICE  
UNDER 37 C.F.R. §§ 42.6(e), 42.105(a)**

I, Sanya Sukduang, hereby certify that on November 24, 2025, the foregoing **PATENT OWNER'S BRIEF IN SUPPORT OF DISCRETIONARY DENIAL and Exhibit 2001** pursuant to 37 C.F.R. § 42.8 were served electronically via email on the following counsel of record for Petitioner as follows:

Nathanael Luman  
Eric S. Furman  
Phillip J. Minnick  
KNOBBE, MARTENS, OLSON, & BEAR, LLP  
2nrl@knobbe.com  
2esf@knobbe.com  
2pjm@knobbe.com  
BoxFalkPharma@knobbe.com

DATED: November 24, 2025

/Sanya Sukduang/  
Sanya Sukduang  
Reg. No. 46,390