

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BONERGE LIFESCIENCE (HUNAN) CO., LTD.,
Petitioner,

v.

NANJING NUTRABUILDING BIO-TECH CO., LTD.,
Patent Owner.

IPR2025-01593
Patent 10,278,961

Before KAREN I. SWEENEY, *Trial Paralegal*

**PATENT OWNER NANJING NUTRABUILDING BIO-TECH CO., LTD.'S
DISCRETIONARY DENIAL BRIEF**

Patent Owner, Nanjing Nutrabuilding Bio-Tech Co., Ltd., hereby respectfully
submits its Discretionary Denial Brief to the Board.

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TABLE OF EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
2001	Complaint in Nanjing Nutrabuilding Bio-Tech Co., Ltd. v. Bonerge Lifescience (Hunan) Co., Ltd., United States District Court, Central District of California (text only) (filed January 31, 2025) (“Complaint”)
2002	Exhibit 11 to Complaint – Cease and Desist Letter No. 1 to Petitioner (dated September 12, 2024)
2003	Excerpt of Petitioner’s Responses to Requests for Admissions in parallel litigation in the Central District of California
2004	Exhibit 12 to Complaint – Cease and Desist Letter No. 2 to Petitioner (dated October 29, 2024)
2005	Petitioner’s Amended Answer to Complaint in parallel litigation in the Central District of California (filed April 25, 2025)
2006	Exhibit 13 to Complaint – Cease and Desist Letter to Third Party, Nature’s Fusions, LLC (dated November 4, 2024)
2007	Exhibit 14 to Complaint – Nature’s Fusions, LLC’s Response to Cease and Desist Letter (identifying Petitioner as manufacturer) (dated November 6, 2024)
2008	Return of Service of Summons and Complaint in parallel litigation in the Central District of California
2009	Joint Rule 26(f) Report in parallel litigation in the Central District of California (filed July 25, 2025)
2010	Scheduling Order in parallel litigation in the Central District of California (issued August 20, 2025)
2011	Amended/Supplemental Scheduling Order in parallel litigation in the Central District of California (issued September 23, 2025)
2012	Patent Owner’s Infringement Contentions in parallel litigation in the Central District of California (served September 22, 2025)
2013	Declaration of Mark D. Nielsen
2014	Petitioner’s Motion to Stay Brief in parallel litigation in the Central District of California (filed October 12, 2025)
2015	Order Denying without prejudice Petitioner’s Motion to Stay

	(issued November 5, 2025)
2016	Petitioner's Invalidation Contentions in parallel litigation in the Central District of California (served November 4, 2025)
2017	Interim Processes for PTAB Workload Management, Acting Director Memorandum (March 26, 2025) (https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf)
2018	Pound, P. and Bracken, M.B., Is animal research sufficiently evidence based to be a cornerstone of biomedical research? Brit. Med. J. 2014;348:g3387 (published 30 May 2014)
2019	Small, L. et al., Modeling insulin resistance in rodents by alterations in diet: what have high-fat and high-calorie diets revealed? Am. J. Physiol. Endocrinol. Metab. 314: E251–E265, 2018 (first published Nov. 7, 2017)
2020	Lai, M. et al., You are what you eat, or are you? The challenges of translating high-fat-fed rodents to human obesity and diabetes, Nutrition & Diabetes (2014) 4, e135; doi:10.1038/nutd.2014.30 (published Sept. 8, 2014)

PATENT OWNER’S DISCRETIONARY DENIAL BRIEF

I. INTRODUCTION

Patent Owner, Nanjing Nutrabuilding Bio-Tech Co., Ltd. (“Patent Owner” or “NNB”) is currently in litigation in the United States District Court for the Central District of California over the patent that is the subject of Petitioner Bonerge Lifescience (Hunan) Co., Ltd.’s (“Petitioner” or “Bonerge”) petition for inter partes review. Because of the progression of the litigation, the anticipated timeline of the litigation relative to a proceeding, if instituted, as well as other factors detailed below, a discretionary denial is highly warranted on this record.

II. BACKGROUND

A. Brief Background of U.S. Patent 10,278,961

NNB owns, by assignment, U.S. Patent 10,278,961 (hereafter the “’961 Patent”), independent claim 1 of which reads:

A method of managing glucose tolerance in an individual, the method comprising: administering, to an individual, a pharmaceutically effective amount of dihydroberberine, wherein the pharmaceutically effective amount of dihydroberberine comprises approximately 25 mg to approximately 800 mg of dihydroberberine.

See Exh. 1001.

B. Brief Background of the Parties’ Dispute

NNB and Petitioner are in the business of supplying dihydroberberine to re-

sellers and compounders who then formulate products containing dihydroberberine to sell to consumers. On September 12, 2024, shortly after learning of Petitioner’s infringing activities, NNB notified Petitioner of the alleged infringement. *See* Exh. 2002. Petitioner admits to having received this letter on September 25, 2024. *See* Exh. 2003 at p. 006¹ (Resp. to Req. for Adm. No. 1). NNB sent Petitioner another letter in late October of 2024. *See* Exh. 2004. Petitioner admitted that it did not respond to either of these letters. *Cf.* Exh. 2001 (§ 18) to Exh. 2005 (§ 18).

On or about November 5, 2024, NNB sent a letter to Nature’s Fusions, an entity also selling a dihydroberberine product for blood sugar control. *See* Exh. 2006. Nature’s Fusions responded and directed NNB to its “manufacturer,” which happened to be Petitioner. *See* Exh. 2007 (p. 004).

Without a satisfactory response to its letters, NNB was forced to commence litigation, which it did in the United States District Court for the Central District of California, by filing its Complaint on January 31, 2025. *See* Exh. 2001.

C. The Parallel Litigation

The Complaint and Summons were personally served on a representative of Petitioner in Ontario, California on February 12, 2025. *See* Exh. 2008 (at p. 003).

After an extension of time to respond to the Complaint, Petitioner answered

¹ Exhibit page references herein are to the “Bates” numbered pagination.

the Complaint on April 4, 2025, and then on April 25, 2025, Petitioner filed an Amended Answer to the Complaint to remove a few defenses (*see* Exh. 2005).

On June 25, 2026, the Court issued an Order setting a Scheduling Conference. In response, the parties submitted the Joint Fed.R.Civ.P. 26(f) Report, which included a proposed case schedule. *See* Exh. 2009, Exh. A thereto – p. 018ff. On August 20, 2025, the Court issued its Scheduling Order. (*see* Exh. 2010). The key motion and trial-related dates in the Scheduling Order (*Id.* at p. 001) include:

- Dispositive Motion Hearing Cut-Off² – 2/22/2027;
- Final Pretrial Conference – 4/5/2027;
- Trial Date – 4/20/2027.

Shortly thereafter, the Court issued an Amended Scheduling Order in response to the parties' request for addition of a claim construction-related dates into the Order. *See* Exh. 2011 at p. 002 therein. These dates include:

² This is the last day on which a dispositive motion may be heard by the Court. In the parties' Joint Rule 26(f) Report to the Court, they agreed to submit dispositive motion briefs to the Court 42 days before the hearing date. *See* Exh. 2009 at p. 015, lines 2-5. Based on the Court's deadline and the parties' agreement, dispositive motions in the litigation must be filed on or before January 4, 2027, well before a projected final written decision if review is instituted.

- Claim Construction Discovery Cut- Off – 1/22/2026;
- Joint Claim Construction and Prehearing Statement – 2/19/2026;
- Opening Claim Construction Briefs – 3/12/2026;
- Responsive Claim Construction Briefs – 3/26/2026;
- Claim Construction Hearing – 4/21/2026 (or as soon thereafter as possible).

On September 22, 2025, NNB served its Preliminary Infringement Contentions and supporting documents on Petitioner. *See* Exhs. 2012 and 2013 (¶ 3 therein). To date in the case, NNB produced over 2,000 pages of documents, and Petitioner produced over 1,200 pages of documents. *See* Exh. 2013 (¶ 4 therein).

On September 26, 2025, exactly *a year and a day* after receiving NNB's first *cease and desist letter* (*see* Exhs. 2002, 2003), and 7.5 months after it was served with the Complaint in the lawsuit, Petitioner filed its Petition. *See* Paper No. 2.

On October 12, 2025, Petitioner filed a motion to stay the lawsuit. *See* Exh. 2014. Following briefing on the motion, on November 5, 2025, the Court denied without prejudice Petitioner's motion to stay. *See* Exh. 2015.

On November 4, 2025, Petitioner served its Preliminary Invalidity Contentions and associated document disclosure in the lawsuit. *See* Exhs. 2013 (¶ 5 therein) and 2016. Petitioner's Invalidity Contentions (*see* Exh. 2016) attack claims 1, 2, 5, and 7; expressly indicate their reliance on the petition (*Id.* at p. 002,

lines 11-14); attach the petition to the Contentions; cite the petition 23 times; and, cite the Shebuski Declaration (*see* Exh. 1003) 50 times. Thus, extensive overlap exists between Petitioner's § 103 positions in the litigation and in its petition.

Further, the Invalidity Contentions assert certain § 112 defenses (*see* Exh. 2016 at p. 013, line 12 to 017, line 22) that are not within the purview of the Board to adjudicate. Thus, if the Board were to institute, but affirm patent validity, there would still be additional invalidity issues to litigate in the district court.

The bottom line is that the litigation is efficiently proceeding according to the Court's schedule. On November 18, 2025, the parties exchanged claim terms for possible construction, and by December 3, 2025, the parties will have exchanged their proposed constructions and supporting evidence for such terms. *See* Exh. 2013 at ¶¶ 6, 7. Claim construction will be fully briefed by late March of 2026 (*see* Exh. 2011 at p. 002, lines 18-19), which is before the April 7, 2026 deadline for the Board to decide on institution. If instituted, the anticipated timing of the Final Written Decision would be in April of 2027. The trial date in the district court is also in April of 2027. Thus, no temporal benefit will be gained by instituting review.

III. DISCRETIONARY DENIAL IS WARRANTED ON THIS RECORD

A. Legal Standard

The Director has discretion to deny institution of an IPR petition. *See* 35 U.S.C. § 314(a); *In re Motorola Solutions, Inc.*, ___ F.4th ___, 2025 WL 3096514,

at *3, 5 (Fed. Cir. Nov. 6, 2025); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016). In determining whether to deny institution, the PTAB considers, *inter alia*, “system efficiency, fairness, and patent quality.” *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, Paper 11, at *5 (PTAB May 13, 2020) (“*Fintiv I*”).

Six *Fintiv* factors are commonly considered in deciding whether to institute an IPR where the patent is also the subject of a parallel proceeding. *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15, at *7–8 (PTAB May 13, 2020) (informative) (“*Fintiv II*”). The six (6) *Fintiv* factors are:

- (1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
- (2) proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
- (3) investment in the parallel proceeding by the court and the parties;
- (4) overlap between issues raised in the petition and in the parallel proceeding;
- (5) whether the petitioner and the defendant in the parallel proceeding are the same party;
- (6) other circumstances that impact the Board's exercise of discretion, including the merits.

Fintiv I, Paper 11 at *5-6 (PTAB Mar. 20, 2020) (precedential).

“In evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.* at *8.

Additionally, the USPTO’s Interim Processes for PTAB Workload Management Memorandum (*see* Exh. 2017) (“Workload Management Memo”) identifies additional considerations for deciding discretionary denials, which include: (a) whether the PTAB or another forum has already adjudicated the validity or patentability of the challenged patent claims; (b) whether there have been changes in the law or new judicial precedent issued since issuance of the claims that may affect patentability; (c) the strength of the unpatentability challenge; (d) the extent of the petition’s reliance on expert testimony; (e) settled expectations of the parties, such as the length of time the claims have been in force; (f) compelling economic, public health, or national security interests; and, (g) any other considerations bearing on the Director’s discretion.

B. The *Fintiv* Factors Strongly Warrant Discretionary Denial

An analysis of the six (6) *Fintiv* factors, as well as other considerations strongly supports a discretionary denial of institution.

1. *Fintiv* Factor 1 – The Likelihood of a Stay

Fintiv Factor 1 considers whether the Court granted a stay or evidence exists that one may be granted if the Board institutes review. *Fintiv I* at *5-6.

Here, Petitioner *already* moved the Court for a stay, and the motion was denied. *See* Exh. 2015. The motion was denied without prejudice, but the Court did not say it would stay the case if a proceeding were instituted. *Id.* at p. 004. It merely stated that “if IPR is initiated, Defendant is free to again move for a stay.” *Id.*

Because the Court already denied a motion to stay, and in doing so, noted that “Defendant waited nearly nine months to file its IPR petition, weighing against a stay” (*id.*), there is at least a reasonable likelihood that even if the Board institutes review, a new stay motion would also be denied based on Petitioner’s delay in filing its petition. Furthermore, if review is instituted several months from now, the litigation will be even further along, which would also counsel against a stay. Accordingly, this factor strongly favors, discretionary denial.

2. *Fintiv* Factor 2 – Proximity of the Court’s Trial Date Relative to the Projected Final Written Decision Deadline

Fintiv Factor 2 looks to “proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision.” *Fintiv I* at *5-6.

Here, the Court has issued a Scheduling Order (*see* Exh. 2010) that includes the following dates: (1) Dispositive Motion Hearing Cut-Off – 2/22/2027; (2) Final Pretrial Conference – 4/5/2027; and, (3) Trial Date – 4/20/2027. *Id.* at p. 001.

If the Board institutes review, and if the institution date is assumed to be six (6) months after the Notice of Filing Date Accorded on October 7, 2025 (*see* Paper 3), the anticipated deadline for a Final Written Decision would be about April 7,

2027. This would be *after* the parties' Final Pretrial Conference, *well after* the dispositive motion hearing deadline, and ***two (2) weeks before a jury trial in the parallel litigation***. In fact, the Court could resolve some or all of the litigation based on dispositive motions before a Final Written Decision by the Board.

Should Petitioner argue that the trial date in the litigation is scheduled to occur after a projected Final Written Decision date, such an argument would be unpersuasive. This is so because the Board has denied institution even where trial was set to occur *after* the projected final decision (and here, the dates are a few weeks apart). *See Advanced Micro Devices, Inc. v. Concurrent Ventures, LLC*, IPR2025-00223, Paper 9, at *2 (PTAB June 12, 2025) (exercising discretion to deny institution and reasoning that “[e]ven though a district court trial date that occurs after a projected final written decision date reduces the possibility of conflicting decisions, that benefit does not outweigh the efficiencies gained by avoiding parallel proceedings ... because of the parties’ meaningful investment in the district court proceedings”). As *Fintiv* indicates, “[i]f the court’s trial date is at or around the same time as the projected statutory deadline ***or even significantly after*** ... , the decision whether to institute will likely implicate other factors ... , such as the resources that have been invested in the parallel proceeding.” *Fintiv I*, at *9 (citing factors 3 and 4) (emphasis added). Thus, assuming institution, the Court’s timing would be ahead of (dispositive motions), or in substantial lockstep (trial) with the Board’s timing. This

strongly favors discretionary denial so as to avoid unnecessary use of Board resources and conflicting decisions.

3. *Fintiv* Factor 3 – Investment in the Parallel Proceeding by the Court and the Parties

Fintiv Factor 3 looks to “amount and type of work already completed in the parallel litigation by the court and the parties *at the time of the institution decision.*” *Fintiv I* at *9 (emphasis added); *see also Sand Revolution II, LLC, v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24, at *10 (PTAB June 16, 2020) (informative) (noting that investment in invalidity contentions and claim construction is relevant to this factor).

Substantial activity has already occurred in the parallel litigation as noted in Sections II.B and II.C, *supra*. The parties have heavily invested in the parallel litigation by engaging the Court in terms of scheduling matters, a protective order, and Petitioner’s failed motion to stay. Further, NNB served detailed Preliminary Infringement Contentions and supporting documents; Petitioner served its Preliminary Invalidity Contentions, which largely track its petition here, and made the associated document disclosure; a significant amount of written discovery has been issued by NNB and responded to by Petitioner; NNB has produced over 2,000 pages of documents, Petitioner has produced over 1,200 pages of documents; and, the claim construction process is moving forward in earnest. *See Exhs. 2012, 2013* (at ¶¶ 3-8), 2016.

Per the Court’s case schedule (*see* Exh. 2011), the following will occur before the expected date of an institution decision: (1) the claim construction discovery cut-off – 1/22/2026; (2) the Joint Claim Construction and Prehearing Statement – 2/19/2026; (3) the parties’ opening claim construction briefs – 3/12/2026; and, (4) the parties’ responsive claim construction briefs – 3/26/2026; and, the *Markman* hearing, if one is held, will occur nearly concurrent with the expected time of the institution decision – 4/21/2026 (or as soon thereafter as possible). *Id.* at p. 002, lines 11-22. Thus, prior to the deadline for the institution decision (April 7, 2026), the parties will have fully briefed claim construction to the Court.

Accordingly, the parties are already heavily invested in the parallel litigation, and will invest substantially more in the coming months on discovery and claim construction, before the deadline for the institution decision in April of 2026. For these reasons, this factor also strongly weighs in favor of discretionary denial.

4. *Fintiv* Factor 4 – Overlap Between Issues Raised in the Petition and the Litigation

Fintiv Factor 4 looks to “whether all or some of the claims challenged in the petition are also at issue in district court” and whether the “petition includes the same or substantially the same claims, grounds, arguments, and evidence” as the parallel district court case. *Fintiv I* at *12-13. This factor evaluates “concerns of inefficiency and the possibility of conflicting decisions” when substantially identical prior art is submitted in both the district court and the IPR proceeding. *Id.* at *12.

Here, Petitioner’s invalidity contentions in the litigation and grounds for invalidity in its petition are *identical* (including the identical typo of “**Tuner** in view of Shaw) at page 5 of Exhibit A-1 to its Invalidity Contentions (*see* Exh. 2016 at p. 025 – claim 2)) and page 32 of its petition (*see* Paper 2 herein) (emphasis added)); *except*, that Petitioner’s Ground 4 herein is not raised in the litigation because claim 6 of the ‘261 Patent was not asserted in the litigation, and the § 112 grounds for invalidity asserted in the litigation are not (and cannot be) asserted herein.

Otherwise, a comparison of the claim charts in the petition relative to Petitioner’s Invalidity Contentions in the litigation show that Petitioner’s prior art grounds for invalidity of the claims asserted in the litigation (1, 2, 5, 7) are *precisely the same* (down to the citations to evidence, including the Shebuski Declaration) in both. *Cf.* For Ground 1 – Petition (Paper 2) at pp. 27-40 to Exhibit A-1 of Exhibit 2016 (pp. 021-029 therein); For Ground 2 – Petition (Paper 2) at pp. 40-42 to Exhibit A-2 of Exhibit 2016 (pp. 030-031 therein); For Ground 3 – Petition (Paper 2) at pp. 49-61 to Exhibit A-3 of Exhibit 2016 (pp. 032-040 therein). In fact, Petitioner attached its petition to its Invalidity Contentions. The risk of inefficiency and inconsistent outcomes is high.

Petitioner’s “titles” for the grounds in its petition relative to the litigation (e.g., “Turner in view of Shaw”) do not tell the story. The prior art grounds for invalidity of claims 1, 2, 5, and 7 are *identical* between the litigation and the petition.

The fact that Petitioner submitted a *Sotera* statement to the Board is of minimal import where the evidence tilts heavily in favor of discretionary denial and where other grounds of invalidity are presented in the litigation. *See SAP America, Inc. v. Cyandia, Inc.*, IPR2024-01496, Paper No. 13, at *9 (PTAB Apr. 7, 2025).

For the foregoing reasons, this factors favors a discretionary denial.

5. *Fintiv* Factor 5 - Whether the Petitioner and Defendant in the Parallel Proceeding are the Same Party

Fintiv factor 5 also favors discretionary denial. Where “the petitioner and the defendant in the parallel proceeding are the same party, this factor weighs in favor of discretionary denial.” *Fintiv II* at *15. Here, Petitioner and the defendant in the parallel proceeding are one and the same – Bonerge Lifescience (Hunan) Co., Ltd. *See* Paper 2, at 63-64 (identifying Bonerge Lifescience (Hunan) Co., Ltd. as the real party in interest and identifying it as the defendant in the parallel litigation). Thus, this factor favors, if not strongly favors, discretionary denial.

6. *Fintiv* Factor 6 – Other Circumstances that Impact the Board’s Exercise of Discretion, Including the Merits

Three “other circumstances” including from the Workload Management Memo support a discretionary denial here: (a) settled expectations; (b) Petitioner’s over-reliance on expert testimony; and, (c) the weakness of the petition.

a. Settled Expectations

Settled expectations exist as to the ‘261 Patent, which issued on May 7, 2019,

over 6 ½ years ago. *See* Exh. 1001 (face page).

The Workload Management Memo includes the “settled expectations” of the parties as relevant to the discretionary denial determination. Workload Management Memo, *2. “[T]he longer the patent has been in force, the more settled expectations should” militate against institution of an IPR. *Dabico Airport Sols., Inc. v. Axa Power APS*, IPR2025-00408, Paper 21, at *3 (PTAB June 18, 2025); *see also See Kahoot! AS v. Interstellar, Inc.*, IPR2025-00696, Paper 12, at *2 (PTAB July 31, 2025) (finding settled expectations where patent was in force **six years**) (emphasis added); *Yangtze Memory Techs. Co., Ltd. v. Micron Tech., Inc.*, IPR2025-00498, Paper 11, at *2 (PTAB Aug. 14, 2025) (granting discretionary denial where “the challenged patents have been in force for approximately ten, **six, and six years**, respectively, creating strong settled expectations for Patent Owner”) (emphasis added); *Amgen, Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, 00602, 00603, Paper 9, at *3 (PTAB July 24, 2025) (as to IPR2025-00601 and IPR2025-00602, “the challenged patents have been in force for **seven and six years**, respectively, creating strong settled expectations for Patent Owner”) (emphasis added).

Here, because the ‘261 Patent has been in force for over 6 ½ years, there are settled expectations. And, because Petitioner is actively participating in the parallel litigation, there is no persuasive reason to justify use of Board resources on this matter. *Samsung Elecs. Co. v. GenghisComm Holdings, LLC*, IPR2025-00780,

Paper 11, at *2 (PTAB Aug. 14, 2025) (“the challenged patents have been in force for approximately eight and **six years**, creating strong settled expectations for Patent Owner, and Petitioner does not provide any persuasive reasoning why an inter partes review is an appropriate use of Board resources.”) (emphasis added). Therefore, settled expectations also favor a discretionary denial.

b. Excessive reliance on expert testimony

In evaluating discretionary denial, the Director may also consider the “extent of the petition’s reliance on expert testimony.” Workload Management Memo, at *2; *see also Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper No. 9, at *15 (PTAB Aug. 24, 2022).

Here, it is undeniable that the petition and Petitioner’s expert’s declaration possess a significant amount of identical or substantially similar text. Petitioner extensively relies upon expert testimony regarding how a person of ordinary skill in art would view the prior art, the motivation of a person of ordinary skill in the art to combine references, and whether a person of ordinary skill in the art would have a reasonable expectation of success. Petitioner’s extensive reliance on expert testimony is observable in numerous ways.

First, a simple search of the Petition (Paper 2) for “EX1003,” which is Petitioner’s expert declaration, yielded **92** hits, only one of which appeared to be used for something other than in support of the four (4) grounds of asserted

invalidity, including extensive numbers of hits throughout the claim charts. Thus, the petition cites *extensively* to Petitioner's expert declaration.

Second, a search of the Petition for "POSA" ("person of ordinary skill in the art" – see Paper 2, at 8) where "POSA" was referenced in connection with a citation to Exh. 1003 (Petitioner's Expert Declaration), resulted in approximately **40** hits. See Paper 2, at *8 (¶ 27)³, 19 (¶ 44), 20 (¶¶ 45, 46), 22 (¶ 48), 24 (¶¶ 52, 53), 26 (¶ 57), 27 (¶ 57), 30 (¶¶ 44-57 – at least in part via reference to Part IV.A.1-4), 31 (¶¶ 49-52), 33 (¶¶ 58-60), 34 (¶¶ 44-57 – at least in part via reference to Part IV.A.1-4; 61), 36 (¶¶ 62-64), 37 (¶ 64), 39 (¶¶ 67, 68), 40 (¶¶ 69, 70), 42 (¶¶ 64, 71-73), 44 (¶ 83), 46 (¶ 87), 53 (at least ¶¶ 83, 87), 54 (¶ 83), 55 (¶¶ 87-90), 57 (¶¶ 93, 94), 58 (¶ 97), 59 (¶ 98), 61 (¶ 102), 63 (¶¶ 105, 106). Thus, specifically in connection with what a person of ordinary skill in the art would think, believe, and understand about the prior art, its combination or modification, and whether success could be reasonably anticipated, Petitioner extensively relies upon expert testimony.

Third, as to an alleged reasonable expectation of success, the Expert Declaration (Exh. 1003) discusses it in ¶¶ 45, 48, 53 (twice), 54, 61, 68, 70, 81, 87 (twice), 88, 89, 94, 98, 102, 106. The expert is filling gaps in the prior art, and

³ The citation format here identifies the Petition page (Paper 2) coupled with the cited paragraphs from Petitioner's Expert Declaration (Exh. 1003) in parentheses.

Petitioner's extensive reliance on the expert as to an inherently factual issue where factual issues will likely arise should be addressed by the district court.

Fourth, a search of Petitioner's Expert Declaration for "POSA" also yields 44 hits that correspond to expert opinion. Headings or conclusory statements were *not* counted in the 44 hits and may be found in Exh. 1003 at ¶¶ 8, 10, 13, 15, 26, and on pp. 21 and 40 in headings). Otherwise, most, if not all, uses of "POSA" in the Expert Declaration are the expert's statements about what a person of ordinary skill in the art would understand or think, on which Petitioner relies.

Fifth, NNB non-exhaustively identifies at least the following portions of the petition are taken *verbatim* or nearly *verbatim* from the text in Petitioner's Expert's Declaration (or vice-versa). *Cf. e.g.* Exh. 1003 ¶¶ 17 (to first two sentences under B.1 on p. 4 of the petition (Paper 2), 19 (to paragraph at bottom p. 4/top p. 5 of Paper 2), 20 (to first full paragraph on p. 5 of Paper 2), 21 (to first full paragraph on p. 6 of Paper 2), 22-25 (to last two paragraphs on p. 6/first two paragraphs on p. 7 of Paper 2), 26-27 (to level of skill in the art on p. 8 of Paper 2), 28-35 (to claim construction on p. 9-11 of Paper 2), 40 (to second paragraph on p. 14 of Paper 2), 41 (to paragraph at bottom p. 14/top p. 15 of Paper 2), 44 (to paragraph at bottom p. 18/top p. 19 of Paper 2). Petitioner's heavy reliance on expert testimony in its petition will likely create factual disputes that an Article III court is better positioned than the Board to resolve. Thus, discretionary denial is also favored on this basis.

c. **The Weakness of the Petition**

The weakness of the petition as to at least the reasonable expectation of success is supported the substantial unpredictability in extrapolating animal research to human outcomes. One publication from 2014 question the applicability and predictability of extending animal models to humans. *See* Exh. 2018. In the article, among other things, the authors discuss the Collaborative Approach to Meta-Analysis and Review of Animal Data from Experimental Studies (CAMARADES), which “has been at the forefront of conducting systematic reviews of animal studies.” *Id.* at p. 001. According to the authors, by 2012, CAMARADES found “consistent suggestions of serious bias in animal studies,” that makes it “nearly impossible to rely on most animal data to predict whether or not an intervention will have a favourable clinical benefit-risk ratio in human subjects.” *Id.*

Regarding metabolic disorders such as diabetes and insulin resistance, one article submitted in 2017 and published in 2018, but which is indicative of the art as of the effective filing date of the ‘261 Patent in 2016, and which included the same “Turner” as Petitioner’s cited reference, noted that physiological anomalies with genetically inbred rodents that differences between rodents and humans cause manifestations of metabolic dysfunction that “may not fully reflect metabolic disease etiology in humans” and that “they do not necessarily reflect the complexity and heterogeneity of the metabolic syndrome.” *See* Exh. 2019 at p. 002. Thus, even the

prior art author relied on by Petitioner significantly qualified and urged caution in terms of extrapolating results from genetically inbred animals to humans in connection with metabolic disorders and diabetes.

A 2014 article regarding the use of High-Fat Diet Rodents (as in some of Petitioner's cited art) to mimic human metabolic disorders stated, "it is clear that the natural history and metabolic characteristics of the human condition cannot be effectively recapitulated in a single model or even a combination of these animal models." *See* Exh. 2020 at p. 007. The authors noted divergent outcomes in rodents vs. humans: "In humans, prolonged fasting impairs insulin-stimulated glucose utilization, but the opposite is true for rodents." *Id.* at p. 004. The authors also noted, "Even the standard 'control' animals may not be appropriate controls for obesity research as, in the words of the study author, these mice kept in controlled environments under a sedentary lifestyle with continuous access to food are 'metabolically morbid ... obese, glucose intolerant, and on a trajectory to premature death.'" *Id.* at p. 002. The authors concluded that "[u]nderstanding disease etiopathogenesis is crucial for the development of new therapeutic interventions, but human environmental influence on disease ontogeny cannot be recreated in a laboratory setting nor can they exert the same effect on another species." *Id.* at p. 008.

Thus, researchers in the field, including at least one relied on by Petitioner, do not have a reasonable expectation of success in extrapolating results from the

laboratory or from animal studies to efficacy in humans for a condition as complex as diabetes or related metabolic issues.

In addition to this brief rebuttal to the petition, Patent Owner's Preliminary Response will be forthcoming to further detail the weakness of the petition.

The foregoing demonstrates that other circumstances, including those in the Workload Management Memo, strongly favor discretionary denial.

7. Summary of *Fintiv* Factors

The foregoing demonstrates that at least four (4) of the *Fintiv* factors strongly favor discretionary denial and two (2) at least favor discretionary denial. None are neutral or worse for NNB. Accordingly, a discretionary denial is warranted here.

IV. CONCLUSION

For the aforementioned reasons, discretionary denial is warranted, and Bonerge's Petition should not be referred for institution.

Date: December 2, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105(b), the undersigned hereby certifies that a copy of this **PATENT OWNER NANJING NUTRABUILDING BIO-TECH CO., LTD.'S DISCRETIONARY DENIAL BRIEF** has been served on December 2, 2025 upon the following litigation counsel via electronic means:

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Date: December 2, 2025

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**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME
REQUIREMENTS UNDER 37 C.F.R. § 42.24**

Under 37 C.F.R. § 42.24(d), the undersigned certifies that this **PATENT OWNER NANJING NUTRABUILDING BIO-TECH CO., LTD.'S DISCRETIONARY DENIAL BRIEF** complies with the page limitation in that it contains 20 pages.

This paper also complies with the typeface requirements of 37 C.F.R. § 42.6(a)(2)(ii) and the type style requirements of 37 C.F.R. § 42.6(a)(2)(iii) and (iv).

Date: December 2, 2025

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