

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR HEALTH, INC.,  
Petitioner,

v.

INFORLIFE, S.A.,  
Patent Owner.

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Case PGR2026-00036  
Patent 12,370,153

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**PATENT OWNER'S PRELIMINARY RESPONSE**

**TABLE OF CONTENTS**

|                                                                                                                                                              |     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| TABLE OF AUTHORITIES .....                                                                                                                                   | iii |
| EXHIBIT LIST .....                                                                                                                                           | ix  |
| I. INTRODUCTION .....                                                                                                                                        | 1   |
| II. PATENT OWNER HAS STATUTORILY DISCLAIMED CLAIMS 1,<br>3-5, 13 and 18 .....                                                                                | 7   |
| III. LEGAL REQUIREMENTS OF THE PETITION .....                                                                                                                | 8   |
| A. The Particularity Requirement .....                                                                                                                       | 8   |
| B. Petitioner’s Burden to Establish Unpatentability .....                                                                                                    | 10  |
| 1. Anticipation – 35 U.S.C. § 102.....                                                                                                                       | 10  |
| 2. Obviousness – 35 U.S.C. § 103 .....                                                                                                                       | 11  |
| IV. LEVEL OF ORDINARY SKILL IN THE ART .....                                                                                                                 | 14  |
| V. CLAIM CONSTRUCTION .....                                                                                                                                  | 14  |
| VI. THE PETITION DOES NOT SATISFY THE STATUTORY<br>THRESHOLD FOR INSTITUTING PGR.....                                                                        | 16  |
| A. Petitioner Fails to Establish that the Primary Reference Relied<br>Upon for All Grounds (Biomed, Ex. 1005) is Prior Art .....                             | 16  |
| B. Ground 1 Fails to Establish Anticipation by Biomed and Should<br>be Denied.....                                                                           | 22  |
| 1. Petitioner supplies no evidence that Biomed meets the<br>“sterile” limitation.....                                                                        | 23  |
| 2. Claim 19 is not anticipated by Biomed.....                                                                                                                | 25  |
| 3. Claim 20 is not anticipated by Biomed.....                                                                                                                | 30  |
| C. Ground 2 Fails to Establish Obviousness Over Biomed in View of<br>Remington 2021 and Commercially-Available Infusion Bags and<br>Should Be Denied.....    | 31  |
| 1. Petitioner’s failure to supply evidence of inherency<br>dooms its Ground 2 challenges and the secondary<br>references fail to remedy those failures ..... | 33  |
| a. Petitioner fails to meet the high standard required to<br>establish inherent obviousness.....                                                             | 34  |

|       |                                                                                                                                                                                          |    |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| b.    | Petitioner fails to show that the sterility limitations are necessarily present or the natural result of modifying Biomed using the secondary references .....                           | 37 |
| c.    | Petitioner fails to show the Claimed Storage Stability is necessarily present or the natural result of modifying Biomed as proposed by Petitioner.....                                   | 40 |
| d.    | Petitioner fails to show the Claimed Chemical Stability is necessarily present or the natural result of modifying Biomed as proposed by Petitioner.....                                  | 46 |
| 2.    | Ground 2 improperly relies on general knowledge and fails to establish a motivation or reasonable expectation of success for the sterilization-related terms.....                        | 50 |
| a.    | Petitioner improperly relies on general knowledge for “sterile” in claims 2, 6-12, 14-15, 21, and 23 .....                                                                               | 51 |
| b.    | Petitioner fails to establish a reasonable expectation of success for “terminally sterilized” in claims 2, 16, 17, and 22.....                                                           | 55 |
| c.    | Petitioner fails to establish a reasonable expectation of success for “autoclaved” in claim 15 .....                                                                                     | 60 |
| d.    | Petitioner fails to establish a motivation or a reasonable expectation of success for “aseptically filled” in claim 21. ....                                                             | 63 |
| e.    | Petitioner fails to establish a reasonable expectation of success in achieving the 24 month chemical stability required by claims 22 and 23.....                                         | 65 |
| 3.    | The Petition improperly uses the patent specification as a roadmap and fails to establish a motivation or reasonable expectation of success for claims 6–12 and 14 (IV Bag Claims) ..... | 68 |
| VII.  | DISCRETIONARY DENIAL .....                                                                                                                                                               | 75 |
| VIII. | CONCLUSION.....                                                                                                                                                                          | 76 |

**TABLE OF AUTHORITIES**

**Cases**

|                                                                                                       |                |
|-------------------------------------------------------------------------------------------------------|----------------|
| <i>Adama Agan Ltd. v. Bayer CropScience LP</i> ,<br>PGR2022-00057, Paper 9 (PTAB Feb. 13, 2023) ..... | 16, 17, 18, 22 |
| <i>Allergan, Inc. v. BTL Med. Techs. S.R.O.</i> ,<br>PGR2021-00020 (PTAB June 16, 2021) .....         | 21             |
| <i>Amgen Inc. v. F. Hoffmann-La Roche Ltd.</i> ,<br>580 F.3d 1340 (Fed. Cir. 2009).....               | 13             |
| <i>Apple Inc. v. MemoryWeb, LLC</i> ,<br>No. 2023-2361, 2025 WL 3494991 (Fed. Cir. Dec. 5, 2025)..... | 9              |
| <i>Apple Inc. v. Resonant Sys., Inc.</i> ,<br>IPR2024-00983, Paper 27 (PTAB Oct. 23, 2025) .....      | 36             |
| <i>Apple Inc. v. Samsung Elecs. Co., Ltd.</i> ,<br>839 F.3d 1034 (Fed. Cir. 2016).....                | 33, 48, 67     |
| <i>Apple Inc. v. Squires</i> ,<br>166 F.4th 1349 (Fed. Cir. 2026) .....                               | 75             |
| <i>Arendi S.A.R.L. v. Apple Inc.</i> ,<br>832 F.3d 1355 (Fed. Cir. 2016).....                         | passim         |
| <i>Belden Inc. v. Berk-Tek LLC</i> ,<br>805 F.3d 1064 (Fed. Cir. 2015).....                           | 57, 62         |
| <i>BTC Corp. v. TG Biotech Co., Ltd.</i> ,<br>IPR2022-00998, Paper 44 (PTAB Nov. 13, 2023) .....      | 34             |
| <i>Cont’l Can Co. USA, Inc. v. Monsanto Co.</i> ,<br>948 F.2d 1264 (Fed. Cir. 1991).....              | 11, 26, 49     |
| <i>DSS Tech. Mgmt., Inc. v. Apple Inc.</i> ,<br>885 F.3d 1367 (Fed. Cir. 2018).....                   | 10             |
| <i>Eli Lilly &amp; Co. v. Barr Labs., Inc.</i> ,<br>251 F.3d 955 (Fed. Cir. 2001).....                | 24, 29         |

|                                                                                                              |        |
|--------------------------------------------------------------------------------------------------------------|--------|
| <i>Endo Pharms. Sols., Inc. v. Custopharm Inc.</i> ,<br>894 F.3d 1374 (Fed. Cir. 2018).....                  | 35, 49 |
| <i>Eton Pharms., Inc. v. Exela Pharma Scis., LLC</i> ,<br>No. PGR2020-00086 (P.T.A.B. Apr. 23, 2021) .....   | 9      |
| <i>Finnigan Corp. v. Int'l Trade Comm'n.</i> ,<br>180 F.3d 1354 (Fed. Cir. 1999).....                        | 21     |
| <i>Graham v. John Deere Co.</i> ,<br>383 U.S. 1 (1966).....                                                  | 12     |
| <i>Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V.</i> ,<br>865 F.3d 1348 (Fed. Cir. 2017)..... | 13, 70 |
| <i>Hulu, LLC v. Sound View Innovations, LLC</i> ,<br>IPR2018-01039, Paper 29 (PTAB Dec. 20, 2019) .....      | 17     |
| <i>Immersion Sys. LLC v. Midas Green Techs., LLC</i> ,<br>PGR2021-00104 (PTAB Jan. 31, 2022) .....           | 75     |
| <i>In re Dow Chem. Co.</i> ,<br>837 F.2d 469 (Fed. Cir. 1988).....                                           | 13, 75 |
| <i>In re Hall</i> ,<br>781 F.2d 897 (Fed. Cir. 1986).....                                                    | 16     |
| <i>In re Kahn</i> ,<br>441 F.3d 977 (Fed. Cir. 2006).....                                                    | 12     |
| <i>In re Magnum Oil Tools Int'l, Ltd.</i> ,<br>829 F.3d 1364 (Fed. Cir. 2016).....                           | 10, 12 |
| <i>In re Montgomery</i> ,<br>677 F.3d 1375 (Fed. Cir. 2012).....                                             | 11, 24 |
| <i>In re NuVasive, Inc.</i> , 842 F.3d 1376 (Fed. Cir. 2016) .....                                           | 12, 55 |
| <i>In re Oelrich</i> ,<br>666 F.2d 578 (C.C.P.A. 1981) .....                                                 | passim |
| <i>In re O'Farrell</i> ,<br>853 F.2d 894 (Fed. Cir. 1988).....                                               | 13     |

|                                                                                                              |                |
|--------------------------------------------------------------------------------------------------------------|----------------|
| <i>In re Rijckaert</i> ,<br>9 F.3d 1531 (Fed. Cir. 1993).....                                                | 13, 14, 37, 40 |
| <i>In re Robertson</i> ,<br>169 F.3d 743 (Fed. Cir. 1999).....                                               | 11             |
| <i>In re Wyer</i> ,<br>655 F.2d 221 (C.C.P.A. 1981) .....                                                    | 16             |
| <i>Incyte Corp. v. Concert Pharms., Inc.</i> ,<br>IPR2017-01256, Paper 14-15 (PTAB Apr. 9, 2018) .....       | 19             |
| <i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.</i> ,<br>821 F.3d 1359 (Fed. Cir. 2016).....        | 8              |
| <i>InTouch Techs., Inc. v. VGo Commc’ns, Inc.</i> ,<br>751 F.3d 1327 (Fed. Cir. 2014).....                   | 12             |
| <i>InVue Sec. Prods., Inc. v. Mobile Tech., Inc.</i> ,<br>IPR2019-00078, Paper 7 (P.T.A.B. May 1, 2019)..... | 8              |
| <i>Jazz Pharms., Inc. v. Amneal Pharms., LLC</i> ,<br>895 F.3d 1347 (Fed. Cir. 2018).....                    | 16             |
| <i>K/S HIMPP v. Hear-Wear Techs., LLC</i> ,<br>751 F.3d 1362 (Fed. Cir. 2014).....                           | 76             |
| <i>Kinetic Concepts, Inc. v. Smith &amp; Nephew, Inc.</i> ,<br>688 F.3d 1342 (Fed. Cir. 2012).....           | 69             |
| <i>KSR Int’l Co. v. Teleflex Inc.</i> ,<br>550 U.S. 398 (2007).....                                          | 11, 12         |
| <i>Life Tech., Inc. v. Clontech Labs., Inc.</i> ,<br>224 F.3d 1320 (Fed. Cir. 2000).....                     | 71             |
| <i>Luv n’ Care, Ltd. v. Laurain</i> ,<br>98 F.4th 1081 (Fed. Cir. 2024) .....                                | 33, 49, 67     |
| <i>Medichem, S.A. v. Rolabo, S.L.</i> ,<br>437 F.3d 1157 (Fed. Cir. 2006).....                               | 13             |

|                                                                                                                    |        |
|--------------------------------------------------------------------------------------------------------------------|--------|
| <i>Mylan Pharms. Inc. v. Boehringer Ingelheim Int’l GmbH</i> ,<br>IPR2016-01563, Paper 16 (PTAB Feb. 3, 2017)..... | 17, 19 |
| <i>Mylan Pharms. Inc. v. Boehringer Ingelheim Int’l GmbH</i> ,<br>IPR2016-01565, Paper 17 (PTAB Feb. 9, 2017)..... | 20     |
| <i>Mylan Pharms. Inc. v. Boehringer Ingelheim Int’l GmbH</i> ,<br>IPR2016-01565, Paper 23 (PTAB Aug. 1, 2017)..... | 19     |
| <i>Net MoneyIN, Inc. v. VeriSign, Inc.</i> ,<br>545 F.3d 1359 (Fed. Cir. 2008).....                                | 10     |
| <i>Orexo AB v. Actavis Elizabeth LLC</i> ,<br>903 F.3d 1265 (Fed. Cir. 2018).....                                  | 70     |
| <i>Par Pharm., Inc. v. TWi Pharms., Inc.</i> ,<br>773 F.3d 1186 (Fed. Cir. 2014).....                              | passim |
| <i>Pfizer, Inc. v. Biogen, Inc.</i> ,<br>IPR2017-01166, Paper 9 (PTAB Nov. 13, 2017).....                          | 17     |
| <i>Raytheon Techs. Corp. v. General Electric Co.</i> ,<br>993 F.3d 1374 (Fed. Cir. 2021).....                      | 7      |
| <i>Realtime Data, LLC v. Iancu</i> ,<br>912 F.3d 1368 (Fed. Cir. 2019).....                                        | 14     |
| <i>Ruiz v. A.B. Chance Co.</i> ,<br>357 F.3d 1270 (Fed. Cir. 2004).....                                            | 12, 68 |
| <i>Scaltech, Inc. v. Retec/Tetra, LLC</i> ,<br>269 F.3d 1321 (Fed. Cir. 2001).....                                 | 21     |
| <i>TQ Delta, LLC v. Cisco Sys., Inc.</i> ,<br>942 F.3d 1352 (Fed. Cir. 2019).....                                  | 8, 73  |
| <i>Transclean Corp. v. Bridgewood Servs., Inc.</i> ,<br>290 F.3d 1364 (Fed. Cir. 2002).....                        | 11     |
| <i>Trintec Indus., Inc. v. Top–U.S.A. Corp.</i> ,<br>295 F.3d 1292 (Fed. Cir. 2002).....                           | 11     |

|                                                                                                                   |           |
|-------------------------------------------------------------------------------------------------------------------|-----------|
| <i>TriVascular, Inc. v. Samuels</i> ,<br>812 F.3d 1056 (Fed. Cir. 2016).....                                      | 69        |
| <i>Verdegaal Bros., Inc. v. Union Oil Co. of Cal.</i> ,<br>814 F.2d 628 (Fed. Cir. 1987).....                     | 11        |
| <i>Vivid Techs., Inc. v. Am. Sci. &amp; Eng’g, Inc.</i> ,<br>200 F.3d 795 (Fed. Cir. 1999).....                   | 14        |
| <i>Xerox Corp. v. Bytemark, Inc.</i> ,<br>IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022) .....                   | 8, 23, 61 |
| <i>Zhuhai Cosmox Battery Co., Ltd. v. Ningde Amperex Tech. Ltd.</i> ,<br>IPR2025-00405 (PTAB Oct. 15, 2025) ..... | 76        |

## **Statutes**

|                       |                |
|-----------------------|----------------|
| 35 U.S.C. § 102 ..... | 10, 16, 20, 22 |
| 35 U.S.C. § 103 ..... | 11, 12, 67, 70 |
| 35 U.S.C. § 253 ..... | 7              |
| 35 U.S.C. § 312 ..... | 9              |
| 35 U.S.C. § 321 ..... | 16             |
| 35 U.S.C. § 322 ..... | passim         |
| 35 U.S.C. § 324 ..... | 7, 8           |
| 35 U.S.C. § 326 ..... | 44             |

## **Other Authorities**

|                                                                                                |    |
|------------------------------------------------------------------------------------------------|----|
| U.S. Patent & Trademark Office, <i>Consolidated Trial Practice Guide</i> , 36 (Nov. 2019)..... | 36 |
|------------------------------------------------------------------------------------------------|----|

## **Rules**

|                           |    |
|---------------------------|----|
| 37 C.F.R. § 1.321(a)..... | 7  |
| 37 C.F.R. § 42.1(b) ..... | 76 |

|                               |        |
|-------------------------------|--------|
| 37 C.F.R. § 42.104(b)(4)..... | 9      |
| 37 C.F.R. § 42.204(b)(4)..... | 8, 9   |
| 37 C.F.R. § 42.65(a).....     | passim |

**EXHIBIT LIST**

| <b>Exhibit No.</b> | <b>Exhibit Description</b>                                                                                                                                              |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2001               | 37 C.F.R. 1.321(a) Statutory Disclaimer covering Claim Nos. 1, 3-5, 13 and 18 for U.S. Patent No. 12,370,153                                                            |
| 2002               | Memorandum regarding “Enforcement and Non-Waiver of 37 C.F.R. § 42.104(B)(4) and Permissible Uses of General Knowledge in <i>Inter Partes Reviews</i> ” (July 31, 2025) |

## I. INTRODUCTION

Patent Owner InfoRLife, S.A. ("Patent Owner") submits its Preliminary Response to the Petition for Post-Grant Review No. PGR2026-00036 ("Petition") filed by Par Health, Inc. ("Petitioner") challenging claims 1–23 of U.S. Patent No. 12,370,153 (the "'153 patent," Ex. 1001). Patent Owner has disclaimed claims 1, 3–5, 13 and 18 to simplify the issues before the Board. *See* Section II *infra*.

Pursuant to 37 C.F.R. § 42.207(e), "[n]o post-grant review will be instituted based on disclaimed claims." Thus, only claims 2, 6–12, 14–17, and 19–23 are at issue.

The '153 patent is directed to an innovative sterile, ready-to-use (RTU) ketamine product that is preservative-free, anti-microbial free, and has both long shelf-life and high chemical stability when stored at room temperature. The '153 patent describes advantages of the claimed ketamine products, including avoiding the cost, inconvenience, and risk of contamination or overdose that can be associated with reconstituting or diluting a concentrated ketamine formulation prior to administration to a patient. Ex. 1001 at 7:19-34.

The '153 patent explains that ketamine in aqueous solution was known to react under accelerated conditions such as high temperature to form impurities. *Id.* at 14:41–15:40. The tendency of ketamine to form impurities, particularly upon exposure to high temperatures such as during terminal sterilization, presented challenges for the development of a ready-to-use, sterile, aqueous ketamine

product. Examples 2, 3, and 4 provide experimental results demonstrating that the inventors of the '153 patent met the need for high chemical stability and long-term shelf-life in a sterile, ready-to-use ketamine product, without the use of preservatives or anti-microbial agents. *Id.* at 24:55–45:30.

The '153 patent also explains that terminal sterilization is one of the most difficult requirements for medical devices because it involves conditions that can affect the integrity of the packaging, cause leaching of packaging components into the pharmaceutical solution, cause degradation of the drug product, and otherwise affect the stability the pharmaceutical solution. *Id.* at 10:53-60.

The inventors produced a novel ketamine product that is ready-to-use, preservative-free, anti-microbial free, and can withstand the terminal sterilization process without losing either chemical stability of the ketamine or the shelf-life of the packaged RTU product. The '153 patent explains that Tables 6–9 surprisingly showed that the claimed sterile ketamine products, formulated without any antimicrobial, stabilizer or preservative, were at least as stable as the commercial formulation (containing the conventional antimicrobial agent benzethonium chloride) under accelerated conditions and long-term storage. *Id.* at 31:28-33. The '153 patent demonstrates that chemical stability of the ketamine product in the infusion bag of Example 2 remained high, without any significant change during stability studies. *Id.* at 32:19-22. The '153 patent further demonstrates excellent

shelf-life, *i.e.*, after long term storage at room temperature for 12 months and accelerated stability testing at 40°C for 6 months, the claimed ketamine product showed no degradation despite not containing any antimicrobial, stabilizer or preservative. *Id.* The '153 patent thus claims a ketamine product that “has a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” in every independent claim (“Claimed Storage Stability”). Further, the '153 patent demonstrates that the ketamine solution is chemically stable following 24 months of storage at 25° C±2° C with relative humidity (RH) at 40%±5% as recited in claims 18, 19, 22 and 23, and shown in Example 3 and Tables 6–9 (“Claimed Chemical Stability”).

Importantly, Example 4 demonstrates that the ketamine product produced highly desirable terminal sterilization results in a heat degradation stress study performed on the ketamine solution in the same infusion bags described in Example 2. No significant degradation of the ketamine solution in the primary packaging was observed after two terminal sterilization cycles conducted at 121° C for 15 minutes each. Ex. 1001 at 43:30–44:35.

The Board should decline to institute Post-Grant Review (PGR) because Petitioner has not established that it is more likely than not that at least one of the challenged claims is unpatentable. Both of Petitioner's challenges fail for multiple reasons.

*First*, Petitioner failed to carry its burden to establish that its primary reference, Biomed, was more likely than not publicly accessible before the critical date. Not only does Petitioner fail to show that the Biomed document was publicly available in the prior art, but Petitioner also implies without evidence that Biomed represents an approved, manufactured, or marketed product that therefore would have had certain properties that are not disclosed anywhere in Biomed itself. None of Petitioner's assumptions are supported by evidence of record, and the Petition can be denied for this reason alone.

*Second*, Petitioner's challenges require findings of inherent anticipation or inherent obviousness that are not supported by the record. Petitioner has not presented any experimental evidence or credible scientific rationale to establish that the claimed invention, as a whole, was necessarily present in Biomed, which fails to disclose multiple claimed elements. Likewise, Petitioner's obviousness combinations require modifying Biomed based on publications disclosing general pharmaceutical processes or commercially available infusion bags—none of which relate to ketamine solutions—and Petitioner fails to provide data or information about what properties would have necessarily resulted from Petitioner's proposed modifications to Biomed. Petitioner impermissibly uses the patent specification as a roadmap to identify the claimed elements and to allege that it would have been obvious to use any and all combinations of those elements to modify Biomed, and

that doing so would inherently result in a ketamine product having the claimed chemical stability and long-term shelf-life properties. Petitioner's unsupported assumptions do not remotely meet the high standard for inherency.

*Third*, Petitioner impermissibly substitutes conclusory expert testimony for missing claim elements that are not disclosed in Biomed. Petitioner has not met its burden on the merits because each challenged claim requires that the ketamine product be sterile (*e.g.*, terminally sterilized or aseptically filled). Petitioner has not identified any of the claimed sterility limitations in Biomed. Instead, Petitioner only relies on expert testimony to fill the missing limitation by arguing that *silence* in the Biomed reference would be understood as disclosing a sterile product.

Petitioner also makes internally inconsistent arguments that further undercut its Ground 2 challenge. While Petitioner claims that Biomed was sterile, ready-to-use, shelf-stable and suitable for treating patients in asserting anticipation (Pet. at 28-30), Petitioner argues that a POSA would have modified Biomed, *e.g.*, by changing its infusion bag, container closure system, overwrap, and sterilization techniques in Ground 2. No motivation is alleged other than based on impermissible hindsight that the Commercially Available bags listed in the '153 patent existed and that various sterilization techniques existed. Petitioner likewise fails to establish a reasonable expectation of success in modifying Biomed to

obtain the claimed sterility, bag, container closure, and overwrap limitations, each **in combination with** the claimed chemical stability and shelf-life limitations.

The Examiner correctly allowed the claims and did not commit any material errors during prosecution. The Examiner performed three separate prior art searches for ketamine solutions (search results posted in Patent Center on October 23, 2024, December 19, 2024, and March 27, 2025). Ex. 1002 at 204-208, 249-251, and 342-346. The Biomed reference did not appear as a prior art publication in any of those searches. And no published reference of record mentioned the existence of a ketamine product as purportedly described by Biomed reference. Petitioner also fails to produce a scintilla of evidence on the record that the alleged Biomed product actually existed or was recognized in the published literature in the field before the critical date.

Rather, the record evidence shows that the field recognized Ketalar® as the commercially available ketamine preparation in the prior art, which was also recognized by the Examiner during prosecution. The Examiner correctly reasoned in the Notice of Allowance that:

What the prior art does not disclose, however, is how to prepare one such preservative-free formulation, which is ready-to-use and stable over time. To this end, the commercially available preparation (Ketalar®) has the preservative benzethonium chloride. Applicant was

able to develop and test as suitable a preservative-free formulation, which is ready-to-use and stable over time.

Ex. 1002 at 365.

The Petition failed to establish that any challenged claim is more likely than not unpatentable and thus the Petition should be denied. 35 U.S.C. § 324(a).

## **II. PATENT OWNER HAS STATUTORILY DISCLAIMED CLAIMS 1, 3-5, 13 and 18**

Patent Owner disclaimed claims 1, 3-5, 13 and 18. Each disclaimer was made under 35 U.S.C. § 253(a), in compliance with 37 C.F.R. § 1.321(a). A copy of the Statutory Disclaimer is attached as Exhibit 2001.

The disclaimer does not constitute any admission or acquiescence to the Petition or as to the validity of the disclaimed claims. Patent Owner disagrees with Petitioner's arguments and makes the disclaimer without prejudice to Patent Owner's ability to rebut such arguments with respect to any patents and/or patent applications in any forum. *See Raytheon Techs. Corp. v. General Electric Co.*, 993 F.3d 1374, 1379, n.4 (Fed. Cir. 2021) ("Disclaimed claims are treated as if they never existed, ... and disclaimer does not legally constitute an admission that the subject of the disclaimer appears in the prior art.") (internal citations and quotations omitted).

Patent Owner does not concede unpatentability of the disclaimed claims and does not disclaim any other patentable subject matter encompassed by the patent.

### III. LEGAL REQUIREMENTS OF THE PETITION

Institution of PGR is only appropriate where the Board determines that the information in the petition, if not rebutted, would demonstrate that it is more likely than not that at least one of the claims challenged is unpatentable. 35 U.S.C. § 324(a). This burden falls to Petitioner, and Petitioner has not met its burden for instituting PGR.

#### A. The Particularity Requirement

Under 35 U.S.C. § 322(a)(3), a petition must identify in writing and with particularity each claim challenged, the grounds on which the challenge is based, and the evidence supporting the grounds. *See InVue Sec. Prods., Inc. v. Mobile Tech., Inc.*, IPR2019-00078, Paper 7, at 14–19 (P.T.A.B. May 1, 2019) (exercising discretionary denial for lack of particularity). The Federal Circuit has emphasized the critical importance of this requirement. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (explaining that petitioners must identify with particularity evidence supporting each challenged claim). The Petition must also specify where each element of the claim is found in the prior art. 37 C.F.R. § 42.204(b) (4). Conclusory and unsupported expert testimony cannot support a finding of obviousness. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9, at 15 (P.T.A.B. Aug. 24, 2022) (Precedential); 37 C.F.R. § 42.65(a); *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (“This court’s

opinions have repeatedly recognized that conclusory expert testimony is inadequate to support an obviousness determination on substantial evidence review.”).

Furthermore, the Director has stated that the PTAB will no longer waive the requirements of 37 C.F.R. § 42.104(b)(4), and “applicant admitted prior art (AAPA), expert testimony, common sense, and other evidence that is not ‘prior art consisting of patents or printed publications’ (collectively, ‘general knowledge’) may not be used to supply a missing claim limitation.” Memorandum dated July 31, 2025 regarding “Enforcement and Non-Waiver of 37 C.F.R. § 42.104(B)(4) and Permissible Uses of General Knowledge in *Inter Partes* Reviews” (“Non-waiver Memorandum,” Ex. 2002), at 1. While the Non-waiver Memorandum refers to IPR petitions, its principles apply with equal force in PGR proceedings because the PGR analog, 37 C.F.R. § 42.204(b)(4), imposes an identical requirement to “specify where each element of the claim is found in the prior art,” and the statutory particularity mandates of 35 U.S.C. § 322(a)(3) (PGR) and 35 U.S.C. § 312(a)(3) (IPR) are substantively identical. *See Apple Inc. v. MemoryWeb, LLC*, No. 2023-2361, 2025 WL 3494991, at \*13 (Fed. Cir. Dec. 5, 2025) (applying the same particularity framework to PGR); *see also Eton Pharms., Inc. v. Exela Pharma Scis., LLC*, No. PGR2020-00086, Paper 11, at 16-17 (P.T.A.B. Apr. 23, 2021) (“Section 312(a) relates to *inter partes* reviews (IPRs) and the similarly

worded Section 322(a) relates to post-grant reviews (PGRs); we interpret these two statutory sections similarly.”).

Relatedly, “common sense” may not be used to supply a missing claim limitation unless “the limitation in question was unusually simple and the technology particularly straightforward.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361-62 (Fed. Cir. 2016); *see also DSS Tech. Mgmt., Inc. v. Apple Inc.*, 885 F.3d 1367, 1374-75 (Fed. Cir. 2018) (common-sense references cannot substitute for reasoned analysis when a limitation is missing from specified prior art). The claimed limitations at issue here—sterility, chemical stability, shelf-life, and multilayer container closure features—are neither unusually simple nor do they involve particularly straightforward technology, so the *Arendi* exception does not apply.

## **B. Petitioner's Burden to Establish Unpatentability**

Petitioner bears the burden to prove unpatentability; that burden never shifts to Patent Owner. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375-77 (Fed. Cir. 2016).

### **1. Anticipation – 35 U.S.C. § 102**

With respect to anticipation under 35 U.S.C. § 102, each and every element, arranged as recited in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

Each claimed element must be found either expressly or inherently in the prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation....” *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002); *In re Montgomery*, 677 F.3d 1375, 1384 (Fed. Cir. 2012). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” *Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)); *see also Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (“Inherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.”) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

## **2. Obviousness – 35 U.S.C. § 103**

A claim is unpatentable under 35 U.S.C. § 103 only if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying

factual determinations, including “the scope and content of the prior art”; “differences between the prior art and the claims at issue”; and “the level of ordinary skill in the pertinent art,” and any evidence of non-obviousness, if presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). A party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools*, 829 F.3d at 1381 (citations omitted).

It is impermissible to engage in hindsight reconstruction or to use the invention as a roadmap to find its prior art components; section 103 requires assessment of the invention “as a whole.” *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004); *see also InTouch Techs., Inc. v. VGo Commc'ns, Inc.*, 751 F.3d 1327, 1347 (Fed. Cir. 2014).

The Petition must articulate “‘reasoning with some rational underpinning to support the legal conclusion of obviousness’.” *KSR Int’l Co.*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Moreover, “the PTAB cannot rely solely on common knowledge or common sense” to support a finding of motivation to combine, and conclusory statements alone are insufficient. *In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016).

An obviousness determination requires that “a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art.” *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009). “[T]o have a reasonable expectation of success, one must be motivated to do more than merely to ‘vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.’” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)). Moreover, “the expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

“[I]nherency in the context of obviousness must be carefully circumscribed because ‘[t]hat which may be inherent is not necessarily known’ and that which is unknown cannot be obvious.” *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, 865 F.3d 1348, 1354 (Fed. Cir. 2017) (quoting *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)). “[T]he concept of inherency must be limited when applied to obviousness....” *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014) (quoting *In re Oelrich*, 666 F.2d at 581). “[T]he limitation at issue necessarily must be present, or the natural result of the

combination of elements explicitly disclosed by the prior art.” *Id.* “The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency].” *In re Rijckaert*, 9 F.3d at 1533–34 (quoting *In re Oelrich*, 666 F.2d at 581-82).

#### **IV. LEVEL OF ORDINARY SKILL IN THE ART**

For purposes of this Preliminary Response, Patent Owner demonstrates that the Petition fails even adopting Petitioner’s proposed definition of a person of ordinary skill in the art (“POSA”). Patent Owner does not necessarily agree with that definition and reserves the right to address it in more detail should trial be instituted.

#### **V. CLAIM CONSTRUCTION**

Petitioner proposes constructions for two terms: “ready-to-use (RTU)” and “chemically stable.” Pet. at 13–17. The Board need not address these constructions to deny institution and find that Petitioner has not met its burden. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms ... that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Patent Owner reserves the right to assert its own claim construction positions to the terms identified by Petitioner and/or to other terms should the Board institute PGR.

Petitioner improperly conflates the distinct claim limitation “chemically stable” with the concept of “having an acceptable shelf-life.” Pet. at 17. The specification expressly defines “chemically stable” as a compound (*i.e.*, ketamine in the ’153 patent) that “retains its chemical structure and useful properties on a timescale of its expected usefulness” and is “resistant to degradation of ketamine into its known or unknown decomposition elements.” Ex. 1001 at 15:44—52. The specification discusses “shelf-life” in terms of storage duration of the product (*e.g.*, greater than six, twelve, eighteen, or twenty-four months at room temperature), discussing product-specific attributes such as levels of leachables from the packaging, microbial and fungal contamination, container-closure integrity, physical stability such as visible particle counts, discoloration, osmolality, and pH. Ex. 1001 at 4:48-61; 10:53-65; 17:23-29; 18:8-11; 31:19-22; 31:37–32:22. Thus, Petitioner’s claim construction that the phrase “chemically stable” would “equate to ‘having an acceptable shelf-life’ of the product” (Pet. at 17) is clearly erroneous and conflicts with the specification.

For the reasons discussed below, however, the Board need not address Petitioner’s constructions to deny institution because regardless of these constructions, Petitioner has not met its burden to demonstrate that it is more likely than not that at least one of the claims challenged is unpatentable.

**VI. THE PETITION DOES NOT SATISFY THE STATUTORY THRESHOLD FOR INSTITUTING PGR**

**A. Petitioner Fails to Establish that the Primary Reference Relied Upon for All Grounds (Biomed, Ex. 1005) is Prior Art**

As a threshold matter, the Petition fails to establish that Biomed (Ex. 1005) is prior art under 35 U.S.C. § 102. Because both asserted grounds rely on Biomed, the Petition can be denied based on this failing alone.

The decision to institute a trial is based on “the information presented in the petition filed under Section 321.” 35 U.S.C. § 324(a). The petitioner has the burden to prove that a reference is a printed publication. *See Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018); *Adama Agan Ltd. v. Bayer CropScience LP*, PGR2022-00057, Paper 9, at 29-30 (PTAB Feb. 13, 2023) (holding petitioner in a PGR bears the burden to show it is “more likely than not” that a reference qualifies as a printed publication).

Public accessibility is the “touchstone” in determining whether a reference is a printed publication. *Jazz Pharms.*, 895 F.3d at 1355; *In re Hall*, 781 F.2d 897, 898-99 (Fed. Cir. 1986). A reference is considered publicly accessible “upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it . . . .” *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981) (citation omitted). “[A]t the institution stage, the

petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the critical date . . . and therefore that there is a reasonable likelihood that it qualifies as a printed publication.” *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, at 13 (PTAB Dec. 20, 2019) (Precedential).

There is “no presumption in favor of finding that a reference is a printed publication.” *Adama Agan Ltd.*, PGR2022-00057, Paper 9, at 31 (citing *Hulu, LLC*, IPR2018-01039, Paper 29, at 16); *see also Pfizer, Inc. v. Biogen, Inc.*, IPR2017-01166, Paper 9, at 17-18 (PTAB Nov. 13, 2017) (explaining that the burden is on the Petitioner and not the Patent Owner to demonstrate that a reference is prior art).

Petitioner has not provided sufficient evidence to demonstrate that it is more likely than not that Biomed was publicly available prior to the July 12, 2023 priority date of the '153 Patent. *See Mylan Pharms. Inc. v. Boehringer Ingelheim Int'l GmbH*, IPR2016-01563, Paper 16, at 13-14 (PTAB Feb. 3, 2017) (explaining that an expert declaration is not enough to prove the publication date of a pharmaceutical label where the expert declaration merely repeats assertions made by the petitioner); *Pfizer, Inc.*, IPR2017-01166, Paper 9, at 15-16 (explaining that the mere existence of a pharmaceutical label accessed at an unspecified recent date coupled with “unsupported and conclusory” expert testimony is given “little

weight”); *Adama Agan Ltd.*, PGR2022-00057, Paper 9, at 33 (“Without any additional evidence, such as testimonial evidence from someone with knowledge about what this electronic record [stating ‘Posted by the Environmental Protection Agency on Feb 23, 2018’] means in terms of the public accessibility of the reference for persons interested an ordinarily skilled in the subject matter or art, Petitioner has submitted insufficient evidence that the EPA Section 18 Memorandum is publicly accessible.”).

In alleging that Biomed is prior art, Petitioner only cites the Maurin declaration. Pet. at 5-6; Ex. 1003. The Maurin declaration, in turn, only states “Biomed is dated June 15, 2021 and is prior art to the ’153 patent” (Ex. 1003 ¶ 60), and “[t]he medical regulatory body in New Zealand is MedSafe. MedSafe relies on the British Pharmacopoeia, which incorporates the European Pharmacopoeia. The European Commission is a founding member of the International Council for Harmonization (ICH) which provides guidance on sterility testing.” Ex. 1003 ¶ 58. Maurin does not provide any explanation or basis for these statements, does not state that he has any personal knowledge as to when, whether, or how Biomed was made available to the public, and does not state that he obtained the Biomed reference from Medsafe or any other source. Maurin also does not provide any evidence that a product corresponding to the Biomed reference was publicly available on the June 15, 2021 date or at any time prior to the July 12, 2023 critical

date. Accordingly, Maurin's conclusory reliance on a "date of revision" listed in the Biomed reference does not establish that the reference was publicly accessible or that it is prior art. *See* Ex. 1005 at 11; *Mylan Pharms. Inc. v. Boehringer Ingelheim Int'l GmbH*, IPR2016-01565, Paper 23 (PTAB Aug. 1, 2017), at 7-8 (holding expert declaration is not enough to prove a publication date where the expert declaration does not point to any evidence that would reasonably suggest that the expert has personal knowledge as to when and how the reference was made available to the public).

Maurin's Declaration is not enough to demonstrate public availability prior to the July 12, 2023 priority date of the '153 patent. *See Mylan Pharms. Inc.*, No. IPR2016-01563, Paper 16, at 14 ("[Dr. Davidson's] Declaration does not provide a sufficient explanation or foundation to establish his personal knowledge of the Glucophage Label's alleged publication in February 2001. Dr. Davidson's statements that Glucophage® was approved by the FDA in 1994 and Glucophage® XR in 2000 are insufficient, by themselves, as a threshold showing that the Glucophage Label was a publicly available printed publication as of February 2001."); *Incyte Corp. v. Concert Pharms., Inc.*, IPR2017-01256, Paper 14-15, at 14 (PTAB Apr. 9, 2018) (rejecting expert's conclusory statement that pharmaceutical label constitutes prior art without evidence of personal knowledge or source-

identifying information from relevant regulatory agency, and holding petitioner failed to make a threshold showing that the label constitutes a printed publication).

Biomed only states a “date of first approval” and a “date of revision of the text” on its last page. Ex. 1005 at 11. Petitioner cites the June 15, 2021 “date of revision” as its public availability date. Pet. at 6. However, by its plain terms, the June 15, 2021 date only indicates when the document was *revised*, and has no bearing on whether or when the document was *published*, much less whether or when any alleged product described by the document became publicly available. The date stated on a pharmaceutical label, without more, is insufficient evidence of public availability as of a particular date. *See Mylan Pharms. Inc.*, IPR2016-01565, Paper 17, at 19-20 (PTAB Feb. 9, 2017) (noting that Petition failed to provide information about whether the label was publicly accessible in the relevant time frame, how one might have obtained a copy of it, or whether it was reasonably accessible through generally available means, and holding that “a date merely printed on a reference is not synonymous with a publication date”).

In addition, Petitioner fails to identify which category of prior art set forth in 35 U.S.C. § 102(a)(1) it alleges Biomed represents. Petitioner does not allege that Biomed was sold or offered for sale before the priority date of the '153 patent, and instead merely alleges without evidence that “Biomed is a product approved for sale in New Zealand.” Pet. at 36. The Maurin declaration states, without support,

that Biomed “is offered for sale in New Zealand.” Ex. 1003 ¶ 58. Maurin provides no basis for this allegation and does not state that Maurin has any personal knowledge of whether the Biomed exhibit actually corresponds to a product that has been sold or offered for sale in New Zealand. *See* Ex. 1003 ¶ 58. The Board has denied institution of PGR proceedings where public sale was asserted based on uncorroborated testimony. *Allergan, Inc. v. BTL Med. Techs. S.R.O.*, PGR2021-00020, Paper 16, at 25 (PTAB June 16, 2021) (“The law has long looked with disfavor upon invalidating patents on the basis of mere testimonial evidence absent other evidence that corroborates that testimony.”) (quoting *Finnigan Corp. v. Int’l Trade Comm’n.*, 180 F.3d 1354, 1366 (Fed. Cir. 1999)). Here, not only is Maurin’s testimony uncorroborated, but Maurin makes no attempt to establish that he has any personal knowledge or basis for the belief that Biomed “is offered for sale in New Zealand,” much less that it was offered for sale before the ’153 patent’s priority date. Ex. 1003 ¶ 58.

Petitioner fails to provide any evidence to establish that a product corresponding to the Biomed reference was ever actually offered for sale, much less that such a product would have explicitly or inherently satisfied “each claim limitation of the patent.” *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1329 (Fed. Cir. 2001). Neither Petitioner, nor Maurin alleges to have purchased, obtained, or tested the purported Biomed product.

In view of the foregoing, there is an insufficient factual basis to show that either Biomed (Ex. 1005) or any alleged Biomed product is prior art under 35 U.S.C. § 102(a)(1). Because Biomed forms the basis of all Grounds in the Petition and has not been shown to qualify as prior art, Petitioner has failed to show that it is more likely than not that it would prevail on any Ground presented in the Petition. Institution should be denied. *See Adama Agan Ltd.*, PGR2022-00057, Paper 9, at 33-34.

**B. Ground 1 Fails to Establish Anticipation by Biomed and Should be Denied**

Ground 1 challenges claims 1, 3–5, 13, and 18–20 as anticipated by Biomed under § 102. Pet. at 26. Patent Owner has disclaimed claims 1, 3-5, 13, and 18, rendering the challenges of those claims moot. The Petition fails to establish anticipation of claim 19 or 20. First, as explained above, the Petition fails to show that Biomed is prior art. Because Ground 1 asserts anticipation by Biomed, institution should be denied on that basis alone. 35 U.S.C. § 324(a). Even if Biomed were available as prior art, Ground 1 fails on the merits.

Biomed (Ex. 1005) is purportedly a New Zealand data sheet for a “clear, colourless isotonic solution” containing ketamine hydrochloride (100 mg/100 mL), sodium chloride, and water for injection, pH 3.5–5.5, and no preservative. Ex. 1005 at 1, 10. Biomed states that “infusion bags have a shelf life of 24 months

from the date of manufacture” and must be stored “at or below 25°C.” *Id.* at 10.

Biomed fails to disclose multiple elements of claims 19 and 20, as shown below.

Ground 1 turns on impermissible reliance on general knowledge to supply a missing claim limitation and unfounded allegations of inherency. Therefore, the Petition does not establish that it is more likely than not that any challenged claim is anticipated by Biomed and institution on Ground 1 should be denied.

**1. Petitioner supplies no evidence that Biomed meets the “sterile” limitation**

Claims 19-20 incorporate the limitation “wherein the ketamine product is sterile...” from claim 1. Petitioner admits that Biomed does not expressly disclose that the purported product is sterile and instead alleges that “sterilization is a consideration.” Pet. at 29. Rather than pointing to disclosures in the reference itself or any other evidence (*e.g.*, obtaining and testing the alleged Biomed product), the Petition alleges that “[t]he POSA would recognize that as an approved product in New Zealand for intravenous administration, Biomed would have needed to be sterile,” *id.*, which is repeated in the Maurin declaration, Ex. 1003 ¶ 114. Such conclusory and unsupported testimony “adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.” *Xerox Corp.*, IPR2022-00624, Paper 9, at 15. Inherency must “flow[] from the reference’s explicitly explicated limitations.” *Eli Lilly & Co. v. Barr*

*Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001). And inherency may not be established by probabilities or possibilities. *In re Montgomery*, 677 F.3d at 1380.

First, as discussed in Section VI.A above, the Petition fails to show that Biomed represents an actual product that was approved, marketed or publicly available. Petitioner makes an unsupported leap to assume that the “data sheet” represents a product that must have been sterile to have been approved. *See, e.g.* Pet. at 29-30; Ex. 1003 ¶ 114. Neither the Petition nor the Maurin declaration provides any support for the assertion that Biomed actually is an approved sterile product, much less that it was publicly available before the critical date.

Accordingly, there is no basis for a legal conclusion that Biomed must have inherently disclosed a sterile product meeting all of the limitations of claim 1, or claims 19-20 which depend from it. This is precisely the type of reliance on alleged “general knowledge” to supply a missing claim limitation prohibited by the Non-waiver Memorandum.

Maurin alleges that “[t]he POSA would recognize that as an approved product in New Zealand for intravenous administration, Biomed would have needed to be sterile” and relies on guidance from the European Pharmacopoeia (Ex. 1018) to support this assertion. Ex. 1003, ¶ 114. Maurin alleges that “the relevant regulatory guidance for New Zealand products [is] the European Pharmacopoeia” without pointing to any evidentiary support for this assertion. *Id.*

Maurin's conclusory statements are entitled to little weight because they do not disclose underlying facts or data demonstrating that Biomed was publicly available before the critical date, was tested and found to be sterile, or was approved after undergoing regulatory review according to the alleged European Pharmacopoeia standards. 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Because the claim limitation "sterile" is not expressly, implicitly, or inherently disclosed in Biomed, and because the Petition relies only on conclusory and unsupported expert opinions, and allegations of general knowledge to supply a missing claim limitation, which is prohibited by the Non-waiver Memorandum, rather than evidencing explicit, implicit, or inherent disclosure of the missing element in the reference itself, Petitioner's anticipation argument fails for both claims 19 and 20. *See* Non-waiver Memorandum at 1; 37 C.F.R. § 42.65(a).

**2. Claim 19 is not anticipated by Biomed**

Petitioner's inherent anticipation arguments against claim 19 also fail. Claim 19 requires ketamine content *greater than 97%* after accelerated storage at 40°C ± 2°C / <25% RH for 6 months and/or after long-term storage for 12 months at 25°C ± 2°C / 40% ± 5% RH.

The Petition does not point to any disclosure in Biomed regarding the ketamine content after storage. Instead, the Petition alleges without basis that “ketamine content after this length of time of storage at these conditions is an inherent characteristic that will naturally result from storing the formulation at these conditions.” Pet. at 34. The Petition and Maurin do not provide any experimental evidence or other evidence to support these allegations. The Maurin declaration provides the same conclusory statements as in the Petition. Ex. 1003 ¶ 130.

Rather than providing any experimental evidence of the properties of the alleged Biomed product, Petitioner instead attempts to rely on the data in the '153 patent's Table 6 to allege that Biomed would have the same results as in Table 6 (Pet. at 34–35; Ex. 1003 ¶ 130). The Federal Circuit has held, however, that extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.” *Cont'l Can Co.*, 948 F.2d at 1268. The product used to generate the data in Table 6 is not “the thing described in” the Biomed reference and thus Petitioner failed to provide any evidence of the inherent results of the Biomed product. *Id.*

The data in Table 6 of the '153 patent were generated using “terminally sterilized infusion bags, as described in Example 2, comprising a preservative-free aqueous ketamine solution with the formulation described in Table 1 (1 mg/ml) or

Table 2 (2 mg/ml).” Ex. 1001 at 26:13-16. The infusion bags used were “an infusion bag comprising a flexible multilayer film comprising a 3-layer polypropylene styrene-block copolymer based film (APP114S film manufactured by Polycine); a tube port comprising a multilayer polyolefin and styrene block copolymer tube material (APP107 manufactured by Polycine); and a twist off closure composed of low density polyethylene (LDPE) and polypropylene (PP).” *Id.* at 24:61–25:2. Biomed only discloses a “flexible 100 ml IV bag with overwrap,” Ex. 1005 at 10, which does not demonstrate—or even suggest—that it is the same bag described in Example 2 that was used to generate the data in Table 6 of the ’153 patent. The Petition makes no attempt to show that the Biomed reference inherently uses the same bag used in Example 2 of the ’153 patent. Instead, Petitioner’s expert admits that “numerous” bags, made of different materials, are commercially available. Ex. 1003 ¶ 141. Therefore, the product used to generate the data in Table 6 is not the thing described in the Biomed reference and thus Petitioner failed to provide any evidence that the product described in Biomed would inherently achieve the results required by claim 19.

Additionally, the bags in Example 2 of the ’153 patent were terminally sterilized by “[a]utoclaving of the primary packaging filled with the preservative-free ketamine formulations of Table 1 (1 mg/ml) and Table 2 (2 mg/ml), respectively, was conducted at a target temperature  $T=121^{\circ}\text{C.} \pm 1^{\circ}\text{C.}$  and time at

F0=15 according to USP <1222>.” Ex. 1001 at 25:6-11. The Petition *admits* that that the Biomed reference does not disclose terminal sterilization of any kind, Ex. 1003 ¶ 135-136, and certainly does not disclose that it was autoclaved at all, much less at the same temperature and time conditions as in Example 2 of the ’153 patent. Therefore, for each of these additional reasons, the product used in the ’153 patent to generate the stability results relied upon by the Petition is not the thing described in the Biomed reference, and thus Petitioner failed to provide any evidence of any inherent results of the Biomed reference.

Even more, the data in Table 6 of the ’153 patent was generated using the formulations stated in Tables 1 and 2 (Ex. 1001 at 26:13-16), which are different formulations than in the Biomed reference. Table 1 shows that the formulation contained 250 mg ketamine as ketamine HCl in a 250 ml container, 2250 mg/ml sodium chloride, and q.s. water. In contrast, the Biomed reference discloses 100 mg of ketamine in a “flexible 100 ml IV bag with overwrap” and sodium chloride and water for injection. Ex. 1005 at 10. There is no disclosure about the amount of sodium chloride in Biomed. There is no evidence in the Petition that the Biomed product used the same formulation as in Table 1 or the same type of bag as in Example 2. Table 2 of the ’153 patent is even further distinguished from the Biomed reference because it discloses that the formulation contained 500 mg ketamine as ketamine HCl in a 250 ml container, 2250 mg/ml sodium chloride, and

q.s. water. Thus, the formulation of Table 2 contains 2 mg/ml ketamine, in contrast to the 1 mg/ml concentration disclosed in Biomed. Thus, the Biomed reference does not disclose the same formulation as in Table 2 or the same type of bag as in Example 2.

For experimental data to prove the Claimed Chemical Stability was inherent, the experiments conducted to obtain the data must adhere to methods *explicitly* disclosed *by the prior art*. *Eli Lilly*, 251 F.3d at 970 (inherency must “flow[] from the reference’s explicitly explicated limitations”). Here, the data that Petitioner cites from the examples of the ’153 patent are not data from experiments adhering to methods or a product explicitly disclosed by Biomed. Therefore, for each of these additional reasons, the product used to generate the data in Table 6 is not the thing described in the Biomed reference and thus Petitioner failed to provide any evidence of the inherent results of the Biomed product.

In sum, Petitioner’s argument for inherent anticipation fails because Petitioner’s sole ground for challenging claim 19 is based on a flawed attempt to rely on Patent Owner’s results in Table 6 of the ’153 patent. Because the product used to generate the data in Table 6 is not the thing described in the Biomed reference, Petitioner failed to establish inherent anticipation of claim 19.

Therefore, the Petition does not establish that it is more likely than not that claim 19 is anticipated by Biomed and institution on Ground 1 should be denied.

**3. Claim 20 is not anticipated by Biomed**

Petitioner's anticipation argument against claim 20 also fails. Claim 20 recites administering the ketamine product of claim 1 to a subject as a "continuous infusion." Petitioner fails to establish that Biomed disclosed administering to a subject by "continuous infusion." Petitioner's only argument is the conclusory allegation that the phrase "[i]t is recommended that ketamine infusion be administered slowly (over a period of 60 seconds)" anticipates administration by "continuous infusion." Pet. at 35. The allegation is erroneous.

Petitioner's own expert agrees that continuous intravenous infusion of ketamine is performed "over a period of hours or days." Ex. 1003 ¶ 39. Maurin further notes that such continuous infusions involve specific amounts and rates "ketamine/kg/hour." *Id.* Maurin's description of continuous infusion of ketamine as being over hours or days accords with the ketamine literature as evidenced by Ex. 1012 at 642 ("a single **4 h IV infusion** of ketamine 600 microgram/kg" and "Ketamine **100 mg/24 h by CIVI for 2 days**") and at 645 ("start with **50-200 microgram/kg/h** and titrate as necessary, ...if necessary, repeat daily for up to 5 days"). In contrast to Dr. Maurin's and the ketamine literature's explanations of continuous infusion of ketamine at specific rates over hours or days, Petitioner erroneously alleges that Biomed's instruction to administer 100 ml of ketamine over a period of merely **60 seconds** (as opposed to hours or days), and without

specifying any infusion rate much less a continuous infusion rate of ketamine/kg/hour, anticipates administering by “continuous infusion.” *Compare* Ex. 1003 ¶ 39 with Pet. at 35 (emphasis added); Ex. 1003 ¶ 132.

The Petition provides no construction or analysis of what “continuous infusion” means and is completely divorced from the explanation of ketamine continuous infusion provided by its own expert. Ex. 1003 ¶ 39. Thus, Petitioner fails to establish that Biomed discloses administering the ketamine product “as a continuous infusion.” The Petition fails to identify with particularity the evidence that supports the grounds for the challenge to claim 20 for these additional reasons. 35 U.S.C. § 322(a)(3). Petitioner’s reliance on conclusory statements and unsupported and internally inconsistent assertions is inadequate to meet its burden.

Therefore, the Petition does not establish that it is more likely than not that claim 20 is anticipated by Biomed and institution on Ground 1 should be denied.

**C. Ground 2 Fails to Establish Obviousness Over Biomed in View of Remington 2021 and Commercially-Available Infusion Bags and Should Be Denied**

Ground 2 alleges that claims 1, 2, 4, 6–17, and 21–23 are obvious over Biomed; Remington 2021 (Ex. 1006); and M312 Film Data Sheet (Ex. 1007), M315 Film Data Sheet (Ex. 1008), and Technoflex Inerta (Ex. 1009) (collectively, the “Commercially-Available Infusion Bag references”). Pet. at 35.

As explained above, Petitioner fails to establish Biomed as prior art. Because Ground 2 relies on Biomed as the primary reference, institution should be denied for at least that reason. 35 U.S.C. § 324(a). Moreover, even if Biomed were available as prior art, Ground 2 fails on the merits.

Patent Owner has disclaimed claims 1, 4, and 13 challenged in Ground 2, rendering to the challenges of those claims moot. Petitioner fails to meet the high standard of establishing that it is more likely than not that any of challenged claims 2, 6-12, 14-17, and 21-23 is obvious for multiple independent reasons, any one of which is sufficient to deny institution. Ground 2 fails for at least the following fundamental flaws: (1) unsupported allegations of inherency; (2) improper reliance on general knowledge to supply missing claim limitations; (3) conclusory allegations of motivation to combine; (4) use of the specification as a roadmap for impermissible hindsight reconstruction; and (5) failure to demonstrate reasonable expectation of success. Therefore, the Petition does not establish that it is more likely than not that any challenged claim is rendered obvious and institution on Ground 2 should be denied.

In Ground 2, Petitioner incorporates its anticipation analysis, stating that “the analysis regarding the anticipation of claim 1 at Section VIII.A is incorporated herein by reference.” Pet. at 42. Petitioner attempts to obfuscate the claimed sterility elements missing from the Biomed reference by merely stating that “a

POSA would find any differences between the prior art and the claim insubstantial and any necessary modification of the prior art to achieve the limitations of claim 1 would be well within the ordinary skill, and a POSA would have more than a reasonable expectation of success in achieving the limitations of claim 1.” *Id.* Petitioner fails to meet the high standard for proving inherent obviousness. *See* Section VI.C.1 *infra*.

Obviousness challenges require Petitioner to “ascertain[] the differences between the claimed invention and the prior art” and to make its case by applying all four *Graham* factors. “A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors . . . .” *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016); *Luv n’ Care, Ltd. v. Laurain*, 98 F.4th 1081, 1100 (Fed. Cir. 2024) (same). Petitioner fails to address the differences between the claims and Biomed or explain its rationale for why any claim would have been obvious, as discussed further below.

**1. Petitioner’s failure to supply evidence of inherency dooms its Ground 2 challenges and the secondary references fail to remedy those failures**

Ground 2 incorporates the same types of inherency arguments that fail under Ground 1. Pet. at 41–43, 47–48, 51. Section VI.B above explains why Biomed fails to inherently anticipate the challenged claims and that analysis also applies to Ground 2. Remington 2021 (Ex. 1006) and Commercially-Available Infusion Bag

references (Exs. 1007–1009) do not remedy the deficiencies and unsupported inherency arguments identified in Section VI.B and discussed below.

**a. Petitioner fails to meet the high standard required to establish inherent obviousness**

“[T]he concept of inherency must be limited when applied to obviousness, and is present only when the limitation at issue is the ‘natural result’ of the combination of prior art elements.” *PAR Pharm., Inc.*, 773 F.3d at 1195 (quoting *In re Oelrich*, 666 F.2d at 581). “[T]he limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art” to meet this “high standard.” *Id.* at 1195-96. The Board has applied this high standard to deny obviousness challenges where, as here, the petitioner failed to show that claimed limitations were the necessary and natural result of the prior art combination. Where a petitioner fails to “provide[] sufficient evidence from which to conclude that the application of [a cited reference’s] methods as applied to the [active pharmaceutical ingredient] would necessarily result in the [claimed] levels,” the petitioner fails to establish inherent obviousness. *BTC Corp. v. TG Biotech Co., Ltd.*, IPR2022-00998, Paper 44, at 32 (PTAB Nov. 13, 2023).

Here, in addition to failing to establish the sterility limitations required by the challenged claims as discussed in Section VI.B, Petitioner admits that Biomed did not disclose a product that meets each limitation of the Ground 2 claims **together with** the Claimed Storage Stability nor the Claimed Chemical Stability

limitations, and attempts to fill the missing gaps using inherent obviousness arguments merely referring to Biomed and general references about sterile pharmaceuticals, none of which relate to ketamine aqueous ready-to-use solutions. *See* Exs. 1018<sup>1</sup>, 1020, 1006 (the “General Pharmaceutical Publications”).

Petitioner provides no experimental evidence or scientific rationale for how one would modify Biomed to arrive at the claimed ketamine product having the Claimed Storage Stability, the Claimed Chemical Stability, and the specifically claimed container and/or sterilization features, and fails to establish that these limitations are the necessary and natural result of combining the cited references.

The Federal Circuit has emphasized that “inherency may only supply a missing claim limitation if the limitation at issue is the ‘natural result’ of the combination of prior art elements or a ‘necessarily present’ limitation.” *Endo Pharms. Sols., Inc. v. Custopharm Inc.*, 894 F.3d 1374, 1379 (Fed. Cir. 2018) (holding that a prior art reference does not inherently disclose a specific formulation “simply because this formulation was what had been used in the studies forming the basis of the [prior art references]...[the Petitioner] failed to establish that alternative vehicles could not have been used in the [prior art

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<sup>1</sup> Ex. 1018 is merely an excerpt from a larger document. It lacks a publication date and there is no evidence that it is a prior art reference.

references]”). Given that there is no evidence in the Petition that shows that the missing sterility, Claimed Storage Stability, and Claimed Chemical Stability limitations are the ‘natural result’ of the combination of Biomed with the General Pharmaceutical Publications or a ‘necessarily present’ property, Petitioner fails to provide any, much less sufficient, evidence to establish that any of the claims are more likely than not unpatentable for inherent obviousness.

Petitioner fails to establish that the “sterile” limitations are inherent because Remington 2021 provides only general pharmaceutical principles—not formulation-specific evidence regarding Biomed—and the bag references describe the details of specific intravenous infusion bags, but fail to reveal anything about the Claimed Storage Stability and Claimed Chemical Stability limitations of Biomed or the natural and necessary result of modifying Biomed by using any of those bags. As discussed in Section III.A and Section VI.B, general knowledge and common sense cannot be used to supply these missing limitations. *See* Non-Waiver Memorandum at 1; *Arendi*, 832 F.3d at 1362; *Apple Inc. v. Resonant Sys., Inc.*, IPR2024-00983, Paper 27, at 40 (PTAB Oct. 23, 2025) (“Expert testimony ... cannot take the place of a disclosure in a prior art reference.”) (quoting U.S. Patent & Trademark Office, *Consolidated Trial Practice Guide*, 36 (Nov. 2019)). And the General Pharmaceutical Publications and infusion bag references cannot serve as sufficient evidence on the record to prove that the Claimed Stability and Claimed

Chemical Stability limitations are the natural or necessary result of modifying Biomed because they provide nothing more than general guidance in the abstract and fail to evidence the actual results of modifying the purported Biomed product. *Par Pharm., Inc.*, 773 F.3d at 1195-96 (“[T]he limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.”). “The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency].” *In re Rijckaert*, 9 F.3d at 1533–34 (quoting *In re Oelrich*, 666 F.2d at 581-82).

Petitioner has not provided any experimental data demonstrating that the Claimed Storage Stability, Claimed Chemical Stability, or claimed container limitations are the necessary and natural result of the cited references. Thus, Petitioner has failed to establish that any of the claims are more likely than not unpatentable based on inherent obviousness.

**b. Petitioner fails to show that the sterility limitations are necessarily present or the natural result of modifying Biomed using the secondary references**

As discussed in Section VI.B, Biomed does not expressly disclose sterility and the Petition's arguments rest merely on impermissible general-knowledge inference without any experimental data or reasoned scientific rationale about the results of modifying Biomed. Remington 2021 merely confirms the general principle that parenteral products must be tested for sterility—it provides no

formulation-specific evidence that the Biomed product is sterile or how sterilizing it would affect its stability and shelf-life properties. Likewise, the Commercially-Available Infusion Bag references describe the container material properties and low extractable levels for sterilization, not the sterility of any ketamine aqueous solution placed within those bags and sterilized in the various possible alternative ways that are discussed in the Petition and the General Pharmaceutical Publications. An infusion bag's capacity to withstand sterilization is not a disclosure that a ketamine aqueous solution that is terminally sterilized within that bag inherently meets the Claimed Storage Stability and Claimed Chemical Stability limitations. Petitioner provided no experimental evidence or scientific rationale that modifying Biomed by using any of the General Pharmaceutical Publications to sterilize the Biomed product and/or the claimed infusion bags would inherently meet the Claimed Storage Stability and Claimed Chemical Stability properties.

For the same reasons as discussed in Section VI.C.2 *infra*, Petitioner and Maurin merely rely on assertions of common general knowledge rather than experimental data or other evidence proving that the claimed invention is “the natural result of the combination of elements explicitly disclosed by the prior art,” and therefore fail to meet the high standard of establishing inherent obviousness. *Par Pharm., Inc.*, 773 F.3d at 1195-96. Petitioner fails to provide any

experimental evidence, data, or information to establish what would necessarily have resulted if Biomed were modified in any of the various ways vaguely implied by reference to Remington or the Commercially-Available Infusion Bag references.

Remington specifically states that “[m]any products, both pharmaceutical and biological, are affected adversely by temperatures required for thermal sterilization. Therefore heat-labile products should be sterilized by a nonthermal method, usually by filtration through bacteria-retaining filters. Subsequently, all operations must be carried out in an aseptic manner, so that contamination is not introduced into the filtrate.” Ex. 1006 at 597.

Neither the Petition nor the Maurin declaration address the fact that ketamine in aqueous solution was known to react under accelerated conditions such as high temperature to form impurities, *e.g.*, when exposed to high temperatures for terminal sterilization. Ex. 1001 at 14:41–15:40. Petitioner fails to provide evidence to demonstrate how Biomed’s ketamine solution would have reacted upon terminal sterilization/autoclaving or aseptic filling, including the issues of: 1) leaching of infusion bag components into the ketamine solution upon exposure to high temperatures during sterilization; 2) contamination risk issues with container closure systems; and 3) contamination risks during aseptic filling of an infusion bag with a ready-to-use aqueous solution. Objective record evidence

states that “[s]terility cannot be assured by testing, it needs to be assured by the use of a suitably designed, validated and controlled manufacturing process.” Ex. 1020 at 4. There is no evidence on the record that the Biomed product was manufactured, marketed, tested, sterile, terminally sterilized, or aseptically filled. Thus, Petitioner’s inherent obviousness challenge fails because there is no evidence on which the Board can conclude that Petitioner established that “the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.” *Par Pharm., Inc.*, 773 F.3d at 1195. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency].” *In re Rijckaert*, 9 F.3d at 1533–34.

**c. Petitioner fails to show the Claimed Storage Stability is necessarily present or the natural result of modifying Biomed as proposed by Petitioner**

Petitioner has not met the high standard required to rely on inherency when applied to obviousness because Biomed alone, or in view of the secondary references, does not disclose or render obvious the Claimed Storage Stability recited in claims 2, 6-12, 14-17, and 21-23. There is “a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—the limitation at issue necessarily must be present, or the natural result of **the combination of elements explicitly disclosed by the prior**

**art.”** *Par Pharm., Inc.*, 773 F.3d at 1195-96. Petitioner does not dispute that Biomed fails to anticipate claims 2, 6-12, 14-17, and 21-23. Petitioner also does not allege that the secondary references, Remington 2021 (Ex. 1006) and Commercially-Available Infusion Bag references, disclose or suggest that modifying Biomed by using various possible sterilization techniques (*e.g.*, autoclaving/terminal sterilization, and aseptic filling) and by using various different commercial infusion bags would result in a ketamine product comprising an aqueous ketamine solution that is preservative-free and anti-microbial free, terminally sterilized/autoclaved (as in claims 2, 15-17 and 22) or aseptically filled (as in claims 21 and 23), ready-to-use (RTU), and has the Claimed Storage Stability (*i.e.*, a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C).

Petitioner relies solely on the conclusory allegation that “Biomed discloses that it has a shelf life of 24 months for the 100 mg per 100 mL (*i.e.* 1 mg/mL) IV Infusion bags ... a POSA would find any differences between the prior art and the claim insubstantial and any necessary modification of the prior art to achieve the limitations of [the challenged claims] would be well within the ordinary skill.” Pet. at 30 (citing Ex. 1005 at 10; Ex. 1003, ¶ 116) and 42 (citing Ex. 1003, ¶ 145). Petitioner fails to evidence that, after each of the various modifications to Biomed, the Claimed Storage Stability “at issue necessarily [would] be present, or the

natural result of **the combination of elements explicitly disclosed by the prior art.**” *Par Pharm., Inc.*, 773 F.3d at 1195-96. Indeed, the ’153 patent explains that ketamine in aqueous solution has been shown to react under accelerated conditions such as high temperatures (needed for terminal sterilization/autoclaving) to form impurities. Ex. 1001 at 14:41–15:40. Further, the ’153 patent explains that “terminal sterilization is one of the most difficult requirements for medical devices” because “it involves conditions that can affect the integrity of the packaging, cause leaching of packaging components into the pharmaceutical solution, cause degradation of the drug product, and otherwise affect the stability the pharmaceutical solution.” *Id.* at 10:53-60.

Maurin admits that “when using terminal sterilization, consideration must be given to the container and the drug product itself to ensure that the container can withstand the intensity of the cycle without itself degrading and contaminating the product,” Ex. 1003 at ¶ 55, and cites exhibits that highlight these challenges. *See, e.g.*, Ex. 1020 at 4 (“Sterility cannot be assured by testing, it needs to be assured by the use of a suitably designed, validated and controlled manufacturing process. Sterility is achieved by controlling several factors such as the bioburden, the sterilization procedure, the integrity of the container closure system and in the case of aseptic processing, the use of satisfactory aseptic technique.”); Ex. 1006 at 597 (“Many products, both pharmaceutical and biological, are affected adversely by

temperatures required for thermal sterilization.”). No inherency of the Claimed Storage Stability has been established on this record as there is no evidence thereof. Instead, record evidences the chemical and shelf-life stability challenges with both the ketamine drug substance itself and the ketamine aqueous solution as well as the issues of 1) leaching of infusion bag components into the ketamine solution upon exposure to high temperatures during sterilization, 2) contamination risk issues with container closure systems, and 3) contamination risks during aseptic filling of an infusion bag with a ready-to-use aqueous solution.

Thus, the Board has no basis to conclude that modifying Biomed in the various ways proposed in the Petition would inherently, *i.e.*, necessarily or naturally, result in the Claimed Storage Stability required by claims 2, 6-12, 14-17, and 21-23.

The secondary references provide only general pharmaceutical principles and commercially available bags—not product-specific evidence of what would result from modifying Biomed—and therefore do not remedy the deficiencies of Biomed. Remington 2021 contains no stability or shelf-life data for any dilute ketamine formulation (Ex. 1006 at 600–601). Petitioner fails to provide any evidence of the effects of autoclaving or otherwise terminally sterilizing Biomed on its shelf-life. And the Commercially-Available Infusion Bag references contain no stability or shelf-life data for any aqueous ketamine formulation and are silent

on whether such a formulation stored in those bags would achieve the Claimed Storage Stability. Maurin does not introduce any experimental data or other factual evidence into the record to establish the results of Petitioner's proposed modifications to Biomed. Petitioner's superficial references to Remington and Commercially-Available Infusion Bag references fail to supply the requisite evidence that the Claimed Storage Stability was "necessarily [] present, or the natural result of the combination of elements explicitly disclosed by the prior art." *Par Pharm., Inc.*, 773 F.3d at 1196. Therefore, Petitioner has not met the high standard required to rely on inherency when applied to obviousness.

Claims 16 and 21 are not dependent on claim 1, yet Petitioner provides no independent analysis addressing the differences between claim 16 (requiring terminal sterilization and a shelf-life of more than six months when stored at a controlled room temperature) and claim 21 (requiring aseptic filling and a shelf-life of more than six months when stored at a controlled room temperature) and the Biomed reference or explain its rationale for why claim 16 or claim 21 would each have been inherently obvious. *See* 35 U.S.C. § 326(e) (explaining that in a PGR proceeding "the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.").

Petitioner fails to show that the shelf-life sterility limitations are necessarily present in or the natural result of modifying Biomed using the secondary

references, particularly in combination with the sterility limitations of claims 2, 15 16 and 21. *See supra* Section VI.C.1.b. Petitioner's own references further undermine its position that various sterilization methods are interchangeable and fail to affect shelf-life. Ex. 1006 at 597 ("Many products, both pharmaceutical and biological, are affected adversely by temperatures required for thermal sterilization."). Ketamine is such a pharmaceutical product that has been shown to form impurities when exposed to high temperatures. Ex. 1001 at 14:1–15:40. Yet Petitioner offers no data establishing that the Claimed Storage Stability limitations are necessarily met after modifying Biomed in the various ways discussed in the Petition.

Regarding dependent claims 6-12 and 14, which incorporate the Claimed Storage Stability limitations from claim 1, and recite various container materials, closure systems, and overwraps, Petitioner fails to provide any evidence that changing the Biomed infusion bag to a different bag and sterilizing it would not change the shelf-life of the resulting ketamine product. Indeed, the Biomed reference itself discloses that the same ketamine formulation stored in different containers has significantly different shelf-life results, *e.g.*, the ketamine formulation stored in the polypropylene syringe has a 12-month shelf life, whereas the infusion bag disclosed in Biomed is purported to have a 24-month shelf-life. Ex. 1005 at 10. This is objective evidence that the shelf-life of an aqueous

ketamine solution is not an inherent property of the formulation itself, which eviscerates Petitioner's argument that changing the infusion bag of Biomed and subjecting it to terminal sterilization would not affect the shelf-life of the resulting ketamine product. *See* Pet. at 46.

**d. Petitioner fails to show the Claimed Chemical Stability is necessarily present or the natural result of modifying Biomed as proposed by Petitioner**

In addition to the failures to establish inherency of the Claimed Storage Stability limitations of claims 2, 6-12, 14-17, and 21-23 discussed above in Section VI.C.1.c, Petitioner has also not met the high standard required in order to rely on inherency when applied to obviousness because none of the secondary references contain the Claimed Chemical Stability recited in claims 22 and 23.

First, Petitioner's inherent obviousness position against claims 22 and 23 fails because it turns on conflating the Claimed Chemical Stability with shelf-life. As discussed in Section V, chemical stability is not synonymous with shelf-life. Claims 22 and 23 require, *inter alia*, that the ketamine "is chemically stable following 24 months of storage at 25° C.±2° C. with relative humidity (RH) at 40%±5%." Petitioner failed to provide any disclosure or evidence of inherency of either of claims 22 and 23 as a whole, including the Claimed Chemical Stability limitations.

Second, as discussed above, via its dependency on claim 16, claim 22 requires that the ketamine solution be “contained in a **terminally-sterilized**, ready-to-use infusion container,” but Petitioner merely makes the same arguments as for claim 2 and fails to establish whether or not Biomed was sterile, terminally-sterilized or aseptically filled, and provides no explanation of why or how a POSA would have modified Biomed, why a POSA would have had motivation to do so, or why a POSA would have had a reasonable expectation of success in making the claimed product of claim 22 as a whole, including terminally sterilized and having “a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” despite the risk of degradation and formation of impurities of ketamine at high temperatures, and further that in such a terminally sterilized, ready-to-use container, “the ketamine or a pharmaceutically acceptable salt thereof is chemically stable following 24 months of storage at 25° C.±2° C. with relative humidity (RH) at 40%±5%.” *See* Pet. at 51. Further exacerbating these failings, Petitioner does not even attempt to argue inherent obviousness of claim 22 as a whole. Thus, Petitioner’s challenge fails for multiple reasons.

And with regard to claim 23, Petitioner makes the exact same arguments as for claim 18 and fails to establish whether or not Biomed was sterile, terminally-sterilized, or aseptically filled, and provides no explanation of why or how a POSA would have modified Biomed, why a POSA would have had motivation to do so,

or why a POSA would have had a reasonable expectation of success in making the claimed product of claim 21 *as a whole*, including aseptically filled and having “a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” and “wherein the ketamine or a pharmaceutically acceptable salt thereof is chemically stable following 24 months of storage at 25° C.±2° C. with relative humidity (RH) at 40%±5%” despite the lack of any information in Biomed about the infusion bag, the container closure system, ports, or any other information that would be necessary to determine if aseptic filling would apply to Biomed. Petitioner and Maurin failed to obtain, analyze, or test the alleged Biomed product and merely rely on conclusory general knowledge. *See* Pet. at 52. Petitioner provides no analysis and instead merely refers to its discussion of claim 18. *Id.* at 51-52. Claim 18 is dependent on claim 1 and does not contain the same limitations as independent claim 16 or dependent claim 22, or independent claim 21 or dependent claim 23. Thus, in merely referring to its discussion of claim 18, Petitioner fails to address the differences between the claims and the Biomed reference or explain its rationale for why claim 22 or claim 23 would have been obvious. Petitioner fails to identify any gaps in the Biomed reference or explain how a POSA would know to bridge such a gap. “A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors . . . .” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d at 1048; *Luv n’*

*Care, Ltd.*, 98 F.4th 1 at 1100 (same). Further exacerbating these failings, Petitioner does not even attempt to argue inherent obviousness of claim 23 as a whole. Thus, Petitioner's challenge fails for multiple reasons.

The Petition, Maurin declaration, and Biomed all fail to disclose any degradation data, assay results, or testing under any stability protocol to establish that “the ketamine or a pharmaceutically acceptable salt thereof is chemically stable following 24 months of storage at 25° C.±2° C. with relative humidity (RH) at 40%±5%” either before or after modifying Biomed as proposed in the Petition. A purported product label containing no chemical stability data does not establish that the Claimed Chemical Stability limitations *inevitably* would have resulted from Biomed, either before or after modifying it as proposed in the Petition. Inherency “may not be established by probabilities or possibilities” and “[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Cont'l Can Co.*, 948 F.2d at 1269; *see also Endo Pharms. Sols., Inc.*, 894 F.3d at 1379 (Fed. Cir. 2018) (“inherency may only supply a missing claim limitation if the limitation at issue is the ‘natural result’ of the combination of prior art elements”). Petitioner fails to meet the high standard of establishing more likely than not that claim 22 and 23 are inherently obvious.

The secondary references provide only general pharmaceutical principles and commercially available bags—not formulation-specific evidence regarding

Biomed or the chemical stability results of Biomed modified in various ways, and therefore do not remedy the deficiencies of Biomed to establish inherent obviousness.

The claims require shelf stability exceeding six months at 15–30°C, and the dependent claims extend this to 24 months at 25°C ± 2°C with 40% ± 5% relative humidity. The Petition provides no evidence that *any* dilute ketamine product would meet the stringent stability requirements and the prior art gave no indication of which parameters were critical and no direction as to which of many possible formulation, bag and sterilization choices is likely to be successful. The Petition's conclusory assertion that a POSA “would expect commercially available bags to withstand sterilization and that the shelf life would not decrease once the bags were either aseptically filled or terminally sterilized” (Pet. at 41; Ex. 1003, ¶ 133) is hindsight-driven speculation, not an expectation of success founded in the prior art.

**2. Ground 2 improperly relies on general knowledge and fails to establish a motivation or reasonable expectation of success for the sterilization-related terms**

While it was generally known to sterilize IV formulations before infusing them into patients, the record evidence shows that how a specific drug product and the specific drug substance contained in that product will react to any given sterilization procedure could not be predicted without testing the sterility, the

chemical stability of the drug, and the shelf-life of the drug product after storage.

Ex. 1020 at 4; Ex. 1006 at 597. The sterilization procedure was known to impact the chemical stability and also the storage stability of drug products. *Id.* Thus, Petitioner improperly relies on “general knowledge” and fails to show a motivation or reasonable expectation of success for the claimed sterility limitations in combination with the Claimed Chemical Stability and Claimed Storage Stability limitations, as explained below.

**a. Petitioner improperly relies on general knowledge for “sterile” in claims 2, 6-12, 14-15, 21, and 23**

As discussed in Section VI.B.1., independent claim 1 and its dependents (claims 2, 6-12, and 14-15) require that the ketamine product be sterile. The same is true for independent claim 21 and its dependent claim 23. Petitioner admits that Biomed does not expressly disclose that the purported product is sterile and instead alleges that “sterilization is a consideration.” Pet. at 29. Rather than pointing to disclosures in the reference itself or any other evidence (*e.g.*, obtaining and testing the purported Biomed product), the Petition alleges that “[t]he POSA would recognize that as an approved product in New Zealand for intravenous administration, Biomed would have needed to be sterile,” *id.*, which is repeated in the Maurin declaration. Ex. 1003 ¶ 114.

Petitioner's Ground 2 challenge against independent claim 1 merely incorporates its Ground 1 anticipation argument by reference and likewise does not

provide any evidence. Pet. at 42; Ex. 1003 ¶ 145 (Maurin similarly incorporates by reference his anticipation arguments and does not add anything further); *see also* Ex. 1003 ¶ 168 (addressing “sterile” in independent claim 21 by reference to anticipation argument for claim 1). For the reasons discussed in section VI.B.1 above, because the claim limitation “sterile” is not expressly, implicitly, or inherently disclosed in Biomed, and because the Petition relies on conclusory and unsupported expert opinions, and allegations of general knowledge to supply this missing claim limitation, which is prohibited by the Non-waiver Memorandum, rather than evidencing explicit, implicit, or inherent disclosure of the missing element in the reference itself, Petitioner's obviousness argument fails. *See* Non-waiver Memorandum at 1; *see also* 37 C.F.R. § 42.65(a).

Further, as explained in Section III.A above, the *Arendi* exception for reliance on common-sense to supply a missing claim limitation does not apply here. The '153 patent explains that ketamine in aqueous solution has been shown to react and form impurities under conditions such as the high temperatures used for terminal sterilization/autoclaving. Ex. 1001. at 14:41–15:40. Further, the '153 patent explains that “terminal sterilization is one of the most difficult requirements for medical devices” because it involves conditions that “can affect the integrity of the packaging, cause leaching of packaging components into the pharmaceutical solution, cause degradation of the drug product, and otherwise affect the stability

the pharmaceutical solution.” *Id.* at 10:53-60; *see also* Ex. 1006 at 584.

Petitioner's expert admits that “when using terminal sterilization, consideration must be given to the container and the drug product itself to ensure that the active pharmaceutical ingredient does not degrade at those conditions, and that the container can withstand the intensity of the cycle without itself degrading and contaminating the product.” Ex. 1003 at ¶ 55.

Because sterility of a ready-to-use aqueous solution ketamine product requires specific manufacturing processes, validated conditions, control of formation of impurities, and documented regulatory compliance—it is neither “unusually simple” nor “straightforward.” *Arendi*, 832 F.3d at 1361–62.

Petitioner's exhibits highlight the same challenges and the empirical nature of sterility assurance procedures. Ex. 1020 at 4 (“Sterility cannot be assured by testing, it needs to be assured by the use of a suitably designed, validated and controlled manufacturing process. Sterility is achieved by controlling several factors such as the bioburden, the sterilization procedure, the integrity of the container closure system and in the case of aseptic processing, the use of satisfactory aseptic technique.”); Ex. 1006 at 597 (“Many products, both pharmaceutical and biological, are affected adversely by temperatures required for thermal sterilization. Therefore heat-labile products should be sterilized by a nonthermal method, usually by filtration through bacteria-retaining filters.

Subsequently, all operations must be carried out in an aseptic manner, so that contamination is not introduced into the filtrate.”).

Neither the Petition nor the Maurin declaration address the fact that ketamine in aqueous solution was known to react under high temperature conditions to form impurities, *e.g.*, when exposed to high temperatures for terminal sterilization. Ex. 1001. at 14:41–15:40. Rather than addressing these challenges with both the ketamine drug substance itself and the ketamine aqueous solution as well as the issues of 1) leaching of infusion bag components into the ketamine solution upon exposure to high temperatures during sterilization, 2) contamination risk issues with container closure systems, and 3) contamination risks during aseptic filling of an infusion bag with a ready-to-use aqueous solution, Petitioner and Maurin merely argue that “the European Pharmacopoeia, confirms that parenteral preparations ‘should be tested for sterility’ to assess compliance with the European Pharmacopoeia.” Pet. at 30; Ex. 1003 ¶ 114. But Petitioner’s own reference states that “[s]terility cannot be assured by testing, it needs to be assured by the use of a suitably designed, validated and controlled manufacturing process.” Ex. 1020 at 4.

Petitioner provides no evidence that the purported Biomed product was manufactured, marketed, tested, sterile, terminally sterilized, or aseptically filled. No record evidence shows that Biomed was tested for sterility and confirmed to be

sterile. Thus, Petitioner's attempt to supply the missing limitations through conclusory statements, unfounded assumptions, and unsupported allegations that lack nexus to Biomed, is impermissible under both the Non-waiver Memorandum and Federal Circuit precedent. *See NuVasive*, 842 F.3d at 1383.

**b. Petitioner fails to establish a reasonable expectation of success for “terminally sterilized” in claims 2, 16, 17, and 22**

Regarding claim 2, which requires that “the ketamine product has been terminally sterilized,” and claim 16 and its dependent claims 17 and 22, which require “the ketamine solution is contained in a terminally sterilized ... container,” Petitioner similarly fails to carry its burden. Petitioner merely assumes without evidence that Biomed “would have needed to be sterile.” Pet. at 42. In addition to failing to establish that Biomed discloses a sterile product, much less a terminally sterilized product as required by claims 2, 16, 17, and 22, Petitioner merely makes the conclusory argument that “sterilization *could be* accomplished *either* by terminal sterilization *or* through the use of aseptic filling methods, as disclosed in Remington 2021 and confirmed by relevant guidelines. Therefore, claim 2 of the '153 patent is invalid as obvious.” Pet. at 42 (internal citations omitted, emphasis added); *see also id.* at 47 (referring to claim 2 discussion for claim 16).

Petitioner fails to support its assertion that terminal sterilization would have been obvious for the same reasons discussed in Section VI.C.2.a above, and

inherency cannot be established by probabilities or possibilities. Moreover, Petitioner fails to demonstrate that a POSA would have had a reasonable expectation of success in achieving the Claimed Storage Stability with a terminally sterilized product, as required by claim 2. Petitioner's own exhibit states that "[m]any products, both pharmaceutical and biological, are affected adversely by temperatures required for thermal sterilization." Ex. 1006 at 597. Ketamine is such a pharmaceutical product that has been shown to form impurities when exposed to high temperatures. Ex. 1001 at 14:41–15:50. Ex. 1006 states that for such pharmaceutical products that degrade when exposed to high temperatures, a non-thermal technique such as filter sterilization and aseptic filling should be used instead of terminal sterilization. Ex. 1006 at 597. Petitioner and Maurin fail to address these facts about ketamine and are also completely silent on motivation and reasonable expectation of success. Maurin admits that "when using terminal sterilization, consideration must be given to the container and the drug product itself to ensure that the active pharmaceutical ingredient does not degrade at those conditions, and that the container can withstand the intensity of the cycle without itself degrading and contaminating the product." Ex. 1003 ¶ 55. Maurin even admits that certain formulations cannot be terminally sterilized. *Id.* ¶ 56. Dr. Maurin refers to Ketalar as the marketed ketamine product (rather than the purported product described in Biomed) and, similar to Biomed, Maurin fails to

assert, much less provide evidence that Ketalar was terminally sterilized or aseptically filled. *Id.* ¶ 57.

Petitioner's General Pharmaceutical Publications (Exs. 1006, 1018, and 1020) are merely general publications that are not related to ketamine, much less to the Biomed reference. Neither Petitioner nor Maurin provides evidence or adequate analysis showing that a POSA would have been motivated to combine Biomed and the General Pharmaceutical Publications to modify the alleged Biomed product to be terminally sterilized. Indeed, Petitioner and Maurin failed to supply any disclosure or evidence as to: 1) whether the purported Biomed product is sterile, merely stating that "the European Pharmacopoeia, confirms that parenteral preparations 'should be tested for sterility,'" Pet. at 30; Ex. 1003 ¶ 114; 2) whether or not the purported Biomed product was terminally sterilized (assuming *arguendo* that it exists); 3) *how* the purported Biomed product was terminally sterilized, if it was terminally sterilized; and 4) whether or not the purported Biomed product was sterilized by sterile filtration and aseptic filling.

"[O]bviousness concerns whether a skilled artisan not only *could have made but would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). Here, given the missing information from the Biomed reference and Petitioner's failure to introduce any evidence of the

existence of the Biomed product or any testing of its sterility or stability and impurities, it is impossible to know what modifications, if any, a POSA would have been motivated to make to it, much less what the resultant properties of the product would have been. In such a situation, general knowledge cannot supply the missing information because expert testimony cannot substitute for requisite disclosures in the prior art. Non-waiver Memorandum at 1. The Federal Circuit has “repeatedly warn[ed] that references to ‘common sense’—whether to supply a motivation to combine or a missing limitation— cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified.” *Arendi*, 832 F.3d at 1362.

The same applies to claim 16, which requires that the ketamine solution be “contained in a terminally-sterilized, ready-to-use infusion container.” Petitioner makes the exact same arguments as for claim 2 and fails to establish whether or not Biomed was sterile or terminally-sterilized, and provides no explanation of why or how a POSA would have modified Biomed, why a POSA would have had motivation to do so, or why a POSA would have had a reasonable expectation of success in making the claimed product of claim 16 as a whole, including both “terminally sterilized” and having “a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” despite the risk of

degradation and formation of impurities of ketamine at high temperatures. *See* Pet. at 47-48.

Terminal sterilization requires that the drug product be sterilized in its final sealed container usually using high heat or sometimes radiation. Ex. 1006 at 597; Ex. 1016 at 2. Whether any given drug, formulation, and container system can feasibly be terminally sterilized depends on the heat and moisture sensitivity of the specific drug substance and the properties of the specific container system under terminal sterilization conditions. Ex. 1020 at 6 and 16-17. The Petition and the Maurin declaration fail to evidence that the specific ketamine formulation and infusion bag of Biomed were feasible for terminal sterilization without compromising drug quality or container integrity.

To the contrary, Maurin admits that “when using terminal sterilization, consideration must be given to the container and the drug product itself to ensure that the active pharmaceutical ingredient does not degrade at those conditions, and that the container can withstand the intensity of the cycle without itself degrading and contaminating the product.” Ex. 1003, ¶ 55. The Petition provides no data, studies or testing showing compatibility of that product and infusion bag system with terminal sterilization, or that the ketamine formulation of Biomed maintains required shelf life after terminal sterilization. The General Pharmaceutical Publications merely disclose *possible* sterilization techniques that may or may not

be compatible with some drug compounds and pharmaceutical containers, but do not address ketamine, dilute preservative-free ready-to-use solutions, or sterilization of such a formulation in the infusion bag of Biomed.

**c. Petitioner fails to establish a reasonable expectation of success for “autoclaved” in claim 15**

Petitioner's obviousness arguments for claim 15, which requires that “the ketamine product has been autoclaved,” fail for analogous reasons to the “terminal sterilization” claims. Petitioner impermissibly relies on general knowledge again. In addition to failing to establish that Biomed was sterile, much less autoclaved as required by claim 15, Petitioner refers to terminal sterilization or aseptic filling methods as possible alternate methods to sterilize pharmaceuticals. Pet. at 46. Petitioner admits that there are “many forms” of terminal sterilization. *Id.* Then, Petitioner alleges that one of those many forms is heat and steam sterilization, and that a POSA “would know that this takes place in an autoclave” without citing any evidence that a POSA would have a reasonable expectation of success in using this technique with an aqueous ketamine solution. *Id.* Petitioner also makes the baseless and clearly contradicted statement that “the infusion bags available could be subjected to terminal sterilization **without affecting the drug product.**” *Id.* (emphasis added). Petitioner itself introduced objective evidence contradicting this baseless allegation: Exhibit 1006 states that “[m]any products, both pharmaceutical and biological, are affected adversely by temperatures required for thermal

sterilization.” Ex. 1006 at 597. And ketamine is such a pharmaceutical product that has been shown to form impurities when exposed to high temperatures. Ex. 1001 at 14:41–15:40. Ketamine’s degradation upon exposure to high temperatures is a known problem, and Petitioner’s allegation that available bags could be terminally sterilized or autoclaved without affecting the ketamine drug is baseless. *See* Pet. at 46. Maurin parrots the same phrase and provides no evidence or scientific rationale for these allegations. Ex. 1003 ¶ 154.

To the contrary, objective evidence on the record contradicts Petitioner’s allegations: Ex. 1006 states that for such pharmaceutical products that degrade when exposed to high temperatures, a **non-thermal technique** such as filter sterilization and aseptic filling should be used instead of thermal treatment. Ex. 1006 at 597. Petitioner has not introduced any publication into the record to support the notion that for pharmaceutical products that degrade to form impurities when exposed to high temperatures such as ketamine, placing them in a commercial bag will prevent degradation. These facts demonstrate the baseless nature of Petitioner’s assertions, which Maurin parrots (Ex. 1003 ¶ 154). Conclusory expert testimony that merely parrots the Petition “adds little to the conclusory assertion for which it is offered to support[.]” *Xerox Corp.*, IPR2022-00624, Paper 9, at 15-16; *see also* 37 C.F.R. § 42.65(a).

Petitioner and Maurin fail to address these facts and are also completely silent on motivation and reasonable expectation of success. Petitioner's General Pharmaceutical Publications (Exs. 1018, 1020, 1006) are merely general publications that are not related to ketamine, much less to the Biomed reference. Neither Petitioner nor its expert provides evidence or adequate analysis showing that a POSA would have been motivated to combine Biomed and the cited General Pharmaceutical Publications to modify the Biomed product in the ways necessary to arrive at the challenged claims. Indeed, Petitioner and Maurin failed to supply any disclosure or evidence as to: 1) the sterility of Biomed, merely stating that "the European Pharmacopoeia confirms that parenteral preparations 'should be tested for sterility,'" Pet. at 30; Ex. 1003, ¶ 114; 2) whether or not the purported Biomed product was terminally sterilized (assuming *arguendo* that it exists); 3) *how* the purported Biomed product was terminally sterilized, if it was terminally sterilized; or 4) any disclosure or evidence as to whether or not the purported Biomed product was autoclaved.

"[O]bviousness concerns whether a skilled artisan not only *could have made but would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc.*, 805 F.3d at 1073. Here, given the missing information from the Biomed reference and Petitioner's failure to introduce any evidence of the existence of the Biomed product or any testing of its

sterility or stability and impurities, it is impossible to know what modifications, if any, a POSA would have been motivated to make to it. In such a situation, general knowledge cannot supply the missing information because expert testimony cannot substitute for disclosures in the prior art. Non-waiver Memorandum at 1. The Federal Circuit has “repeatedly warn[ed] that references to ‘common sense’—whether to supply a motivation to combine or a missing limitation— cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified.” *Arendi*, 832 F.3d at 1362.

**d. Petitioner fails to establish a motivation or a reasonable expectation of success for “aseptically filled” in claim 21.**

For analogous reasons to the “terminally sterilized” claims, Petitioner improperly relies on general knowledge to challenge independent claim 21, which also requires that the “ketamine product has been aseptically filled.” Petitioner makes the exact same arguments here as it does for claim 2 and fails to establish whether or not Biomed was sterile, terminally-sterilized, or aseptically filled, and provides no explanation of why or how a POSA would have modified Biomed, why a POSA would have had motivation to do so, or why a POSA would have had a reasonable expectation of success in making the claimed product of claim 21 as a whole, including aseptically filled and having “a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” despite the lack

of any information in Biomed about the infusion bag, the container closure system, ports, or any other information that would be necessary to determine if aseptic filling would apply to Biomed. Petitioner fails to address the fact that:

... it is critical that containers be filled and sealed in an extremely high-quality environment. Aseptic processing involves more variables than terminal sterilization.... Each process could introduce an error that ultimately could lead to the distribution of a contaminated product. Any manual or mechanical manipulation of the sterilized drug, components, containers, or closures prior to or during aseptic assembly poses the risk of contamination and thus necessitates careful control.

Ex. 1016 at 2-3.

Further, Ex. 1016 notes the high risk of contamination with aseptic filling: “Nearly all drugs recalled due to nonsterility or lack of sterility assurance in the period spanning 1980-2000 were produced via aseptic processing.” *Id.* at 3. Petitioner and Maurin failed to address how aseptic filling would be performed in view of these variables and risks with regard to Biomed including its ketamine solution, infusion bag components, and closure system, none of which were described in Biomed, the General Pharmaceutical Publications, the Petition, or the Maurin declaration. Petitioner and Maurin failed to obtain, observe, or test the alleged Biomed product and merely rely on conclusory general knowledge. *See* Pet. at 50.

**e. Petitioner fails to establish a reasonable expectation of success in achieving the 24 month chemical stability required by claims 22 and 23**

Finally, for claim 22, which depends from claim 16, and claim 23, which depends from claim 21, Petitioner similarly fails to carry its burden and impermissibly relies on common knowledge to supply missing limitations. As discussed above, via its dependency on claim 16, claim 22 requires that the ketamine solution be “contained in a terminally-sterilized, ready-to-use infusion container,” but Petitioner merely makes the same arguments as for claim 2 and fails to establish whether or not Biomed was sterile, terminally-sterilized or aseptically filled, and provides no explanation of why or how a POSA would have modified Biomed, why a POSA would have had motivation to do so, or why a POSA would have had a reasonable expectation of success in making the claimed product of claim 22 as a whole, including terminally sterilized and having “a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” despite the risk of degradation and formation of impurities of ketamine at high temperatures, and further that in such a terminally sterilized, ready-to-use container, “the ketamine or a pharmaceutically acceptable salt thereof is chemically stable following 24 months of storage at 25° C.±2° C with relative humidity (RH) at 40%±5%.” *See* Pet. at 51. And with regard to claim 23, Petitioner makes the exact same arguments as for claim 18 and fails to establish

whether or not Biomed was sterile, terminally-sterilized, or aseptically filled, and provides no explanation of why or how a POSA would have modified Biomed, why a POSA would have had motivation to do so, or why a POSA would have had a reasonable expectation of success in making the claimed product of claim 21 *as a whole*, including aseptically filled and having “a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C” and “wherein the ketamine or a pharmaceutically acceptable salt thereof is chemically stable following 24 months of storage at 25° C.±2° C with relative humidity (RH) at 40%±5%” despite the lack of any information in Biomed about the infusion bag, the container closure system, ports, or any other information that would be necessary to determine if aseptic filling would apply to Biomed. Petitioner and Maurin failed to obtain, analyze, or test the alleged Biomed product and merely rely on conclusory general knowledge. *See* Pet. at 52. Petitioner provides no analysis and instead merely refers to its discussion of claim 18. *Id.* at 51-52. Claim 18 is dependent on claim 1 and does not contain the same limitations as independent claim 16 or dependent claim 22, or independent claim 21 or dependent claim 23. Thus, in merely referring to its discussion of claim 18, Petitioner failed to address the differences between the claims and the Biomed reference or explain its rationale for why claim 22 or claim 23 would have been obvious. Petitioner fails to identify any gaps in the Biomed reference or explain how a POSA would

know to bridge such a gap. “A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors . . . .” *Apple Inc.*, 839 F.3d at 1048; *Luv n’ Care, Ltd.*, 98 F.4th 1 at 1100 (same).

Even more, Petitioner’s General Pharmaceutical Publication exhibits highlight that terminal sterilization and aseptic filling impose fundamentally different requirements, stresses, risks, and outcomes, yet Petitioner and Maurin make unsupported conclusory allegations of identical chemical stability and shelf-life results after the proposed modifications. Specifically, Petitioner’s analysis of claim 23 is, in its entirety, a verbatim repetition of its analysis of claim 22. Maurin merely states that “Biomed is a ketamine product wherein the ketamine or a pharmaceutically acceptable salt thereof is chemically stable following 24 months of storage at  $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$  with relative humidity (RH) at  $40\% \pm 5\%$  for the same reasons as set forth for this limitation of claim 18, above at paragraph 128. I incorporate my opinion for claim 18 herein.” Ex. 1003, ¶ 174.

Maurin does not even mention aseptic filling, much less explain (or show any data/evidence for) how the aseptic fill process that distinguishes claim 23 from claim 22 would affect the chemical stability or the storage stability of the ketamine product over 24 months. Furthermore, by incorporating his claim 18 arguments without addressing the fundamentally different limitations of claim 23, Maurin fails to analyze the impacts of the aseptic fill limitation on the Claimed Storage

Stability and the Claimed Chemical Stability limitations. The Petition provides no process-specific stability analyses for claim 23 nor cites any prior art or evidence addressing 24-month stability of an aseptically filled, preservative-free ketamine formulation. Accordingly, Petitioner failed to provide the requisite analysis to demonstrate that it is more likely than not that claims 22 and 23 are unpatentable.

**3. The Petition improperly uses the patent specification as a roadmap and fails to establish a motivation or reasonable expectation of success for claims 6–12 and 14 (IV Bag Claims)**

Claims 6-12 and 14 require specific polymeric materials in the infusion bag port and closure, specific closure structures and membranes, specific layers of a multilayer infusion bag, and specific polymer layers of a multi-layer overwrap. Petitioner fails to carry its burden of establishing that any of these claims are more likely than not obvious.

Section 103 requires assessment of the invention “as a whole” and prohibits hindsight that uses “the invention as a roadmap to find its prior art components, [which] would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention.” *Ruiz*, 357 F.3d at 1275.

Here, the Petition merely assumes without evidence that the purported product of the Biomed reference could have been modified to be filled into various infusion bags having various different materials, layers, closures, membranes, and

overwraps, and sterilized, and that the so-modified products would have inherently achieved the same stability and shelf-life and sterility properties required by the present claims. *See* Pet. at 44-45. This allegation is baseless and not supported by any evidence in the Petition. Instead, Petitioner merely refers to the '153 patent itself and product data sheets for infusion bags disclosed in the '153 patent. Pet. at 45.

By relying solely on the '153 patent itself and product data sheets for infusion bags disclosed in the '153 patent, impermissibly uses the '153 patent's specification to point to the specific infusion bags and components that the inventor identified as suitable for the specific aqueous ketamine solution (*i.e.*, sterile, ready-to-use, preservative-free and anti-microbial free and has the Claimed Storage Stability and Claimed Chemical Stability), and alleges the modification of Biomed with each and every one of those suitable bags and components was obvious because the individual components existed. The “Board ‘must still be careful not to allow hindsight reconstruction of references . . . without any explanation as to *how* or *why* the references would be combined to produce the claimed invention.’” *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (quoting *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1368 (Fed. Cir. 2012)).

Claims 6–12 and 14 recite highly specific bag features: multilayer polyolefin and styrene block copolymer ports (Claim 6), twist-off closures with membrane barriers creating two-part chambers (Claim 8), specific polymer compositions (Claims 9–12), and four-layer overwraps with polyester/aluminum/polypropylene layers (Claim 14). Rather than providing reasoned analysis and evidentiary support for why and how a POSA would have modified the purported Biomed product while achieving the chemical stability and shelf-life limitations of the present claims, Maurin argues “the POSA would understand from reading the specification that the inventors did not invent a novel infusion bag.” Ex. 1003 ¶ 151. Maurin misses the point because the challenge improperly uses the ’153 patent itself as the roadmap to allege that the claimed invention as a whole is obvious because the specifically selected infusion bags of the dependent claims were commercially available. *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018) (“It is inappropriate to use the template provided by the inventor, to render the inventor’s contribution obvious.”). Petitioner does not explain why a POSA would select *these specific* multilayer configurations, polymer blends, and closure designs from among many possible options, and use them to replace the infusion bag of the Biomed product. “§ 103 provides that ‘[p]atentability shall not be negated by the manner in which the invention was made.’” *Honeywell Int’l Inc.*, 865 F.3d at 1355; *Life Tech., Inc. v. Clontech Labs.*,

*Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (“the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute.”).

Maurin further alleges that the specification “merely listed suitable commercially available bags.” Ex. 1003, ¶ 139. But identifying which bags and components are “suitable” for a *specific drug formulation* is itself a significant part of the inventive contribution. The fact that numerous infusion bags existed does not mean a POSA would have selected the claimed infusion bags and used them to modify Biomed, and expected that doing so would result in the claimed aqueous ketamine solution that is sterile, preservative-free and anti-microbial free, and has the Claimed Storage Stability and the Claimed Chemical Stability.

A POSA would have known that modifying any one of the infusion bag, the closure, the manufacturing techniques, the layers of plastics, the overwrap, and the sterilization method applied to the ketamine solution and such containers could impact the resultant product’s chemical stability, shelf-life, and sterility. *See, e.g.*, Ex. 1006 at 597-598; Ex. 1001 at 2:38–40. Petitioner failed to provide any information about the infusion bag, closure(s), materials, layer(s), and overwrap from Biomed, and due to Petitioner’s failure to introduce any evidence of the existence of the Biomed product or any testing of its sterility, stability, or impurities profile, it is impossible to know what modifications, if any, a POSA would have been motivated to make to that product, or what the impacts of such

modifications might have been on the stability and shelf-life properties of the resulting modified Biomed product.

As to Claim 8, which requires a twist-off closure comprising a membrane barrier splitting the closure into two parts, the Petition points to the Technoflex Inerta product disclosed in the '153 patent, but this is only one of many bag configurations available for parenteral products. The Petition does not explain why a POSA would have specifically sought this feature rather than any one of the other known port systems. Petitioner and Maurin did not obtain the purported Biomed product and did not identify which kind of port it might have. Thus, the allegation that POSA would have been motivated to somehow modify the purported Biomed product, despite not knowing what kind of port it had, is baseless. Petitioner impermissibly uses the '153 patent as a roadmap.

As to Claim 14, which requires a four-layer overwrap comprising polyester, aluminum, polypropylene, and polyester, Petitioner does not explain why a POSA would have selected this particular four-layer, four-material overwrap configuration from among all available overwrap options. The Petition does not explain why a POSA would have specifically sought this feature rather than any one of the other known overwrap systems. Petitioner and Maurin did not obtain the purported Biomed product (or show that any such product exists) and did not identify which kind of overwrap it might have. Again, the allegation that POSA

would have been motivated to somehow modify the purported Biomed product, despite not knowing what kind of overwrap it had, is baseless. Petitioner impermissibly uses the '153 patent as a roadmap.

Maurin's declaration establishes that he identified the claimed bags and components only after reading the '153 patent. Ex. 1003, ¶¶ 141-143 ("The patent-admitted commercially available infusion bags satisfy the limitations of claims 6–12 and 14 as *the applicant confirmed* they were suitable for use in the invention") (emphasis added). The Board should give little or no weight to Maurin's conclusory, hindsight-based opinions. 37 C.F.R. § 42.65 (a); *TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (holding "conclusory expert testimony is inadequate to support an obviousness determination"). The Petition fails to establish that a POSA, working without the patent as roadmap, would have arrived at the claimed combination of specific components required by claims 6-12 and 14.

Objective record evidence highlights the need to conduct formulation-specific compatibility and stability studies to determine whether a given bag maintained the sterility, chemical stability, and low extractables/leachables profile required by the claims. *See, e.g.*, Ex. 1020 at 6-7, Ex. 1006 at 597-598. The '153 patent's examples describe stability studies and stress studies that tested the formulation in specific containers under specific conditions to obtain various

chemical stability and shelf-life results. Petitioner and Maurin did not provide any such formulation-specific compatibility and stability data or evidence to establish that modifying Biomed in all of the various ways proposed in the Petition would inherently result in what is claimed in claims 6-12 and 14 as a whole. Thus, Petitioner has not met the particularity requirements of 35 U.S.C. § 322(a)(3) for any of the challenged claims.

Furthermore, claims 6-12 and 14 depend indirectly on claim 1, and thus are directed to a ketamine product that **has a shelf-life of more than six months when stored at a controlled room temperature between 15-30° C.** Thus, Petitioner's rationale that it would have been obvious to modify the infusion bag to administer ketamine to a patient further fails because Petitioner provides no explanation of 1) why one would have been motivated to modify the bag of Biomed that Petitioner purports was already ready-to-use to administer ketamine to a patient (*see, e.g.*, Pet. at 29, 31, 35), or 2) how one of ordinary skill would have modified the bag of Biomed with a reasonable expectation of success that the modified bag would meet the requisite shelf-life and sterility requirements of the challenged claims.

Rather than providing reasoned analysis and evidentiary support for why and how a POSA would have modified the purported Biomed product while achieving the chemical stability and shelf-life limitations of the present claims, Petitioner only superficially relies on the '153 patent itself in an attempt to allege that a

POSA would have had a reasonable expectation of success in using the claimed materials to achieve the claimed stable ketamine formulations. *See* Pet. at 45; Ex. 1003 ¶¶ 137, 151. This reasoning is improper. “[T]he expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Dow Chem. Co.*, 837 F.2d at 473.

Petitioner cannot meet its burden to show it is more likely than not that any of the challenged claims is invalid. Institution should be denied.

## **VII. DISCRETIONARY DENIAL**

The Director possesses broad discretion over institution decisions, which are final and non-appealable. *Apple Inc. v. Squires*, 166 F.4th 1349, 1356-57 (Fed. Cir. 2026) (Director is permitted but never compelled to institute review). The Board has exercised this discretion in PGR proceedings. *See, e.g., Immersion Sys. LLC v. Midas Green Techs., LLC*, PGR2021-00104, Paper 15, at 5-9 (PTAB Jan. 31, 2022).

As discussed in Section VI.A above, the grounds asserted in the Petition are deficient in numerous respects, including that the Petition fails to establish that Biomed (Ex. 1005) is prior art under 35 U.S.C. § 102. Furthermore, the expert testimony is conclusory and lacks evidentiary basis on multiple dispositive issues. Extensive reliance on expert testimony on dispositive issues further supports discretionary denial. *See K/S HIMPP v. Hear-Wear Techs., LLC*, 751 F.3d 1362,

1366 (Fed. Cir. 2014) (“The Board’s decision was correct because an assessment of basic knowledge and common sense as a replacement for documentary evidence for core factual findings lacks substantial evidence support.”).

Institution of these deficient grounds would not represent a judicious use of the Board’s resources. *See Zhuhai Cosmx Battery Co., Ltd. v. Ningde Amperex Tech. Ltd.*, IPR2025-00405, Paper 24, at 2–3 (PTAB Oct. 15, 2025); 37 C.F.R. § 42.1(b).

## **VIII. CONCLUSION**

For each of the foregoing reasons, Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

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**CERTIFICATE OF COMPLIANCE**

This PATENT OWNER'S PRELIMINARY RESPONSE complies with the type-volume limitations as mandated in 37 C.F.R. §§ 42.24(a)(1)(ii) and (b)(1)(i). According to the word processing system used to prepare this document, the brief contains 17,607 (less than 18,700) words, exclusive of the exempted portions.

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 2nd day of July 2026, a true and correct copy of the foregoing PATENT OWNER'S PRELIMINARY RESPONSE was served, via electronic mail upon the following counsel of record for Petitioner Par Health, Inc.:

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