

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MAGNOLIA MEDICAL TECHNOLOGIES, INC.,

Petitioner

v.

KURIN, INC.,
Patent Owner

IPR2026-00097
Patent No. 12,138,052

PATENT OWNER'S PRELIMINARY RESPONSE

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TABLE OF EXHIBITS

Exhibit No.	Description
2001	Kurin's Motion to Amend Answer and Counterclaims, <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. November 13, 2024).
2002	Kurin's Amended Answer and Counterclaims, <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. November 21, 2024).
2003	Magnolia Medical Tech., Inc.'s Opening Brief in Support of its Motion for Summary Judgment of Invalidity of U.S. Patent No. 12,138,052 under 35 U.S.C. §§102 and 103 (Redacted), <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. August 1, 2025).
2004	Memorandum Order (denying Magnolia's Motion for Summary Judgment), <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. September 2, 2025).
2005	Defendant Kurin, Inc.'s Opening Brief in Support of Daubert Motion to Exclude Testimony of Plaintiff's Expert Carl D. Meinhart, <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. August 1, 2025).
2006	Memorandum Order (excluding certain testimony of Dr. Carl Meinhart), <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. November 3, 2025).
2007	Verdict Form (Redacted), <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. December 16, 2025).
2008	Excerpts from Trial Transcript, <i>Magnolia Medical Technologies, Inc. v. Kurin, Inc.</i> , C.A. No. 24-1124-CFC (D. Del. December 8-16, 2025).

Patent Owner respectfully submits this Preliminary Response, and requests that the Board deny the petition for *inter partes* review (“Petition”) because the Petitioner has failed to meet its claim-construction burden (§I, below), has failed to properly identify a key claim term in the prior art (§II, below), and has failed to meet its burden to show obviousness (§III, below).

I. THE PETITION FAILS TO MEET ITS BURDEN REGARDING CLAIM CONSTRUCTION

The Petition should be denied because it fails to fulfill the requirement of 37 C.F.R. § 42.104(b)(3), namely that the Petition explain “how the challenged claim is to be construed.” The Petition fails to meet this requirement because it applies the claims in a manner inconsistent with non-infringement arguments made to the jury in the parties’ co-pending litigation, without any explanation as to why the inconsistency is justified. “[W]hen a petitioner advances different positions before the Board and a district court, that petitioner is required to explain why those different positions are warranted.” *Tesla Inc., v. Intellectual Ventures II, LLC*, IPR2025-00340, Paper 18 at 3 (Director Nov. 5, 2025) (informative).

Patent Owner made a similar argument for discretionary denial (*see* Request for Discretionary Denial, paper 9, pp. 13-23). The discretionary denial decision, however, will weigh the “totality of the evidence and arguments the parties have presented” to determine whether discretion should be applied. *See, e.g., Fujirebio Diagnostics, Inc. v. Quanterix Corp.*, IPR2025-01060, Paper 13 (Acting Director,

October 17, 2025). In contrast, before a merits panel, the requirement to explain “how the challenged claim is to be construed” under 37 C.F.R. § 42.104(b)(3) is a gatekeeping issue, and alone justifies a denial of the Petition before the panel. *See Tesla*, at 3 (informative).

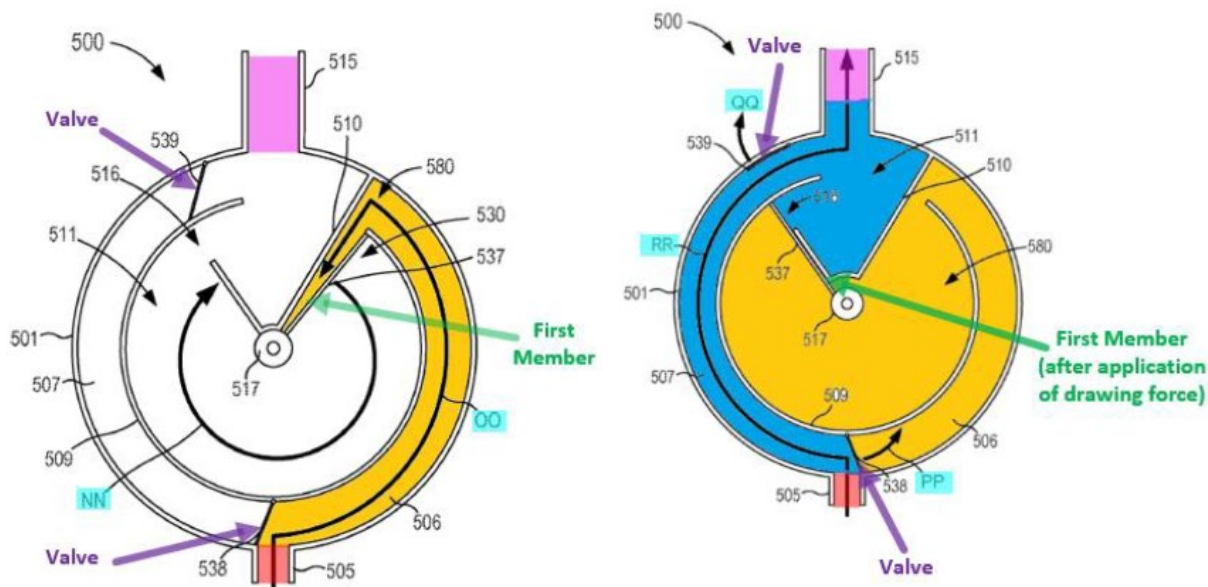
The Petitioner takes inconsistent positions with respect to at least claim elements [1E] and [1C].¹

A. Claim element [1E]

Claim element [1E] reads “a housing that defines the inlet port, the sampling channel, and the outlet port.” Petitioner’s interpretations of this claim element are inconsistent. In the Petition, Petitioner takes a broad view of the term, assuming that claim element [1E] is met when “the housing 501 [of the prior art] **substantially** forms the bordering structure that walls off (i.e., fixes or defines the limits of) the inlet port to the outlet port.” Pet., p. 21 (emphasis added). When arguing non-infringement in the co-pending litigation, however, Petitioner contended that the sampling channel could not be formed, even partially, by other components.

¹ Petitioner challenges claims 1-24 of the ’052 patent under 4 different Grounds, each of which relies principally on the Bullington800 art. Pet., p. 11. Claims 1 and 13 are independent. The issues highlighted herein with respect to independent claim 1 are also present in Petitioner’s analysis of independent claim 13.

The Petition's discussion of claim element [1E] provides the following annotated versions of Figs. 16 and 17 of Bullington800:



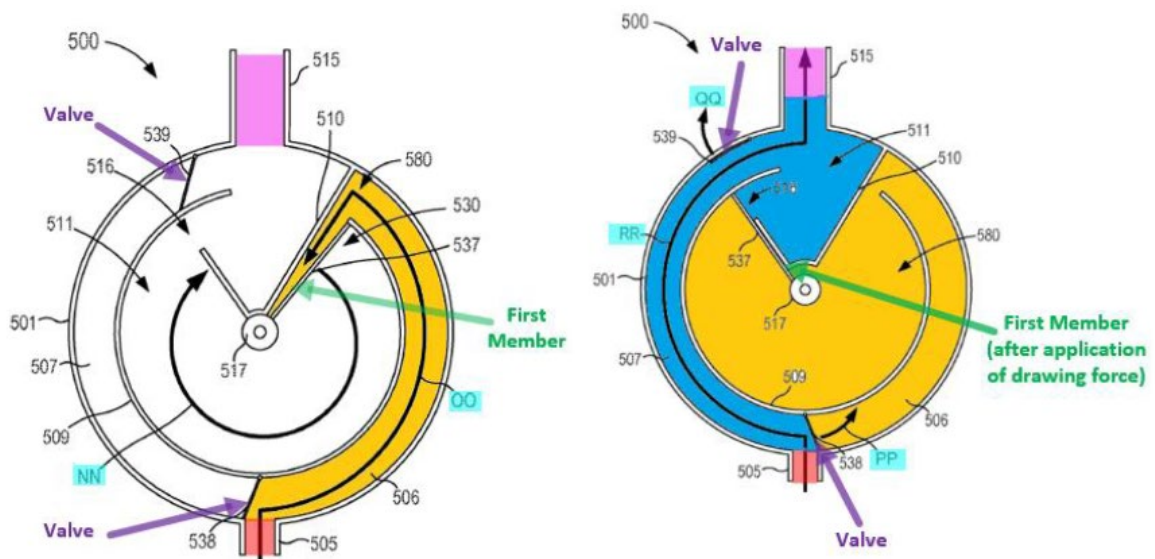
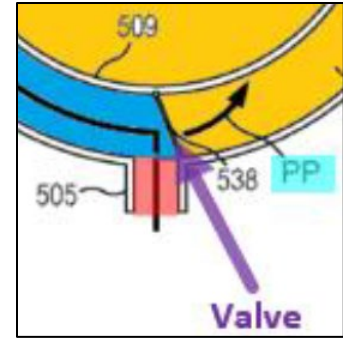
Ex. 1012, Figs. 16 & 17 (annotated)

Pet., p. 18.

Petitioner at first blush appears to argue that the “housing” is composed of elements 501 and 509 (essentially, the narrow black lines enclosing a blank space, e.g. ). Pet., pp. 19-22. Petitioner further appears to contend that the outlet port is the area marked in purple in annotated Fig. 17 (Pet., pp. 19-20), the inlet port is the area marked in red (Pet., pp. 19-20), and the sampling channel is the area marked in blue (Pet., pp. 19-20).

As can be seen from Fig. 17, however, at least the sampling channel as defined by Petitioner (blue) is *also* formed in part by elements 537 and 538. According to

Bullington800, element 537 is a “first member” that is “rotatably coupled to a hub 517”, which allows it to rotate from the position shown in Fig. 16 to the position shown in Fig. 17. EX1012, ¶1109. Element 538 (bottom center) is purportedly a “second member” (EX1012, ¶1109) that can be a valve, and is indicated by Petitioner’s annotated figures as shown at right in the excerpt from annotated Fig. 17. Pet., p. 19. The second member 538 purportedly switches between the first position, shown in Fig. 16, and a second position, as shown in Fig. 17. In the first position (Fig. 16), the alleged sampling channel is closed off from the alleged input port by second member 538. In the second position (Fig. 17), the second member 538 forms part of the alleged sampling channel:



Ex. 1012, Figs. 16 & 17 (annotated)

In other words, portions of the alleged sampling channel in Bullington800 are not

formed by what Petitioner calls the housing (Pet., pp. 19-20), but rather by members 537 and 538. Petitioner seems to acknowledge this at least for member 537, arguing in the Petition that “[t]he first member 537 provides the border for a small portion of the sampling channel near the outlet port while keeping the sampling channel fluidically isolated from the chamber. Ex. 1012, ¶¶[1109]-[1111], [1114], Figs. 16-17; Ex. 1002, ¶87.” Pet., p. 21. Thus, Petitioner asserts that prior art can meet element [1E] even where the housing does not “define” portions of the sampling channel.

To justify this position, Petitioner does not discuss the proper construction of claim element [1E], but rather argues more elliptically that its interpretation of element [1E] is “consistent with the ’052 patent”. In the words of the Petition:

“Thus, to the extent the ’052 Patent describes a housing as claimed, Bullington800 is consistent with it, where both include a set of walls that substantially forms the boundaries of each of the outlet port, inlet port, and sampling channel and the back side of the hydrophobic plug delineates a small portion of the sampling channel near the outlet port while keeping the sampling channel fluidically isolated from the chamber.”

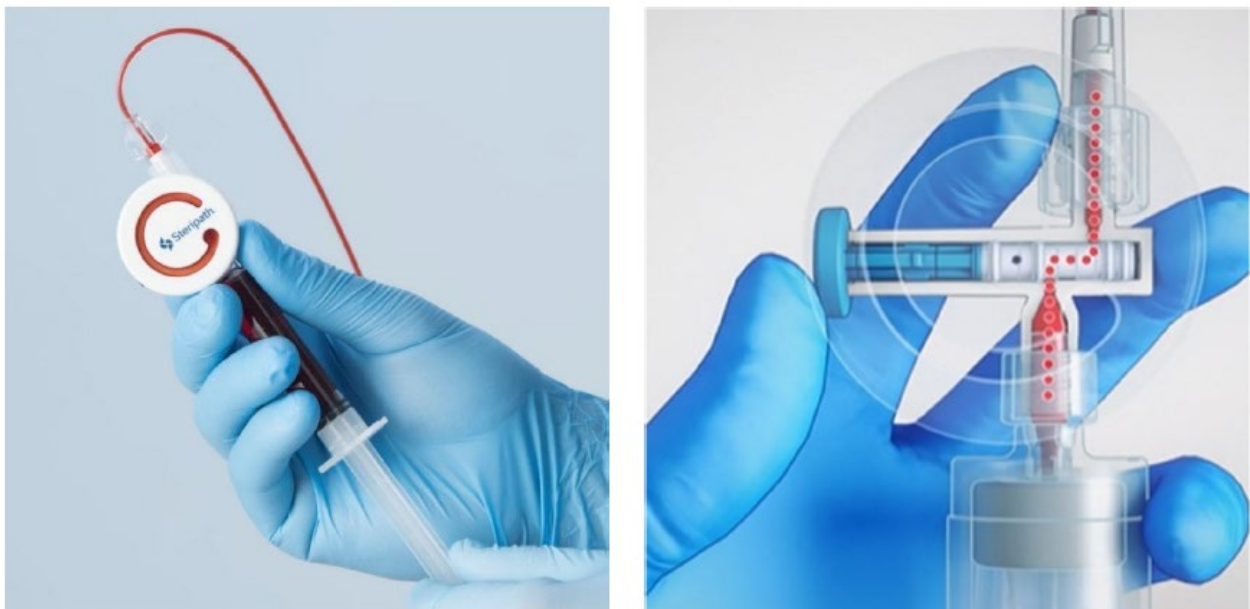
Pet., p. 21.

At trial in the litigation, however, Petitioner appeared to argue that claim element [1E] would not be met unless *every* portion the inlet port, the sampling

channel, and the outlet port were formed by the housing. Specifically, at trial, Petitioner's expert testified that Petitioner's Steripath Micro Device did not infringe the asserted claims of the '052 patent because the housing *by itself* did not define the sampling channel, but rather it was a combination of the *housing* and a *button*. EX2008, Tr. 1601:1-6 (PDF page 067).

Petitioner's trial attorney reinforced this, arguing to the jury that the '052 patent requires a housing that defines the sampling channel, and that Steripath Micro did not meet the claims because without the button, there was no sampling channel. EX2008, Tr. 1808:18-1809:1 (PDF page 119).

This argument can be illustrated with the following diagrams of Steripath Micro (from Patent Owner's counterclaim):



EX2002, pp. 117-122. Blood drawn from a patient initially fills a semi-circular collection chamber (left side). Then the user presses a button (right side diagram),

which actuates an internal valve to bypass the collection chamber and open a sampling channel. Thus, the “button” referred to by Magnolia serves to open the sampling channel, much as the “second member” 538 serves to open the sampling channel in Bullington800. The jury ultimately found that the Steripath Micro Device did not infringe claim 1.²

Petitioner’s arguments in its Petition and before the jury are in direct tension. In the IPR, Petitioner implies that the housing need only roughly and “substantially” define the outline of the sampling channel.³ To avoid infringement in the District Court litigation, however, Petitioner argued that the “sampling path” could not be defined by *anything but* the housing. Petitioner purports to apply the same claim construction as applied in District Court, namely that “a housing that defines” means “a casing that fixes or marks the limits of”. Pet., p. 37 (citing Ex. 1036, p. 1). Yet in practice, Petitioner imports a broader construction in its Petition than in District Court.

It was the Petitioner’s burden to reconcile the inconsistency. Because

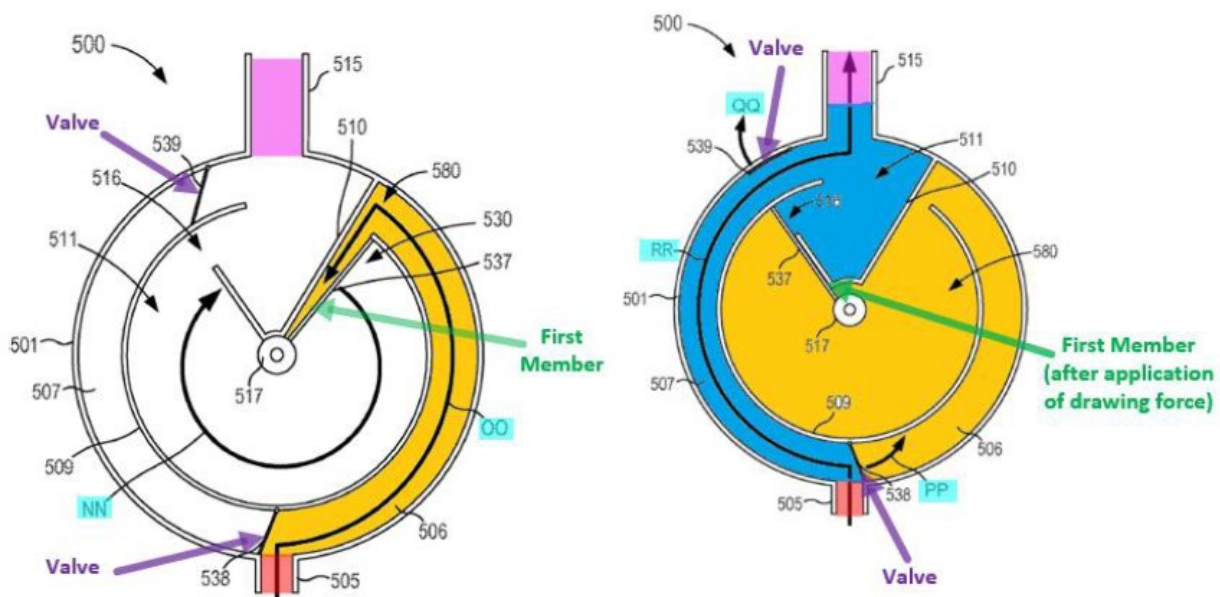
² Claims 1, 10 and 12 of the ’052 patent were asserted at trial.

³ Patent Owner notes that Petitioner’s invalidity expert, perhaps not coincidentally, also failed to explain his construction for the term “housing that defines”, and that this failure led to his testimony being excluded. EX2006, pp. 003-004.

Petitioner's approach leaves the proper claim construction unclear, the Petition has not complied with 37 C.F.R. § 42.104(b)(3), and should be denied.

B. Claim element [1C]

Claim element [1C] reads “a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device”. Petitioner's interpretations of this claim element are again inconsistent. In the Petition, the Petitioner assumes that the “chamber” of claim element [1C] can be “under a drawing force applied from the outlet port” when the drawing force is applied *via intermediate components*. To help illustrate Petitioner's IPR construction, the Petition's annotated versions of Figs. 16 and 17 are provided again here:



Ex. 1012, Figs. 16 & 17 (annotated)

Pet., p. 15.

According to the Petition, the “chamber” of claim element [1E] is space 580 (colored yellow-orange), while the outlet port is colored purple. The Petition contends that a suction force is applied to the outlet port, that the suction force acts to move the member 537, and that this in turn puts the “chamber” under a drawing force. Pet., p. 16. Thus, the Petition contends that in Bullington⁸⁰⁰ the alleged “drawing force” is not applied *directly* from the outlet, but rather provided *via* the member 537. In the words of the Petition:

“When coupled to the outlet port, the syringe ‘introduce[s] a negative pressure in a portion of the inner volume 511 that exerts a suction force...operable in rotating the first member 537.’ Id., ¶¶[1112], [1107], Fig. 16. The rotation of the first member 537 increases a volume of the chamber thus causing the negative pressure to be exerted within the chamber.”

Pet., p. 16.

At trial in the litigation, however, Petitioner sought to avoid infringement by arguing that the accused product’s outlet port did not *directly* apply a drawing force to the relevant chamber. Instead, when a syringe was attached to the outlet port and a negative pressure applied, the drawing force was mediated by an intervening “bladder” element before being applied to the chamber. Petitioner’s non-infringement expert testified that a vacuum flips the bladder, and the bladder that creates the drawing force that pulls in the blood sample. EX2008, Tr. 1597:9-23

(PDF p. 066). For that reason, the expert opined that the Steripath Micro does not practice requirement [1C] of Claim 1 of the '052 patent. Petitioner's trial attorney then argued to the jury that if the jury agreed with Professor Meinhart concerning how the Petitioner's device worked (that the drawing force came from the bladder instead of from the vacuum at the outlet), then there was no infringement of the Patent Owner's claims. EX2008, Tr. 1808:14-17 (PDF p. 119).

Petitioner's litigation and IPR constructions are again inconsistent. The Petition argues that a drawing force acting on member 537, which in turn acts on the alleged "chamber", meets element [1C]. In the litigation, Petitioner argued that a drawing force acting on a "bladder", which in turn acted on the "chamber", did not meet element [1C]. The Petitioner provides no explanation to justify this inconsistency, and thus fails to meet 37 C.F.R. § 42.104(b)(3) for this additional reason.

II. THE PETITION FAILS TO PROPERLY IDENTIFY THE "HOUSING" CLAIM LIMITATION IN BULLINGTON800

The Petition also fails to meet its burden under 37 C.F.R. § 42.104(b)(4) requiring that a petition for *inter partes* review "specify where each element of the claim is found in the prior art patents or printed publications relied upon." 37 C.F.R. § 42.104(b)(4); Memorandum, *Enforcement and Non-Waiver of 37 C.F.R. § 42.104(B)(4) and Permissible uses of General Knowledge in Inter Partes Reviews*,

July 1, 2025.⁴

The Petition fails to meet this requirement because it fails to identify clearly the “housing” of Bullington800. The term “housing” is found in each of the independent claims, and is alleged by the Petition in each Ground to be taught by the Bullington800 prior art. *See* Pet., pp. 14 (Ground A-B, claim [13E]), 60 (Ground C, claim [1E]), 72-73 (Ground C, claim [13E]), 79 (Ground D, claim [13E]). However, the Petition’s identification of the housing is confusing and contradictory.

As noted in the Patent Owner’s Discretionary Denial Brief (p. 15), the Petition appears to argue (at first blush) that the “housing” is composed of elements 501 and 509 (essentially, the narrow black lines enclosing a blank space, e.g. ). Pet., pp. 19-22. For example, the Petition states:

“The housing 501 also **includes** diverter 509 that ‘can be a set of walls that...direct a fluid of bodily-fluid within the inner volume 511.’ Ex. 1012 ¶[1108], Figs. 16-17.”

Pet., p. 19 (Emphasis added).

Upon closer examination, however, the Petition is unclear about the mapping of the “housing”. For example, the Petition later implies that the housing 501 and

⁴ https://www.uspto.gov/sites/default/files/documents/aapa_memo_final__signed.pdf.

diverter 509 are separate elements. Pet., p. 19 (“Bullington800 states that ‘the diverter 509 and a set of wall[s] of the housing 501 defining the inner volume 511 define, at least partially...second channel 507....’ Id., ¶[1108].”). The Petition, moreover, repeatedly refers to Bullington’s “housing 501” as meeting the claim language in the absence of diverter 509. *See, e.g.*, Pet. 20 (“the housing 501 fixes or marks the limits of each of the outlet port, inlet port, and sampling channel”); Pet. (“To any extent that Patent Owner argues that Bullington800 does not expressly disclose that its housing 501 “defines the inlet port, the sampling channel, and the outlet port....”).

The Petition further argues (in the context of claim 4, which requires “the housing is separate from the blood impermeable membrane”) that the housing **501** is separate from other components (members 537 and 538) based on language in Bullington800 that could be equally applied (under the Petitioner’s logic) to show that diverter 509 is separate from housing 501. As argued in the Petition:

“The **membrane is separate from the housing 501** [figure omitted]. The **first member 537** ‘can extend in a radial direction from the hub 517 to be placed in contact with an inner surface of the annular wall forming at least a portion of the diverter **509**.’ Ex. 1012, ¶[1109]. Similarly, **the second member 538** ‘can be rotatably coupled to an outer surface of the annular wall defining **a portion of the diverter 509**. Id. The **first member 537** also ‘can be selectively placed in contact with an inner surface of the housing **501**’ Id. Thus, the

membranes are a component separate from the housing 501 that may be placed in contact with and/or coupled to the housing 501. Id.; Ex. 1002, ¶101.”

Pet. p. 27-28 (Emphasis added).

The ambiguity in the mapping of “housing” is important: as discussed above in §I.B., the “housing” limitation was a cornerstone of Petitioner’s non-infringement argument at trial. A failure to clearly specify a construction of “housing” also caused the Petitioner’s invalidity expert’s testimony to be excluded at trial. EX2006, pp. 2-3. The ambiguity concerning the “housing” mapping appears to be strategic, and intended to maintain its fundamentally inconsistent litigation construction and IPR constructions. Because the Petition provides unclear and inconsistent identification of the “housing” in the prior art, it should be denied. *See Samsung Electronics America, Inc., et al. v. Collision Communications, Inc.*, IPR2024-01248, Paper 11, at 20 (PTAB March 21, 2025) (“[W]e find that the Petition lacks particularity by failing to clearly and consistently identify what aspect of Jin teaches the recited unique estimated signal parameters or unique signal parameters. Therefore, we find that Petitioner has not shown that Jin teaches the subject matter of claim 1.”).

III. THE PETITION FAILS TO MEET ITS BURDEN TO SHOW OBVIOUSNESS

The Petition should also be denied because it fails to meet its burden to make a case for obviousness as to each Ground.

Grounds A-B are styled as “Claims 1-24 are Anticipated and/or Rendered

Obvious by Bullington⁸⁰⁰”. This manner of alternative argument is unclear as implemented in the Petition, because it is difficult to know whether the Petitioner contends anticipation or obviousness for any particular claim elements. Specifically, the Petition makes numerous arguments contending that a POSITA would “understand” a claim element to be present. *See, e.g.,* Pet., pp. 21, 25, 31, 39, 40 (*e.g.* at 21 “a POSITA would understand that the housing 501 substantially forms the bordering structure that walls off (i.e., fixes or defines the limits of) the inlet port to the outlet port.”). These sorts of arguments ambiguously straddle the boundary between the anticipation and obviousness, leaving the Board and Patent Owner to guess whether the POSITA’s alleged “understanding” rises to the strict level required for anticipation, or is rather an argument for obviousness.

To the extent the Petition argues that a POSITA’s understanding supports anticipation, it is incorrect. Anticipation requires that a claim element be expressly or inherently disclosed, and Petitioner alleges neither. *See Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002) (“The difference between a printer and a photocopier may be minimal and obvious to those of skill in this art. Nevertheless, obviousness is not inherent anticipation.”); *Jones v. Hardy*, 727 F.2d 1524, 1529 (Fed. Cir. 1984) (“[T]hough anticipation is the epitome of obviousness, [they] are separate and distinct concepts. . . . Given the strict identity required of the test for novelty, on this record no reasonable jury could conclude that the Sweda

catalogue discloses either expressly or inherently a color photocopier. Because claim 3 is not inherently anticipated, dependent claims 4 and 5 also are not anticipated.”).

To the extent such statements are an argument for obviousness, they are not a *complete* argument for obviousness. As the Federal Circuit has repeatedly made clear, obviousness requires at least consideration of the *Graham* factors, together with a discussion of rationale (motivation) and a reasonable expectation of success. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012) (“A party seeking to invalidate a patent on the basis of obviousness must ‘demonstrate ‘by clear and convincing evidence 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’ [citations omitted].... This court has explained, moreover, that the obviousness inquiry requires examination of all four *Graham* factors.”).

These foundational arguments are nowhere to be found in Grounds A-B. The statements about what a POSITA knows or understands (Pet, pp. 21, 25, 31, 39, 40) are not even clearly tied to obviousness—much less a full case for obviousness—while more explicit invocations of §103 (Pet., pp. 20, 31) amount to *bare assertions* of obviousness, lacking even an attempt to examine the *Graham* factors, or address any motivation or reasonable expectation of success. This failure dooms Grounds

A and B, but also extends to Grounds C and D, because they (a) do not supply needed analysis of the *Graham* factors, and (b) rely directly on deficient portions of Grounds A-B. *See, e.g.*, Pet., pp. 14 (Ground A-B, claim [13E]), 60 (Ground C, claim [1E]), 72-73 (Ground C, claim [13E]), 79 (Ground D, claim [13E]) (relating to the multiple such arguments under claim element [1E] and [13E]).

IV. CONCLUSION

Patent Owner thus respectfully requests that the panel deny institution of the Petition.

Date: <u>February 25, 2026</u>	<u>/Matthew A. Smith/ (RN 49,003)</u> Matthew A. Smith SMITH BALUCH LLP 700 Pennsylvania Ave SE Ste. 2060 Washington, DC 20003 (202) 669-6207 smith@smithbaluch.com <i>Counsel for Patent Owner Kurin, Inc.</i>
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing Patent Owner's Preliminary Response, was served by email on the Patent Owner's counsel of record at the United States Patent & Trademark Office having the following addresses:

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Date: February 25, 2026

/Matthew A. Smith/ (RN 49,003)

CERTIFICATE OF WORD COUNT

The undersigned hereby certifies that the foregoing Patent Owner's Preliminary Response contains 3203 words according to the word processing software used to prepare it.

Date: February 25, 2026

/Matthew A. Smith/ (RN 49,003)