

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NANOBEBE US INC.,
Petitioner

v.

MAYBORN (UK) LIMITED,
Patent Owner

Case IPR2023-00465
Patent 11,207,244

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBITS

EX2001	U.S. Patent No. 6,645,228
EX2002	U.S. Patent No. 6,745,912
EX2003	GROWTH IS FED BY INNOVATION FOR MAKER OF BABY PRODUCTS, <i>Simon Whiteside</i> , The Journal, Manufacturers' League (Thursday, February 19, 2015)
EX2004	Reserved
EX2005	Reserved
EX2006	Petitioner's '244 Patent Invalidation Contentions, <i>Nanobebe US Inc. v. Mayborn (UK) Limited et al.</i> , Case No. 1:21-cv-08444 (S.D.N.Y.)
EX2007	Complaint, <i>Mayborn (UK) Limited, et al. v. Comotomo Inc. et al.</i> , Case No. 1:22-cv-00694 (S.D.N.Y.)
EX2008	Markman Order, <i>Nanobebe US Inc. v. Mayborn (UK) Limited et al.</i> , Case No. 1:21-cv-08444 (S.D.N.Y.)
EX2009	First Amended Case Management Plan and Scheduling Order, <i>Nanobebe US Inc. v. Mayborn (UK) Limited et al.</i> , Case No. 1:21-cv-08444 (S.D.N.Y.)

I. INTRODUCTION

Petitioner launched an unfair serial attack on the '244 Patent that the Board should not endorse. *See infra*, § III. With no explanation at all, Petitioner delayed its Petition for nine months, electing to file on the last permissible day. It can hardly be deemed a coincidence that Petitioner sought to initiate this *inter partes* review only after Patent Owner revealed its defense strategy in a preliminary response against a petition filed by a different infringer. In effect, the prior petition was a test case that offered key insights for Petitioner to leverage here in this proceeding.

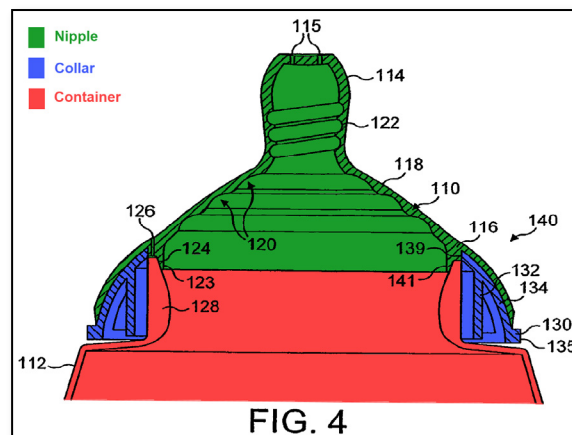
Even with Petitioner's unfair advantages, its Petition still does not make the grade. First, Petitioner fails to explain how the prior art satisfies either of the parties' competing district court constructions of a key claim term. *See infra*, § IV.A. In fact, contrary to the Board's rules, Petitioner fails to even mention, much less address, the constructions at all. And this procedural flaw—which justifies denying institution even standing alone—is only the tip of the iceberg. The more fundamental problem is this: No matter the construction, there is an admitted material gap between the asserted prior art and the '244 Patent's Challenged Claims, and Petitioner attempts to fill that gap with impermissible hindsight bias. Petitioner's hindsight manifests as two self-created drawings that deviate from the prior art by adding new, undisclosed features left unaccounted for in Petitioner's motivation to combine analysis.

Second, Petitioner misses the mark on motivation to combine. *See infra*, § IV.B. The law requires cogent reasoning bolstered by supporting evidence to sustain a combination of prior art references. What's more, the proffered reasoning and evidence must explain why a person of skill in the art would have been prompted to combine the specific references at issue in the way the claimed invention does. Petitioner comes up short in this regard. Instead of cogent reasoning, Petitioner provides terse generalizations. Instead of credible supporting evidence, Petitioner provides conclusory expert testimony that defies common sense.

The above-identified flaws in the Petition, each detailed further below, are fatal to Petitioner's case. Institution is not warranted, deserved, or even tenable.

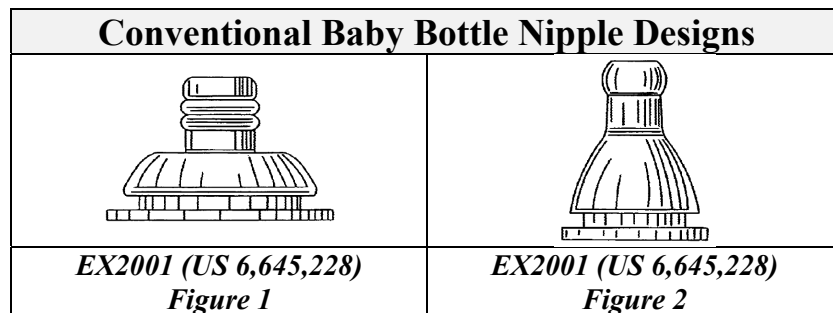
II. THE '244 PATENT

The '244 Patent presents innovative designs for drinking and feeding vessels comprised of a nipple-and-collar assembly mounted to a container. These designs are commonly implemented as baby bottles.

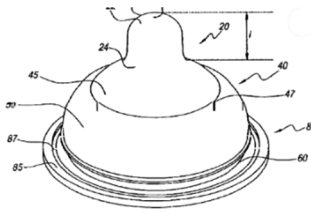
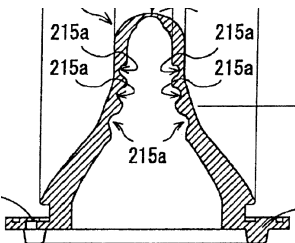


EX1003 ('244 Patent), Figure 4—Annotated by Patent Owner

The concept of using an artificial nipple to facilitate feeding infants from a vessel dates back as far as 1841 when Charles Windship obtained U.S. Patent No. 1,985, entitled “Method of Constructing Lacteal or Artificial Breasts.” In the wake of Mr. Windship’s patent, skilled artisans sought to improve the structure and function of baby-bottle nipples. By the year 2000, baby-bottle nipples were ubiquitous, and many design challenges relating to sanitation, safety, and resilience had been solved. But, as shown below, prevailing nipple designs at that time bore little resemblance to the human body. *See* EX2001, 1:14-18.



As time went on, market participants learned that the unauthentic shape of conventional baby bottle nipples was problematic. EX2001, 1:14-18 (“Due to the significant differences in the shape and function between a woman’s breast and conventional baby bottle nipples, babies experience difficulty in transition from breast-feeding to bottle-feeding.”). They sought new designs focused on “mimic[king] the human breast in operation.” EX1003, 1:29-31. The ’244 Patent’s inventors acknowledged these new breast-like nipple designs (see below) and set out to improve them. EX1003, 1:29-2:7.

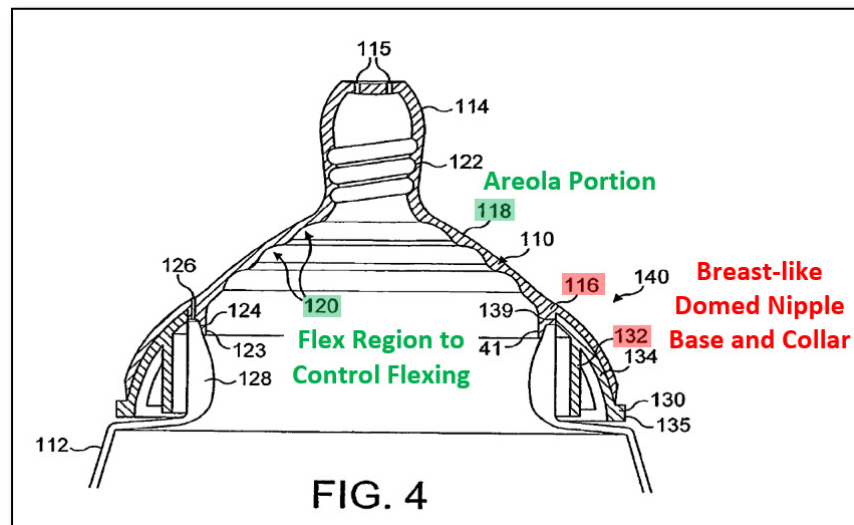
New Breast-Like Baby Bottle Nipple Designs	
	
<i>EX2001 (US 6,645,228) Figure 4 Playtex Design</i>	<i>EX2002 (US 6,745,912) Figure 4 Pigeon Design</i>

The inventors observed that there are “[v]arious problems” with the Playtex Design (above, left), which includes a “progressively thinning wall” in its base that “acts as a spring element” when the infant sucks on the teat. EX1003, 1:29-43. The movement induced by the spring element “does not closely mimic the movement of the human breast during sucking,” and “the amount of flexing and the point at which flexing takes place is undefined and unpredictable.” *Ibid.*

As for the Pigeon Design (above, right), the inventors noted that its “parallel annular grooves” tend to “allow[] stretching of the nipple but only in a constrained direction, and with the risk of flow blockage if the nipple collapses.” *Id.*, 1:44-48. These insights led the inventors to pursue an innovative design where a “flex region is provided in the areola portion allowing the teat portion and/or the areola portion to move towards and away from one another [in] a more natural feeding action.” *Id.*, 2:11-17.

In sum, the '244 Patent's nipple-and-collar arrangement more closely mimics the human breast and better controls and defines nipple flexing. The '244 Patent's

claims reflect these innovations.



EX1003 ('244 Patent), Figure 4—Annotated by Patent Owner

Patent Owner Mayborn's Closer to Nature Products also reflect the innovations of the '244 Patent and embody its claims.



Mayborn's Closer to Nature Products

Since their launch in 2006, the Closer to Nature products have enjoyed immense commercial success, received constant industry praise, and been imitated by competitors. *E.g.*, EX2003 (“[Mayborn’s] revolutionary closer to nature feeding bottle, which is designed to replicate the feel of a mother’s breast to help babies make the transition to bottle feeding, has been inundated with awards since its launch in 2006.”).¹

III. THE *GENERAL PLASTIC* FACTORS EXPOSE THE PETITION AS AN UNFAIR SERIAL ATTACK THAT SHOULD BE DENIED

“Multiple, staggered petitions challenging the same patent and same claims raise the potential for abuse.” *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 18 (PTAB Sept. 6, 2017) (precedential). And “abuse” of the *inter partes* review process is exactly what happened here. Petitioner abused the process by lying in wait while gaining insight from Patent Owner’s defense of the ’244 Patent against an earlier petition filed by a different infringer, Comotomo Inc. and Comotomo Corp. (“Comotomo”), in Case No. IPR2022-01326. *See* EX1015. Despite sharing similar infringement risk contemporaneously with Comotomo, Petitioner was more than five months slower to file its Petition, which challenges far fewer claims than Comotomo’s. It is telling

¹ All emphasis added.

that Petitioner sought to file only after Patent Owner revealed its defense strategy and exposed the weaknesses in Comotomo's petition.

The Comotomo petition was a test case for Petitioner, and Petitioner's Petition is an unfair serial attack on the '244 Patent that should be denied.

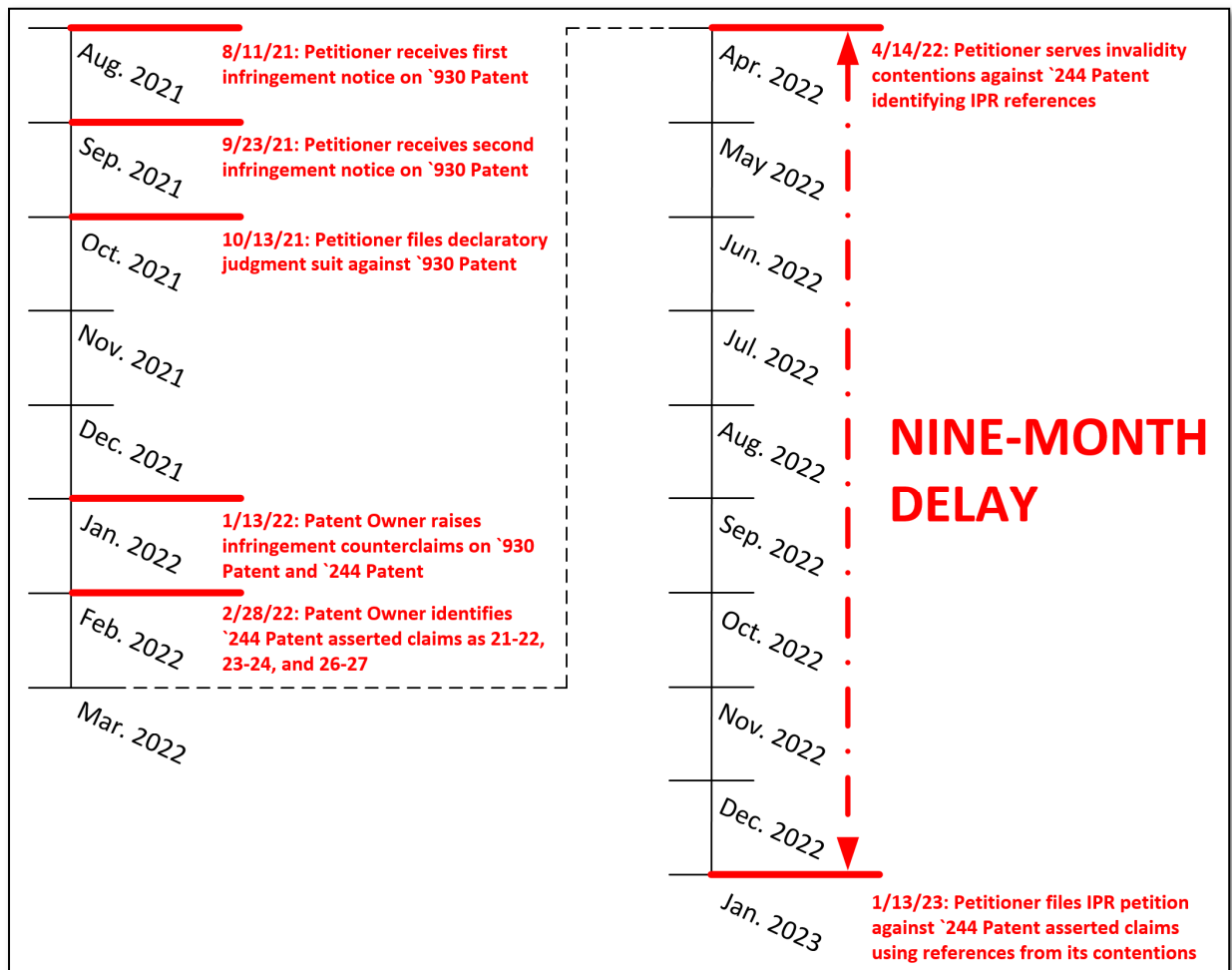
A. Petitioner Delayed in Filing Its Petition

As detailed below, Petitioner was on notice regarding its infringement of the '244 Patent for 12 months and in possession of the asserted art for 9 months before filing its Petition. Petitioner waited (and waited) until, at last, it was forced to file on the final day of the statutory deadline. The Petition is unquestionably delayed.

On August 11, 2021, Petitioner received a notice from Amazon regarding its infringement of the '244 Patent's parent, U.S. Patent No. 10,952,930 ("the '930 Patent"). EX1011, p. 3 (¶15). On September 23, 2021, Petitioner received another infringement notice from Amazon. EX1011, pp. 5-6 (¶¶21-25). This time, Amazon required action on Petitioner's part to resolve Patent Owner's infringement claims regarding the '930 Patent. Petitioner responded on October 13, 2021 by filing suit for a declaratory judgment of non-infringement at the District Court for the Southern District of New York ("the District Court"). *See generally* EX1011. Three months later, on January 13, 2022, Patent Owner raised counterclaims of infringement based on the '930 Patent and the '244 Patent. EX1012, p. 11.

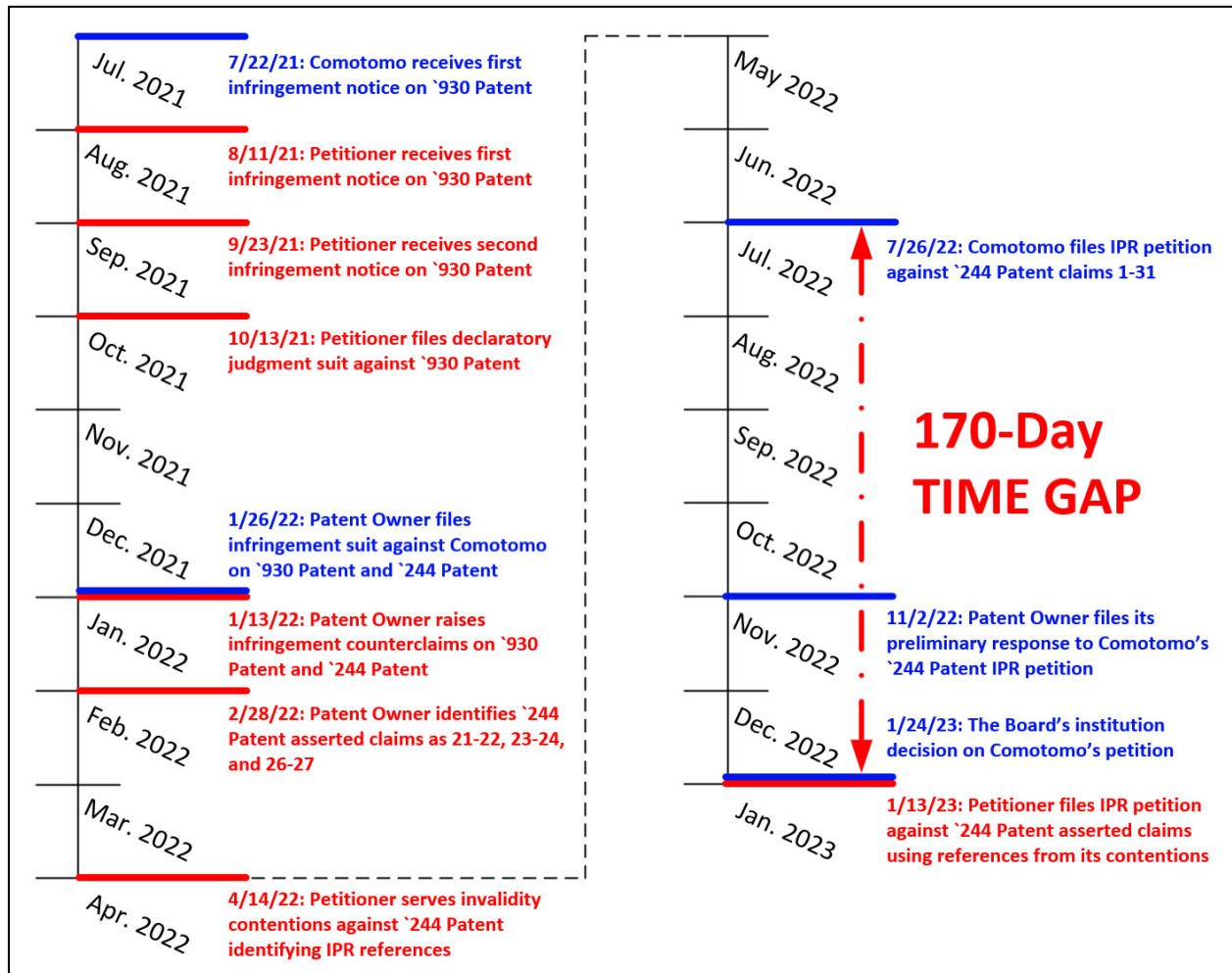
Per the District Court's case management plan, on February 28, 2022, Patent Owner identified claims 21-24, 26, and 27 as being asserted and infringed. EX1016, p.5. These are the same claims Petitioner presently challenges.

Petitioner served invalidity contentions against the '244 Patent on April 14, 2022. *See generally* EX2006. Notably, Petitioner's invalidity contentions include the three references asserted in the Petition (i.e., Ishimaru, Kurkjian, and Atkin). *Id.*, pp. 10-11, 17. And yet, Petitioner did not file its Petition until nine months later, on January 13, 2023. These events are summarized below:



While Petitioner was idle, another infringer, Comotomo, acted with reasonable diligence. Despite facing infringement risk around the same time, Comotomo filed its petition 170 days (more than five months) before Petitioner.

Comotomo was notified of its infringement regarding the '930 Patent through Amazon on July 22, 2021, weeks before Petitioner. EX2007, p.7. Patent Owner initiated an infringement suit asserting the '930 Patent and the '244 Patent against Comotomo on January 26, 2022, around the same time as its infringement counterclaims against Petitioner. *Id.*, pp. 2, 26. Six months later, on July 26, 2022, Comotomo filed its petition for *inter partes* review of the '244 Patent. *See* IPR2022-01326, Paper 2. Patent Owner filed its preliminary response to Comotomo's petition on November 2, 2022, and the Board rendered an institution decision on January 24, 2023. *Id.*, Papers 6 and 7. These Comotomo events (**blue**) are compared to the above-discussed Nanobebe events (**red**) in the timeline on the following page:



B. Petitioner, Through Its Delay, Gained Unfair Advantages Over Patent Owner

There is no legitimate excuse for Petitioner sitting on its hands with prior art for 9 months and moving slower than Comotomo by 170 days. And there is no question that Petitioner gained unfair tactical advantages over Patent Owner because of its delay. For months, Petitioner was able to evaluate Comotomo's prior art and obviousness grounds in view of Patent Owner's rebuttal. This information, and the time to digest it, was a windfall for Petitioner in at least three important ways.

First, Petitioner could account for the exposed flaws in the Comotomo petition and assess its low likelihood of success. As a result, Petitioner knew or should have known that a second attack could significantly improve the odds of invalidating the '244 Patent at the PTAB by fixing the mistakes Comotomo made. Second, Petitioner's April 2022 invalidity contentions show that it evaluated three out of the four references² that Comotomo used and, in effect, was able to test out those references through Comotomo's petition. *Compare* EX1015, pp. 13, 16, with EX2006, pp. 10, 16-17.³ Then, after learning from Patent Owner that the references were deficient, Petitioner was able to strategically select different prior art for its own Petition. Third, Petitioner was able to account for Patent Owner's defense

² The one reference from Comotomo's petition that Petitioner did not list in its contentions is U.S. Patent Pub. No. 2002/0033399 ("Manganiello"), which Comotomo only applied as a secondary reference against a single claim that Petitioner does not challenge.

³ Petitioner's contentions list the initial publication (JP2000271193) of the Kobayashi reference (JP Pat. No. 3209271) in Comotomo's petition. Likewise, Petitioner's contentions list the U.S. counterpart (U.S. 2007/0221604) of the Hakim reference (WO 2004/013001) cited in Comotomo's petition.

strategy against the Comotomo petition when crafting its own element analysis and motivation discussions. As revealed below in Section IV, Petitioner's grounds are still deficient, but they would likely be even worse without insight into Patent Owner's defense.

C. The *General Plastic* Factors Compel Denial of Petitioner's Serial Petition

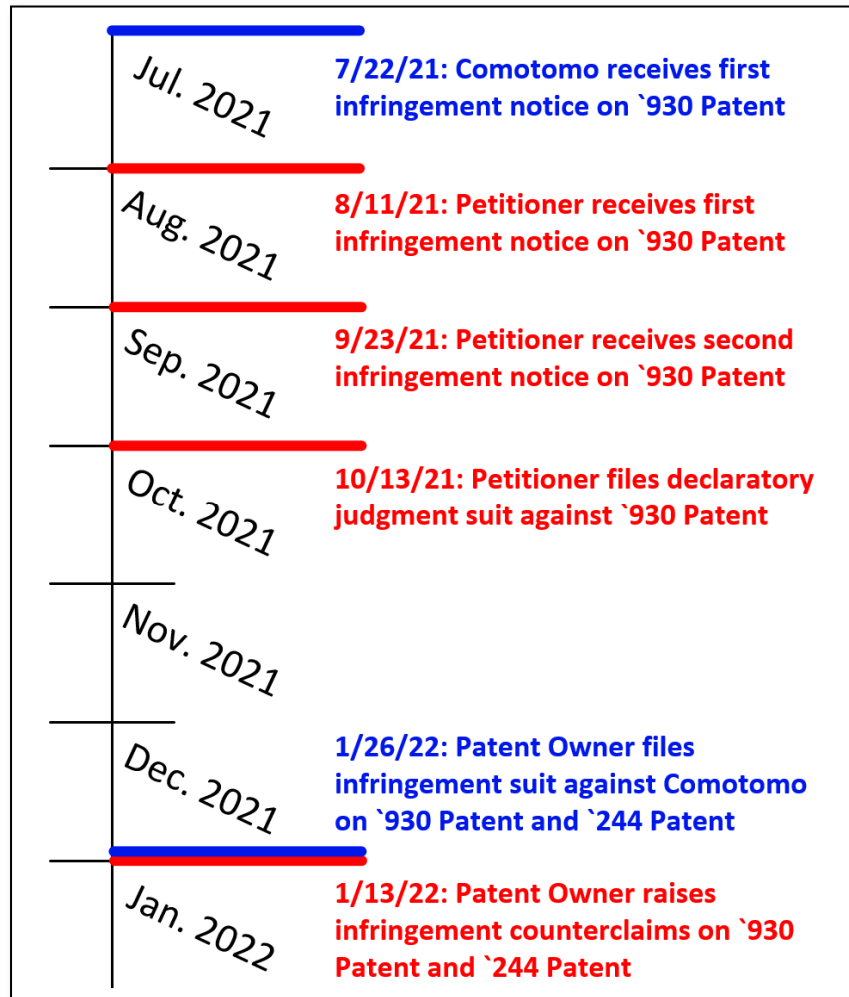
It is clear from the discussion above that Petitioner's Petition is a serial attack on the '244 Patent that used the earlier Comotomo petition as a test case. The Board formulated the *General Plastic* factors to expose—and prevent—this kind of unfair litigation tactic. Thus, unsurprisingly, the factors weigh heavily toward denial when applied to the operative facts here.

1. Factor 1: whether the same petitioner previously filed a petition directed to the same claims of the same patent

Comotomo previously filed a petition against claims 1-31 of the '244 Patent, and Petitioner's Petition challenges the subset of claims 21-24, 26, and 27. It is beyond dispute that the same claims of the same patent are under a serial attack.

It is likewise beyond dispute that Petitioner and Comotomo are similarly-situated defendants that faced similar infringement risk under the '930 and '244 Patents at around the same time. As discussed in Section III.A, Comotomo received an infringement notification on the '930 Patent through Amazon on July 22, 2021, and Petitioner received the same just weeks later on August 11, 2021. Patent Owner

brought its infringement claims based on the '930 and '244 Patent against Petitioner on January 13, 2022 and against Comotomo just weeks later on January 26, 2022.



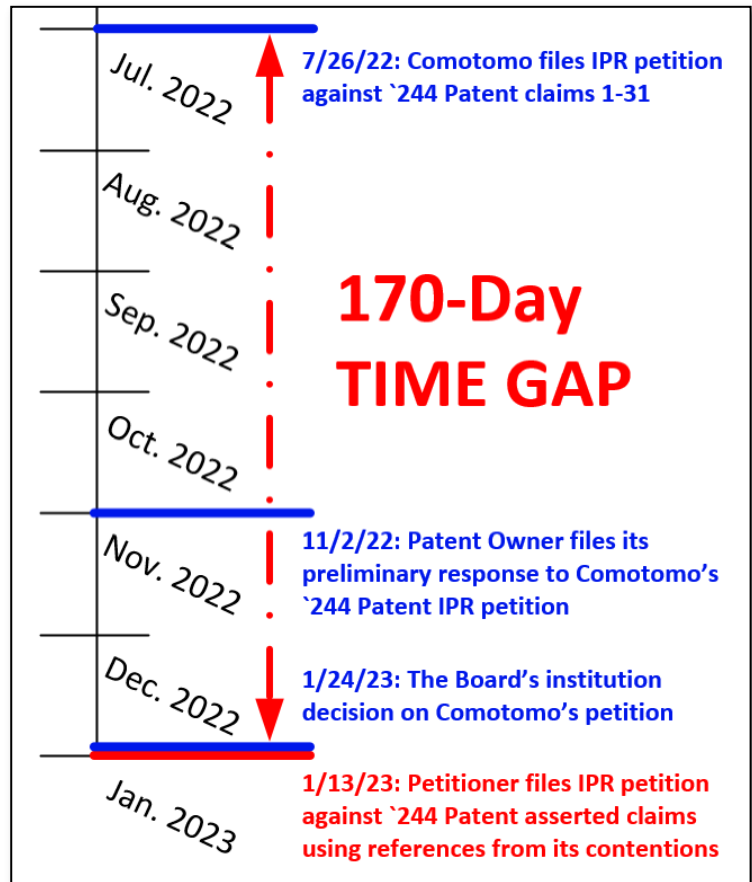
While Comotomo and Petitioner are separate entities, any weight this fact carries under Factor 1 is neutralized by the countervailing facts that Comotomo and Petitioner lodged overlapping challenges and share common circumstances on infringement. Additionally, the considerations supporting denial under Factor 1 are buttressed by those under Factors 2-5, which show that Petitioner's unjustified delay

in pursuing *inter partes* review was strategic and abusive. Whether the staggered petitions were filed by the same petitioner or two different petitioners, the Board has historically denied institution under similar circumstances. *E.g., Shenzhen Silver Star Intelligent Tech. Co., Ltd. v. iRobot Corp.*, IPR2018-00761, Paper 15 (denying institution under *General Plastic* when two different petitioners filed serial petitions); *NetApp, Inc. v. Realtime Data LLC*, IPR2017-01195, Paper 9 (PTAB Oct. 12, 2017) (same); *accord Consolidated Trial Practice Guide* at 58; *Unified Patents Inc. v. Finjan, Inc.*, IPR2019-01611, Paper 18 (PTAB Apr. 13, 2020) (same).

2. Factor 2: whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it

Comotomo filed a first petition for *inter partes* review of the '244 Patent on July 26, 2022. More than three months beforehand, on April 14, 2022, Petitioner served invalidity contentions identifying the prior art (i.e., Ishimaru, Kurkjian, and Atkin) from Grounds 1-2 of its Petition. *See* EX2006, pp. 10-11, 17. Even though it could not have added these references to Comotomo's petition, given the shared circumstances of the two defendants, Petitioner could have filed its Petition around the same time as Comotomo. *Valve Corp. v. Elec. Scripting Prods. Inc.*, IPR2019-00062, Paper 11 at 14 (PTAB April 2, 2019) (precedential) ("Valve could have filed its Petition at or around the same time as HTC."). But Petitioner did not do so.

Instead, Petitioner withheld its Petition for another 170 days until it had time to receive and digest feedback on Comotomo's petition via Patent Owner's preliminary response. Petitioner should not be allowed to use Comotomo's petition as a "test case." *See Shenzhen Silver Star* at 18 (Saindon concurring) ("if two or more co-defendants are sued around the same time, they should, within reason, file their petitions around the same time; it is generally unfair for one defendant to wait for a 'test case' to go through the inter partes review process by another defendant before filing their own petition").



Factor 2 strongly favors denial.

3. Factor 3: whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition

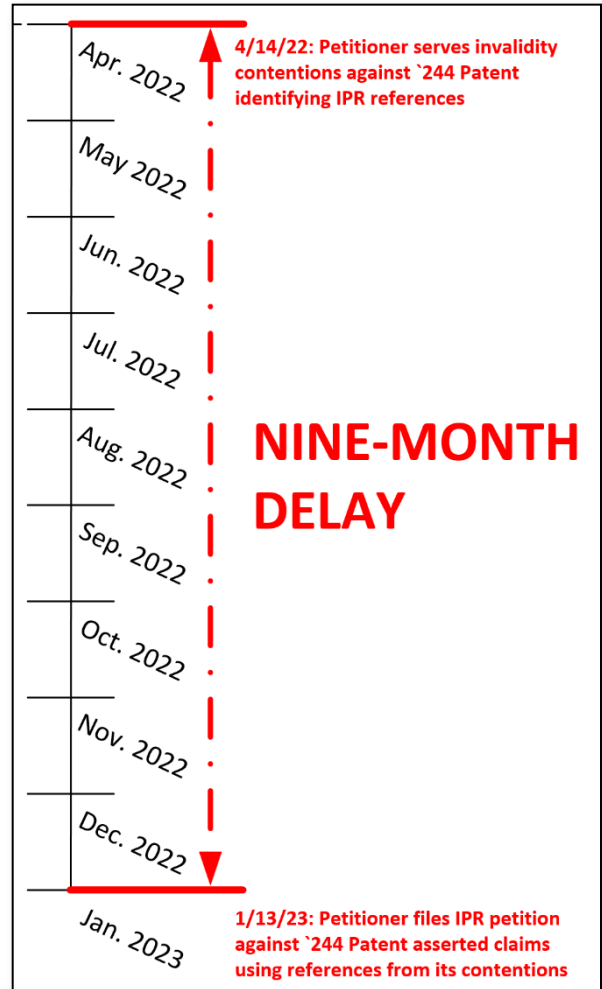
Patent Owner filed its preliminary response to Comotomo's first-in-time petition on November 2, 2022. Petitioner, who does not deny knowledge of the Comotomo proceeding, would have received Patent Owner's filing on the public record around that time. More than two months later, on January 13, 2023, Petitioner filed its second-in-time petition.

As discussed in Section III.B, studying Patent Owner's preliminary response for two months afforded Petitioner at least three tactical advantages: (1) insight into the likelihood of success on Comotomo's petition before determining whether, and to what extent, an additional challenge would improve the odds of invalidating the '244 Patent; (2) insight into the deficiencies of Comotomo's prior art; and (3) insight into Patent Owner's defense strategy for *inter partes* review. These advantages are the "undue inequities and prejudices to Patent Owner" that the Board sought to expose and excise in *General Plastic*. See *General Plastic* at 17 ("Petitioner's potential benefit from receiving and having the opportunity to study Patent Owner's Preliminary Response.").

Factor 3 strongly favors denial.

4. Factor 4: the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition

While it likely learned of the asserted references earlier, Petitioner cannot dispute that it was aware of them by April 14, 2022 when it served invalidity contentions in District Court. As discussed, all three references asserted in the Petition are also identified in Petitioner's contentions. Still, despite possessing the pertinent art and knowing which claims it infringed, Petitioner did not file its Petition for another nine months.



The Board denied institution based on significantly smaller delay periods in the precedential *Valve* case and various other cases. *See Valve* at 14 (“The fact that Valve waited five months after HTC’s petition to file the Petition in this case favors denying institution.”); *Shenzhen Silver Star* at 13 (“Thus, Petitioner knew of the majority of the asserted art for at least five and a half months before filing this Petition.”); *Mitek Sys., Inc. v. United Servs. Auto. Assoc.*, IPR2020-01101, Paper 29

at 33 (PTAB Jan. 26, 2021) (“Petitioner still waited more than seven months to file its Petition”); *Fresenius Kabi USA, LLC v. Amgen Inc.*, IPR2019-00971, Paper 13 at 10 (PTAB Oct. 16, 2019) (“The Petition was filed . . . over six months after” a prior petition asserting the same art.”).

Factor 4 strongly favors denial.

5. Factor 5: whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent

The Board’s precedent on serial petitions is well known, and Petitioner acknowledged Comotomo’s earlier-filed petition against the ’244 Patent. *See* Pet., 2 (citing EX1015). Petitioner knew that its Petition was a serial filing and, thus, knew or should have known that the *General Plastic* factors are highly relevant in this proceeding. Just as Petitioner addressed other aspects of the Board’s precedent on discretionary denial, it also could have addressed *General Plastic*. *See id.*, 6-10 (Petitioner addressing § 325(d) and the *Fintiv* factors). But Petitioner neglected to do so. And because Petitioner offers no explanation at all regarding its nine-month delay in pursuing *inter partes* review, Factor 5 favors denial. *See Apple Inc. v. Uniloc 2017 LLC*, IPR2020-00854, Paper 9 at 11 (PTAB Oct. 28, 2020) (precedential) (given the petitioner’s “lack of explanation, we conclude that this fifth *General Plastic* factor also weighs in favor of denying institution”).

Regardless, Factor 5 would favor denial even if Petitioner had tried to explain away its nine-month delay. In the precedential *Valve* case, the Board weighed this factor toward denial even though the second-in-time petitioner's five-month delay was caused by a confluence of events that included its dismissal from the co-pending district court litigation and a change in law regarding the § 315(b) statutory time bar. *See Valve* at 13-14 (“The *Click-to-Call* decision may have prompted Valve to file the Petition before the deadline under § 315(b), but it does not excuse the five-month delay between the filing of HTC’s petition and Valve’s Petition.”). If the Board did not “excuse” a five-month delay under the extreme circumstances in *Valve*, Petitioner could not expect such a result here regarding its nine-month delay.

Unlike the petitioner in *Valve*, the circumstances involving Petitioner’s infringement risk have not shifted. Patent Owner asserted the ’930 and ’244 Patents against Petitioner in January 2022, and the asserted patents have not changed. Petitioner’s asserted art references were disclosed in April 2022 and have not changed. The parties disclosed their claim construction positions in May 2022, and settlement discussions have not progressed. What’s more, Petitioner could not plausibly complain that activity in the District Court somehow slowed progress on its Petition because Petitioner hired different law firms to conduct the respective proceedings. The simple truth is this: Petitioner was capable of filing its Petition earlier, such as around the same time as Comotomo’s petition, but it chose not to.

6. Factors 6 and 7: the finite resources of the Board; and the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review

“[M]ultiple, staggered petition filings, such as those here, are an inefficient use of the *inter partes* review process and the Board’s resources.” *General Plastic* at 21. The Board’s resources are especially not well spent where, as here: (A) the merits of the Petition are not strong, (*see infra* Section IV); (B) two of the three asserted references were considered during prosecution, (*see* Pet., 6); and (C) an *inter partes* review proceeding would not serve its intended purpose as an efficient alternative to district court litigation.

Not only has Petitioner leveraged its unexplained delay to gain unfair tactical advantages over Patent Owner, it has also increased the likelihood that the District Court will resolve the same or substantially similar validity issues before the Board’s final written decision in July 2024. The parties have already briefed and argued their claim construction disputes, and the District Court resolved them in a detailed 30-page *Markman* order dated April 18, 2023. *See* EX1017, EX1018, EX2008. The close of fact discovery is July 14, 2023, around the same time as the Board’s projected institution decision. EX2009, p. 2. The complete close of discovery is 70 days later, on September 22, 2023, before even the first projected post-institution due date in this proceeding. *Id.* And, absent summary judgment motions, the

District Court’s schedule instructs the parties to be prepared for trial by early November 2023, approximately eight months before the Board’s July 2024 final written decision. *Id.*, p. 3.⁴ Even with discovery delays and pre-trial briefing, the District Court will likely reach a resolution on the ’244 Patent before the Board.

Projected resolution dates aside, the litigation at the District Court is farther along than this proceeding, and Petitioner is the cause. *Inter partes* review is both unfair and inefficient because of Petitioner’s delay. As a result, the Board should deny institution.

IV. THE PETITION SHOULD BE DENIED BECAUSE PETITIONER CANNOT PREVAIL ON ANY CHALLENGED CLAIM

A. Petitioner Fails to Make Its Case on the “Domed Shape” Limitation of Element 21[H] (All Grounds)

The Petition does not establish that its prior art combinations teach, suggest, or otherwise render obvious the feature of Element 21[H] that states, “wherein the collar and the lower portion of the nipple together define a downward domed shape.”

⁴ If no summary judgment motions are filed, the District Court will issue a Joint Pretrial Order by October 22, 2023, i.e., within 30 days of the close of discovery (September 22, 2023). The parties must be ready for trial within two weeks of the Joint Pretrial Order, i.e., no later than November 5, 2023.

The parties presented competing constructions of the term “domed shape” to the District Court, and Petitioner disregards the Board’s rules by failing to disclose and address them. More fundamentally, Petitioner’s asserted prior art lacks any semblance of a “domed” nipple-collar assembly, no matter the construction, and Petitioner fails to explain how or why a POSITA would have known to pursue such an arrangement. With no legally tenable alternative, Petitioner resorts to impermissible hindsight, creating new nipple-collar designs from whole cloth that have no basis in the prior art.

The following discussion identifies the constructions that Petitioner failed to address (§§ IV.A.1 and IV.A.2), explains the deficiencies of Petitioner’s prior art under each (§ IV.A.3), and exposes Petitioner’s improper hindsight bias (§ IV.A.4).

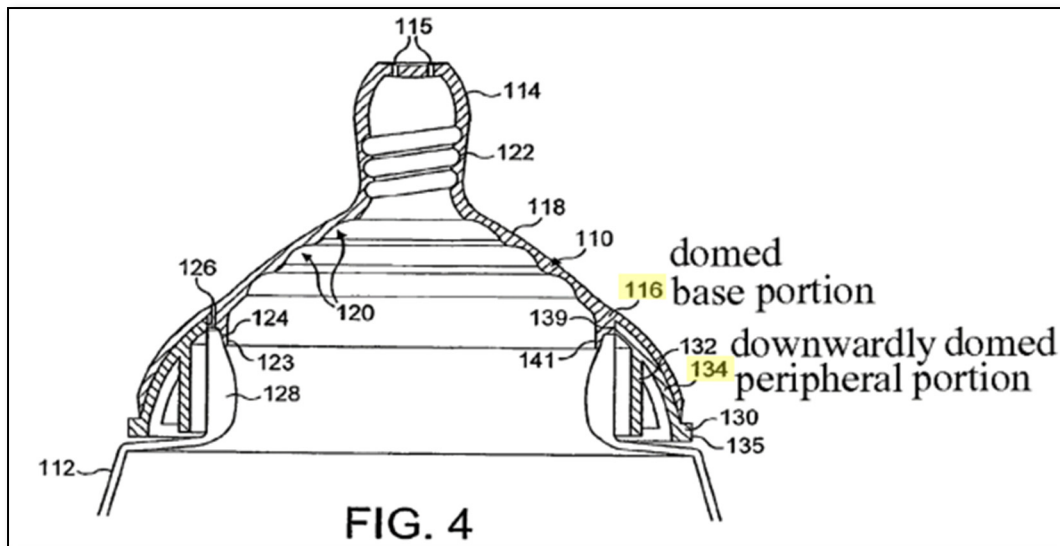
1. The parties’ respective constructions of “domed shape”

The District Court recently adjudicated the parties’ claim construction dispute on the term “domed shaped.” *See* EX2008, pp. 12-15. As summarized in the Court’s *Markman* order, the parties’ proposed constructions are:

Term	Claim	Mayborn	Nanobebe
“domed configuration”/ “a base portion having a domed configuration” /“domed shape”	Claim 14 in ‘930 Patent; Claim 21 in ‘244 Patent	“wide circular base with an arc-shaped cross-sectional profile” Alternatively: “wide circular base with a convex cross- sectional profile”	“having a rounded shape in profile”

EX2008, p.12.

Patent Owner's construction focuses on the '244 Patent's description of a structure that is "shaped like a breast" and has "a wide, domed configuration." EX1003, 4:3-5; EX1017 (Patent Owner's Brief), pp.18.⁵ The proposed construction requires a "wide" structure "with an arc-shaped cross-sectional profile" because that is what a human breast looks like, and it is also what the '244 Patent illustrates. *Id.*; *see also* EX1003, Figure 4 (annotated below).



EX1003 ('244 Patent), Figure 4—Annotated by Patent Owner

⁵ The '244 Patent and its parent, the '930 Patent, share a common specification. Patent Owner's claim construction brief (EX1017) and the District Court's *Markman* order cite the corresponding language in the '930 Patent (EX1001) at Column 4, Lines 1-3 when addressing the '244 Patent term "domed shape," which everyone agrees has the same meaning as the '930 Patent term "domed configuration."

According to Petitioner, its construction of “domed shape”—i.e., “having a rounded shape in profile”—means the structure is “hemispherical” and has “the shape of half of a sphere.” EX1018 (Petitioner’s Brief), p. 18; EX2008 (*Markman* Order), p. 13 (“At the *Markman* hearing, Nanobebe reiterated that the shape of the base portion is the ‘upper half of a sphere’ . . .”).

The District Court rejected Petitioner’s construction due to its overreliance on dictionary definitions and lack of “accord with the intrinsic evidence.” EX2008, p.14. By contrast, the District Court agreed with Patent Owner’s reliance on the ’244 Patent’s description of a “wide” structure that is “shaped like a breast” and its illustration of an arc-shaped profile. *Id.*, 13-15 (citing, *inter alia*, EX1001, 4:1-3, Figure 4). Accordingly, the District Court adopted a construction substantially similar to Patent Owner’s: “wide circular bottom with an arc-shaped cross-sectional profile.” EX2008, p.15. The only deviation is that the District Court replaced Patent Owner’s word “base” with “bottom.”

As the District Court held, Patent Owner’s correct construction comports with the intrinsic evidence and Petitioner’s incorrect construction does not. Regardless, as explained below, Petitioner’s prior art fails to satisfy either party’s construction.

2. Petitioner does not disclose and address the parties' competing constructions of the claim term "domed shape"

Petitioner knew when it filed its Petition that the meanings of multiple claim terms were in dispute, including the term "domed shape." Accordingly, the Petition states: "[F]or purposes of this proceeding, whether the terms of the '244 Patent are afforded Patent Owner's or Petitioner's construction, the grounds render the claims obvious." Pet., 15-16. The Petition goes on to identify the competing constructions for the terms "flex region," "mouthpiece," and "flex of the mouthpiece towards and away from a lower portion of the nipple." *Id.*, 16. Critically, though, the Petition does not identify or substantively address the term "domed shape" from Element 21[H], which was hotly disputed in the co-pending litigation before the Petition was filed. EX1018, 17-19 (contrasting Petitioner's and Patent Owner's competing constructions of "domed shape" in claim 21 of the '244 Patent); EX2008 (the District Court rejecting Patent Owner's construction and adopting Patent Owner's).

The Board's rules "place an affirmative burden on petitioners to 'set forth: . . . [h]ow the challenged claim is to be construed.'" *OrthoPediatrics Corp. v. K2M, Inc.*, IPR2018-01548, Paper 9 at 10 (March 1, 2019) (quoting *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1308 (Fed. Cir. 2017); 37 C.F.R. § 42.104(b)(3)). "This burden continues by requiring petitioners to adequately explain '[h]ow the construed claim is unpatentable.'" *Id.* (quoting 37 C.F.R. § 42.104(b)(4)) (emphasis in

original). Despite accepting this burden when requesting *inter partes* review, Petitioner does not attempt to satisfy it. See *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“While the Board’s requirements are strict ones, they are requirements of which petitioners are aware when they seek to institute an IPR.”).

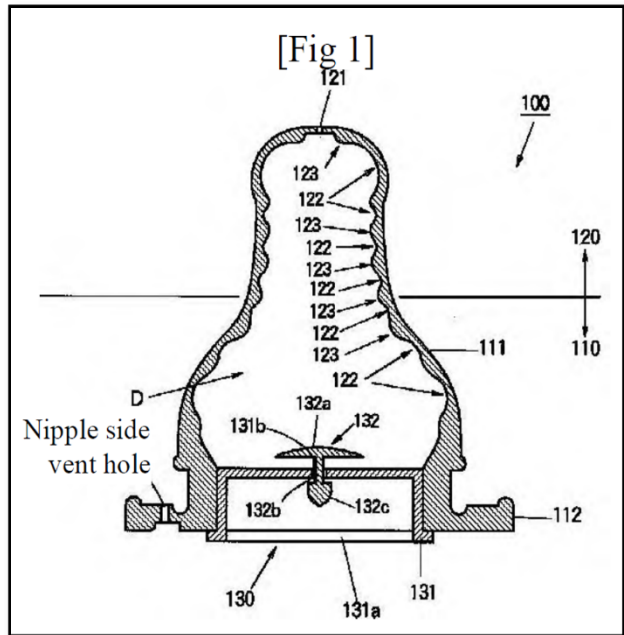
While it indicated in District Court that the construction of “domed shape” is of paramount importance, Petitioner makes no mention at all of this term in the claim construction section of the Petition. Compare EX1018, p.20 (“Mayborn must not be allowed to advance a broader view now.”), with Pet., 15-16. Nor does Petitioner address the parties’ constructions in the Petition’s analysis of Element 21[H]. See Pet., pp. 40-41, 55-57. Thus, the record is utterly devoid of argument and evidence as to how the prior art applies to the construed term “domed shape.” If flouting the Board’s rules in this manner were not reason enough to deny institution (which it is), denial is certainly warranted on substantive grounds because Petitioner’s hindsight-driven alterations to the prior art fail under the law.

3. No matter the construction, Petitioner’s prior art lacks a nipple and a collar that “together define a downward domed shape”

None of Petitioner’s prior art teaches or suggests that “the collar and the lower portion of the nipple together define a downward domed shape,” as required by Element 21[H]. Whether Patent Owner’s correct construction provides the

measuring stick or Petitioner's flawed construction, the prior art falls short.

Starting with Ishimaru, this reference describes “an artificial nipple which is more similar to the mother's nipple.” EX1008, p.1 (Problem to be Solved). Specifically, Ishimaru sought to solve “a problem that the conventional artificial nipple 10 does not elongate the teat portion of the mother's nipple or the portion corresponding to the mammary areola, and thus do[es] not approximate [a real] nipple.” *Id.*, [0004]. Ishimaru's “[m]eans for solving the problem” involve a nipple “wherein the aforesaid teat portion and/or the aforesaid nipple trunk is provided with an elongation portion, which is more easily extensible than other portions.” *Id.*, [0006]. The “elongation portion” that Ishimaru developed features “thin-walled portions . . . in a groove-like pattern” that extend from the trunk through the teat. *Id.*, [0041], Figure 1 (at right). Notably, Ishimaru's “elongation portion” and other developments toward a more breast-like bottle feeding solution concern only the nipple.



EX1008 (Ishimaru), Figure 1

Beyond stating that it is “not shown” in any of the figures, Ishimaru has nothing at all to say about the collar that secures the nipple to the bottle. *E.g.*, [0054]

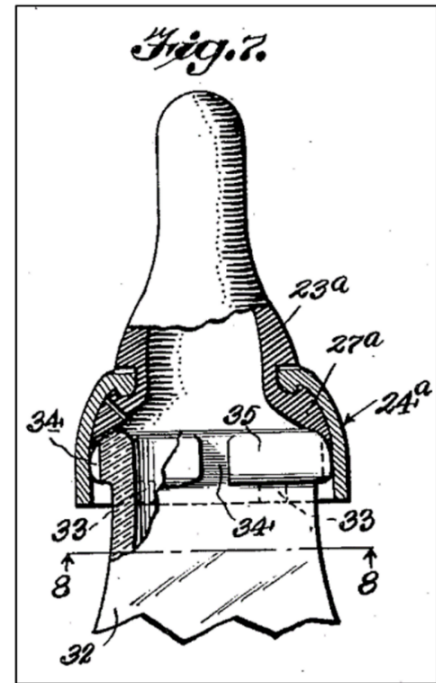
(“it can also be fixed using a detachable feeding bottle mounting cap (not shown in the figure)”). Thus, regardless of how “domed shape” is construed, Ishimaru does not teach or suggest the limitations of Element 21[H]. Petitioner concedes this fact throughout the Petition. *See* Pet., 40 (“*Ishimaru* does not explicitly disclose this limitation”); *id.*, 55 (same).

Unlike Ishimaru, Kurkjian is not concerned with creating a more natural bottle feeding solution. Kurkjian is a patent from the 1930s that sought to solve a more rudimentary problem, i.e., how to secure a nipple to a bottle using a retaining cap (or “collar”) that allows air intake and prevents the nipple from collapsing during use:

This invention relates to nursing units, and has for one of its principal objects the production of a resilient flanged nipple which is so constructed as to permit the nipple to be secured to the mouth of a bottle by means of a retaining cap, and permit the entrance of air into the interior of the bottle, and also prevent the nipple from collapsing inwardly of the retaining cap.

EX1009, 1:1-15. Kurkjian was also concerned with the “production of a nursing unit wherein a nipple retaining cap is constructed in a manner as to present a streamline type of connection between the bottle and the nipple.” *Id.*, 1:16-20.

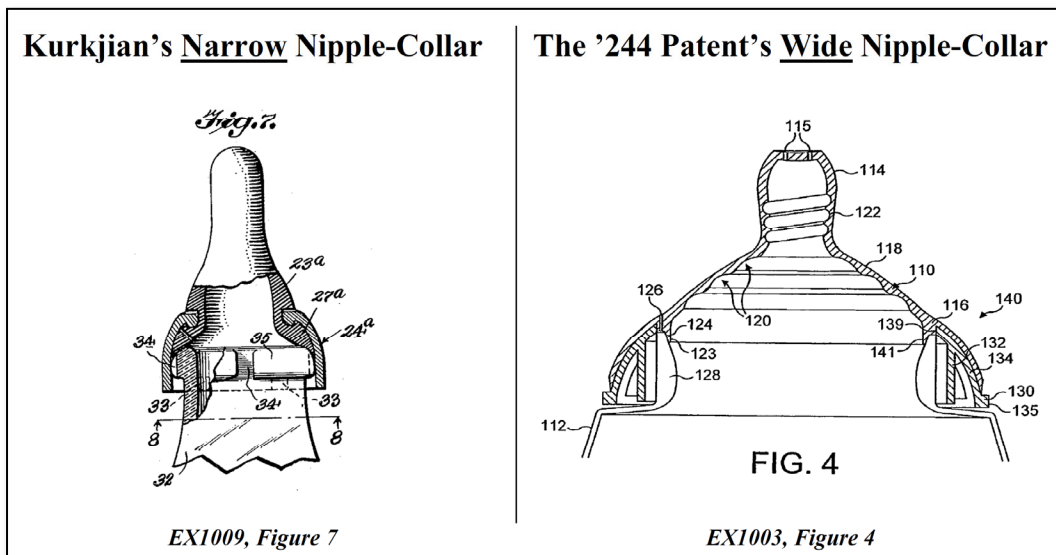
As shown in Figures 6 and 7, “[t]he outer face of the [retaining] cap 24 preferably conforms to the contour of the nipple 23 and constitutes a continuation thereof to provide a streamline type connection between the nipple 23 and the bottle 28.” *Id.*, p.2, 1:42-46. Notably, Kurkjian’s “streamlined embodiments,” which Petitioner relies on in the Petition, involve narrow nipple shapes that were conventional at the time. Kurkjian never disclosed,



EX1009 (Kurkjian), Figure 7

suggested, or even hinted at the notion of a “domed shape,” as required by Element 21[H]. Nor does Petitioner even attempt to explain how Kurkjian’s narrow nipple and collar shapes are “domed” under the parties’ respective constructions.

In fact, Kurkjian narrow nipple-collar design is antithetical to Patent Owner’s court-adopted construction of “domed shape,” which requires a “wide” structure “with an arc-shaped cross-sectional profile.” The comparison below illustrates the stark contrast between Kurkjian’s narrow nipple-collar assembly, and the “wide” breast-like structure of the ’244 Patent.



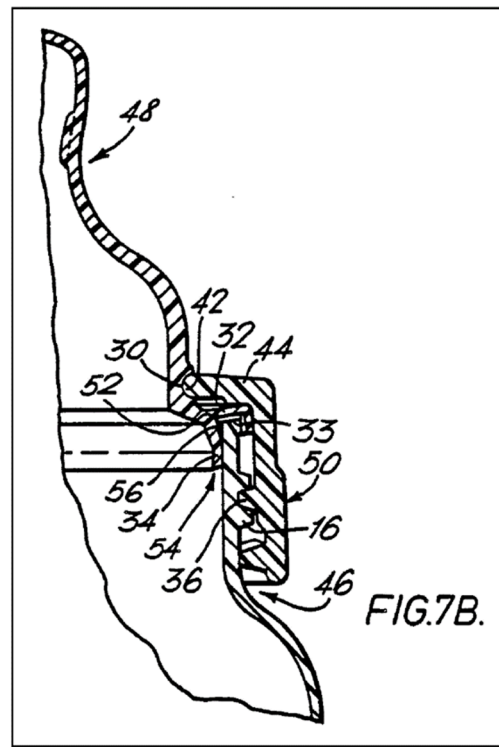
Kurkjian fares no better under Petitioner's construction, which requires "a rounded shape in profile" like "half of a sphere." EX1018, p. 21; EX2008, p. 13. Petitioner could not credibly assert that Kurkjian's nipple-collar design looks like a half sphere.

Similar to Kurkjian, Atkin describes a new design for a vent that solves the "teat collapse" problem. EX1010, 1:33-44. Atkin sought to improve upon prior solutions that had difficulties with "manufacturing tolerances" and teat swelling. *Id.*, 1:55-2:13. Atkin's solution . . .

overcomes this problem by arranging for the lip to fit with a small clearance inside the bottle neck in the absence of [a] screw cap, the arrangement being such that when the cap is screwed down, it acts on the teat to deform the annular flange thereof so that the said lip is turned outwardly to engage the interior surface of the bottle neck to provide a normally closed flap valve.

Id., 2:14-22.

To be sure, Atkin employs a bottle with “a larger diameter neck,” which “enables the user of a larger teat” that “more closely resembl[es] natural feeding.” Pet., 56 (quoting EX1010, 3:10-27). But the shapes of Atkin’s nipple and collar are conventional. As shown in Figures 7A and 7B (at right), the collar does not have a curved profile, and it does not, under any construction, cooperate with the nipple to “together define a downward domed shape.”



EX1010 (Atkin), Figure 7B

4. Petitioner fills the gap between the prior art and the “domed shape” limitation with improper hindsight reasoning

As discussed, Ishimaru, Kurkjian, and Atkin each fail to teach or suggest that “the collar and the lower portion of the nipple together define a downward domed shape.” This leaves a material gap between the teachings and suggestions in the art and the ’244 Patent’s “domed shape” limitation. Rather than attempting to fill that gap with legally sound obviousness theories, Petitioner injects its own improper hindsight bias, which the Board should reject.

To establish obviousness, all elements must be accounted for in the prior art, whether expressly taught or suggested, inherently disclosed, or provided by a

POSITA exercising common sense. *See CFMT, Inc. v. YieldUp Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (“obviousness requires a suggestion of all limitations in a claim”) (citations omitted); *Par Pharm., Inc. v. TWi Pharm., Inc.*, 773 F.3d 1186, 1194-96 (Fed. Cir. 2014) (“We have recognized that inherency may supply a missing claim limitation in an obviousness analysis.”); *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1363 (Fed. Cir. 2016) (“we conclude that while ‘common sense’ can be invoked, even potentially to supply a limitation missing from the prior art, it must still be supported by evidence and a reasoned explanation”). With no hope of establishing express teachings or implied suggestions of the “domed shape” limitation (*see infra*, § IV.A.3), Petitioner’s only hope would seem to lie in inherency or common sense. But those theories are beyond the bounds of this proceeding because Petitioner did not raise them in the Petition. *See In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (“we find no support for the PTO’s position that the Board is free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner”); *Askeladden L.L.C. v. Encoditech LLC*, IPR2017-00452, Paper 8 at 21 (PTAB May 22, 2017) (“we decline to attempt to fill in the blanks for Petitioner”).

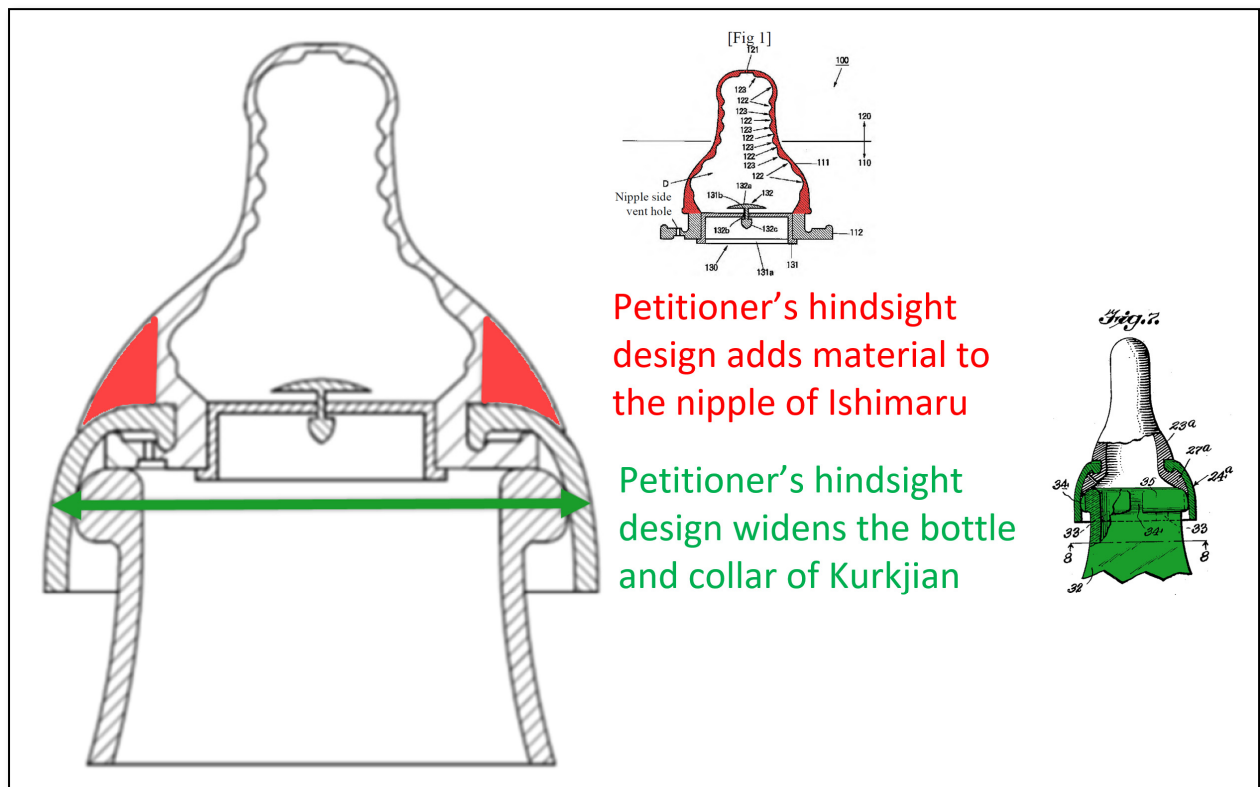
Besides, inherency and common sense have specific tests that Petitioner does not address. “A party must . . . meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness

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 1194-95. As for “common sense,” the *Arendi* standard requires, among other things, that the limitation in question must be “unusually simple,” (832 F.3d at 1362)—e.g., it does not “play[] a major role in the subject matter claimed,” (*id.* at 1362). Petitioner made no attempt to satisfy these tests in its Petition.

Eschewing the legal framework on obviousness, Petitioner falls into the temptation of hindsight, concocting new nipple-collar designs from whole cloth based on the conclusory assertion that a POSITA “would have been motivated to design a nipple and collar similar to the following.” Pet., 29 (citing EX1005, ¶353); *id.*, 50 (citing EX1005, ¶439). The Petition provides no explanation at all as to why or how the POSITA would have arrived at the specific designs Petitioner proposes for the Ishimaru-Kurkjian and Ishimaru-Atkin combinations. The truth is, Petitioner arrived at these designs because it was targeting Element 21[H].

Even a cursory visual inspection of Petitioner’s Ishimaru-Kurkjian design (annotated below), shows that it materially diverges from Ishimaru and Kurkjian. *See* Pet., 30. For example, Petitioner’s design adds downwardly sloped peripheral wings on the nipple from Ishimaru (**red** highlights below) to make the base appear “dome shaped.” Petitioner’s new peripheral wings are not disclosed or suggested in the prior art, nor are they mentioned in the Petition’s discussion on motivation.

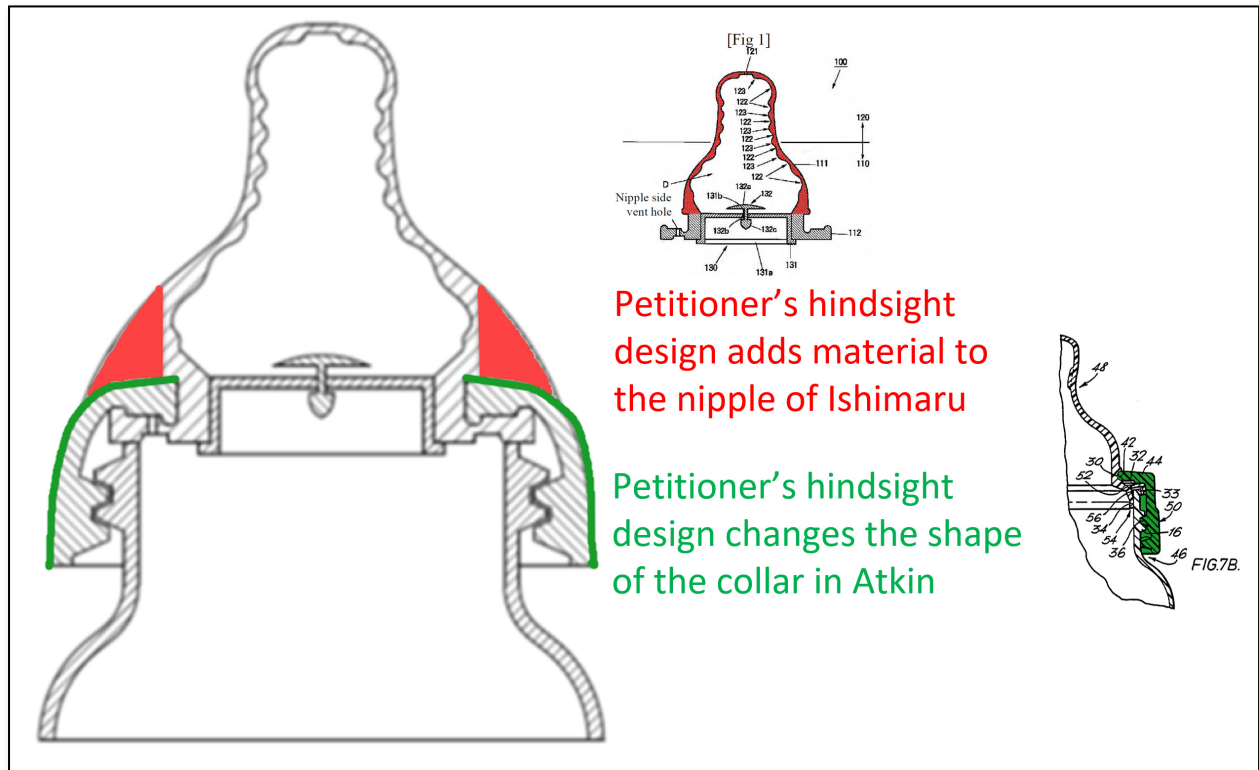
Similarly, Petitioner's design widens the bottle and collar structures from Kurkjian (green arrow below) to make the collar appear "dome shaped." Unlike Petitioner's design, Kurkjian's assembly is narrow, and Ishimaru never shows or substantively discusses a collar or bottle. And, here again, Petitioner's discussion on motivation never mentions this deviation from the art.



Pet. 30—Annotations by Patent Owner

Petitioner's hindsight is even more apparent in the Ishimaru-Atkin combination, where Petitioner proposes a nearly identical design as the Ishimaru-Kurkjian combination. Pet., 51 (annotated below). With Ishimaru-Atkin, Petitioner's added peripheral wings are even more egregious because Atkin does not

provide a teaching like Kurkjian for the nipple and collar to have a matching “streamlined” contour. Additionally, as discussed, Atkin’s collar does not have a domed, or even a curved profile—but Petitioner’s hindsight design does.



Pet, 51—Annotations by Patent Owner

B. Petitioner’s Motivation-to-Combine Analysis is Legally, Logically, and Factually Flawed (All Grounds)

1. The Ishimaru-Kurkjian combination fails (Ground 1)

Petitioner’s opening argument on motivation fails as a matter of law. The fact that “[a] POSA would have considered Ishimaru and Kurkjian in the same field of endeavor,” (Pet., 24, 27), relates to the threshold issue of analogousness, not motivation to combine. *See Johns Manville Corp. v. Knauf Insulation, Inc.*,

IPR2018-00827, Paper 9 at 10–11 (PTAB Oct. 16, 2018) (informative) (“Demonstrating that a reference is analogous art or relevant to the field of endeavor of the challenged patent is not sufficient to establish that one of ordinary skill would have had reason to combine its teachings with other prior art in the manner set forth in the claim.”). It is well established that, to prevail on obviousness, the petitioner “needs to sufficiently explain why a person skilled in the art would have done that” which the claimed invention does. *IBM Corp. v. Rigetti & Co., Inc.*, IPR2020-00496, Paper 10 at 22 (PTAB Aug. 7, 2020). In other words, “obviousness 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) (original emphasis); *see also TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (it is necessary to explain “why the references would be combined”). Petitioner’s attempt to establish analogousness between Ishimaru and Kurkjian does not answer the critical question of why a POSITA would have made the proposed combination. Without answering the why question, Petitioner can prove nothing more than that a POSITA could have made the combination, which *Belden* expressly deems insufficient.

Petitioner’s next assertion fails legally for the same reasons and also lacks support in the record. The references belie Petitioner’s assertion that Ishimaru and

Kurkjian “teach analogous solutions for, and describe the benefits of, realistic, human-like nipples.” Pet., 24, 27. Unlike Ishimaru, Kurkjian never mentions or suggests the goal of achieving a breast-like nipple.

The two Kurkjian pin citations on Page 24 of the Petition prove this point. The first citation at Column 2, Lines 35-49 and the second citation at Column 2, Line 54 to Column 3, Line 10 are about the interaction between the retaining cap 17 (or collar) and the vent 15 on the nipple’s outer flange 14 that allows air into the bottle. There is no discussion here or elsewhere in Kurkjian about making the nipple or collar breast-like.

The Petition also appeals to Kurkjian’s boilerplate language about permitting the details of its disclosure to be changed or combined. Pet., 24, 27. To no avail. The fact that Kurkjian permits changes to its embodiments does not explain why a POSITA would have modified Ishimaru’s nipple design. Common sense debunks Petitioner’s contention.

Next, the Petition argues, “[a] POSA would be further motivated and find it obvious . . . to modify the nipple design of Ishimaru as taught by one or more embodiments of Kurkjian in order to provide a more realistic, breast-like nipple.” Pet., 27. Petitioner performs a sleight of hand by using statements in Ishimaru that “stress[] the importance” of breast-like nipples to justify modifications to Ishimaru based on Kurkjian. *Id.* That reasoning does not follow.

Everyone agrees that Ishimaru teaches a breast-like nipple, at least in the sense of how the nipple moves during the sucking action of an infant. That's not the question. The question, for which Petitioner has no legitimate answer, is whether a POSITA would have been motivated to deviate from Ishimaru's breast-like nipple design based on Kurkjian's disclosure that makes no mention of achieving breast-like properties.

Still, according to Petitioner, "[a] POSA reviewing Kurkjian would be motivated to incorporate the domed collar in Kurkjian in order to modify the shape of the collar in Ishimaru . . . to provide a downward doming shape that further improves the aesthetics of the nipple to provide a realistic, breast-like shape." Pet., 28. This assertion is the heart of the matter, and this is where the Petition falters.

Again, the problem for Petitioner is that Kurkjian says nothing about the nipple or the collar being "dome shaped." *See infra*, Section IV.A.3. Kurkjian's nipple-collar assembly, as shown in Figures 6 and 7 cited by Petitioner, are narrow. *Id.* Distinct from what Kurkjian discloses, Patent Owner's adopted construction of "dome shaped" requires a "wide" nipple-collar assembly, and Petitioner's rejected construction refers to something rounded to the point of being "hemispherical" or shaped like "half of a sphere." *Id.* Kurkjian does not fit the bill. *Id.* Thus, even assuming *arguendo* that a POSITA would have been motivated to modify Ishimaru based on Kurkjian's "streamlined" nipple-collar assembly, such a combination

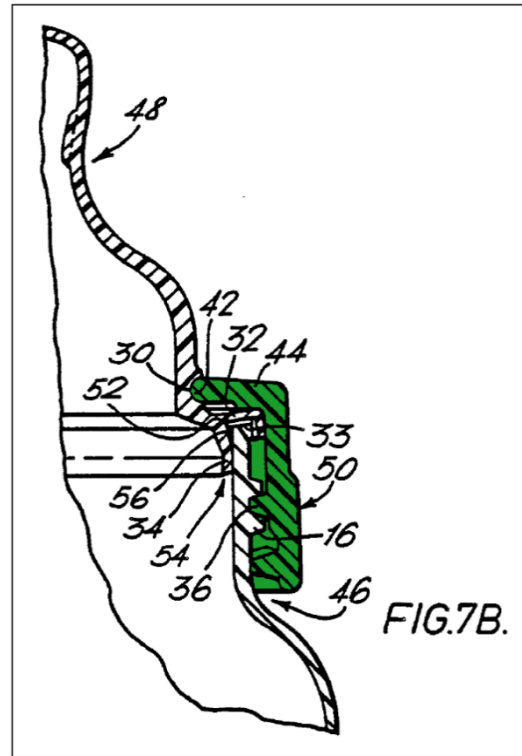
would not have produced anything approximating the “domed shape” limitation. *See KSR*, 550 U.S. at 418 (“[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does[.]”).

Finally, Petitioner argues that Ishimaru and Kurkjian provide “predictable solutions to solve the problem of designing a realistic, breast-like nipple,” and a POSITA “would be motivated to combine and substitute these familiar elements according to known methods to yield predictable results.” Pet., 28-29. But these assertions have already been debunked. Kurkjian’s disclosure is not a solution to the problem of designing a realistic, breast-like nipple, and using Kurkjian’s nipple or collar shape as a substitute for Ishimaru’s would not result in a “dome shaped” nipple-collar assembly.

2. The Ishimaru-Atkin combination fails (Ground 2)

Rather than crafting motivation rationales specific to Atkin, Petitioner recycles the reasoning employed for Kurkjian. *See* Pet., 45-50. This rinse-and-repeat reasoning has all the same flaws, (*see infra*, Section IV.B.1), and fares even worse with Atkin. Perhaps most notably, Atkin lacks Kurkjian’s teaching to provide a “streamlined” nipple-collar assembly where the contour of the collar matches that of the nipple.

Equally problematic, Petitioner argues that “[a] POSA reviewing *Atkin* would be motivated to incorporate the domed collar in *Atkin* in order to modify the shape of the collar in *Ishimaru*[.]” Pet., 49. But, as discussed, (*see infra*, § IV.A.3), and shown on the right, *Atkin*’s collar has vertical sides and is not even remotely “domed”—it certainly does not form an arc-shape or a hemisphere in profile. Accordingly, even



EX1010 (*Atkin*), Figure 7B—Annotations by Patent Owner

assuming *arguendo* that a POSITA would have been motivated to modify *Ishimaru* by incorporating *Atkin*’s collar to “improve[] the aesthetics” or for any other reason, the resulting nipple-collar assembly would not have had a “domed shape,” as the ’244 Patent’s claims require. *See KSR*, 550 U.S. at 418 (“[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does[.]”).

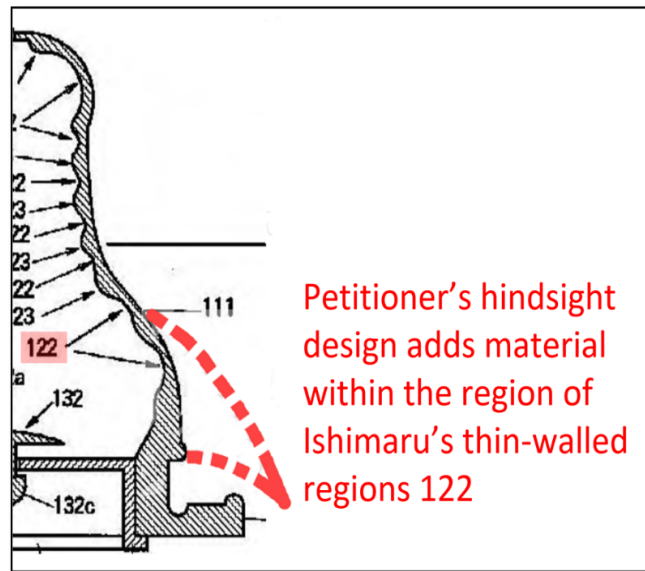
3. Petitioner’s terse motivation analysis ignores the impact on *Ishimaru*’s nipple design

A telltale sign of cursory and hindsight-laden analysis, Petitioner and its expert do not address the impact of their additional, self-created features on the

intended functionality of Ishimaru's nipple. *See infra*, § IV.A.4.

As discussed, Ishimaru is particularly concerned with achieving a specific movement pattern while the infant is sucking on the nipple. EX1008, [0006]. Critically, the new peripheral wings in Petitioner's nipple-collar designs add material in the "elongation portion" of Ishimaru's nipple that features a "groove-like pattern" of "thin-walled portions 122."

Id., [0041], Fig. 1 (at right). For Ishimaru's nipple to work properly and move "similar to the mother's nipple," these thin-walled portions must "elongate" in response to "peristaltic movement of the [infant's] tongue." *Id.*, [0046-0048].



EX1008 (Ishimaru), Figure 1—Annotations by Patent Owner

Petitioner's addition of peripheral wings in this elongation region would plainly impact the movement of Ishimaru's nipple by changing one or more of the thin-walled portions into thick-walled portions. In short, Petitioner's hindsight design is an express departure from, and a potential disruption of, Ishimaru's stated goal to emulate a mother's nipple. Petitioner's failure to justify this incongruity with Ishimaru undermines its unsubstantiated modifications.

V. CONCLUSION

For all the foregoing reasons, the Petition is deficient and beyond repair. Going forward with a trial would serve only to grant Petitioner an unwarranted second bite at the apple and expend further resources highlighting what is already clear: Petitioner cannot satisfy its burden of proving unpatentability based on the arguments and evidence in the Petition. Patent Owner, therefore, respectfully requests that the Board decline to institute *inter partes* review.

Respectfully submitted,

Date: April 26, 2023

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CERTIFICATION UNDER 37 C.F.R. §42.24(d)

Under the provisions of 37 C.F.R. §42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner's Preliminary Response to Petition totals 8,185, which is less than the 14,000 allowed under C.F.R. §42.24(b)(1).

Respectfully submitted,

Date: April 26, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), the undersigned certifies that on April 26, 2023, a complete and entire copy of this Patent Owner's Preliminary Response and its supporting exhibits were provided via email to Petitioner by serving the correspondence email address of record as follows:

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