

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 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 Invalidity 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.)
EX2010	Joint Status Letter, <i>Nanobebe US Inc. v. Mayborn (UK) Limited et al.</i> , Case No. 1:21-cv-08444 (S.D.N.Y.)
EX2011	Declaration of John S. Goetz
EX2012	Letter Motion to Withdraw as Counsel, <i>Nanobebe US Inc. v. Mayborn (UK) Limited et al.</i> , Case No. 1:21-cv-08444 (S.D.N.Y.)
EX2013	Initial Conference, <i>Nanobebe US Inc. v. Mayborn (UK) Limited et al.</i> , Case No. 1:21-cv-08444 (S.D.N.Y.)
EX2014 through EX2019	Reserved
EX2020	U.S. Patent No. 7,712,617 (Silver II)
EX2021	Reserved

EX2022 GB 0502599.4 (foreign priority document)

EX2023 GB 0414560.3 (foreign priority document)

EX2024 U.S. Patent No. 6,161,710 (Dieringer)

EX2025 through EX2028 Reserved

EX2029 Oxford Dictionary of English, Second Edition, Revised (2005) (excerpt)

EX2030 Reserved

EX2031 Nipple confusion: Toward a formal definition, Marianne Neifert, MD, et al. (1995) (excerpt)

EX2032 Declaration of Steve Parkin

EX2033 Transcript of Brian Silver Deposition Taken October 12, 2023 (filed under protective order)

EX2034 through EX2041 Reserved

EX2042 Declaration of Tim Fletcher ('244 Patent)

EX2043 Markman Hearing Transcript, *Nanobebe US Inc. v. Mayborn (UK) Limited et al.*, Case No. 1:21-cv-08444 (S.D.N.Y.)

EX2044 Reserved

I. INTRODUCTION

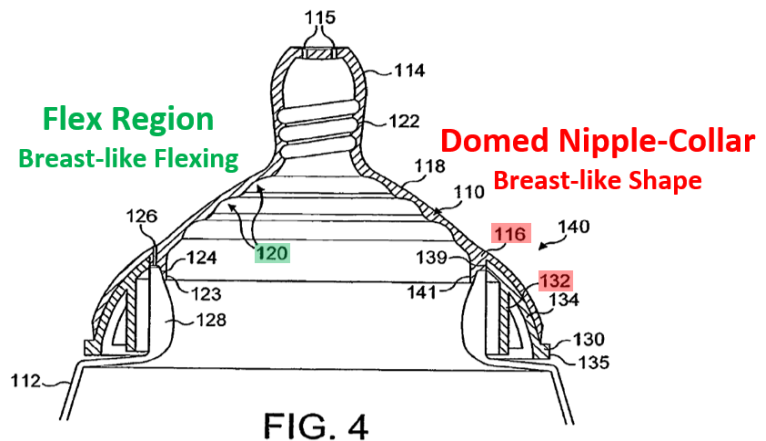
The Board’s preliminary finding that Petitioner’s Ground 2 does not meet even the “reasonable likelihood” standard to justify institution was correct, and those same flaws preclude Ground 2 from reaching the higher “preponderance” threshold necessary for Petitioner to prevail. *See infra*, §III.B. The Board took a more favorable view of Petitioner’s Ground 1. But that preliminary decision was made on an undeveloped record. Much has changed since then.

For one, Patent Owner exposed new deficiencies in Petitioner’s prior art regarding the ’244 Patent’s “flex region” and “flange” limitations. *Infra*, §III.A.1, §III.A.2. Patent Owner also augmented the record with new evidence showing that the “wide” aspect of the District Court’s “domed shape” construction distinguishes Petitioner’s prior art. *Infra*, §III.A.3. Next, Patent Owner shed new light on the dubious nature of Petitioner’s fabricated prior art combination drawing, including the remarkable revelations that Petitioner’s design would not work properly and that Petitioner’s expert had no idea who came up with that unworkable design. *Infra*, §III.A.4. Finally, Patent Owner produced evidence of extensive industry praise for the ’244 Patent’s claim features via the award-winning Closer to Nature baby bottle product. The industry’s acclaim for this patent-practicing product is more objective and potent than any evidence from Petitioner. For all these reasons, each detailed further below, the Board should uphold the validity of the ’244 Patent.

II. INDUSTRY PRAISE SUPPORTS PATENTABILITY

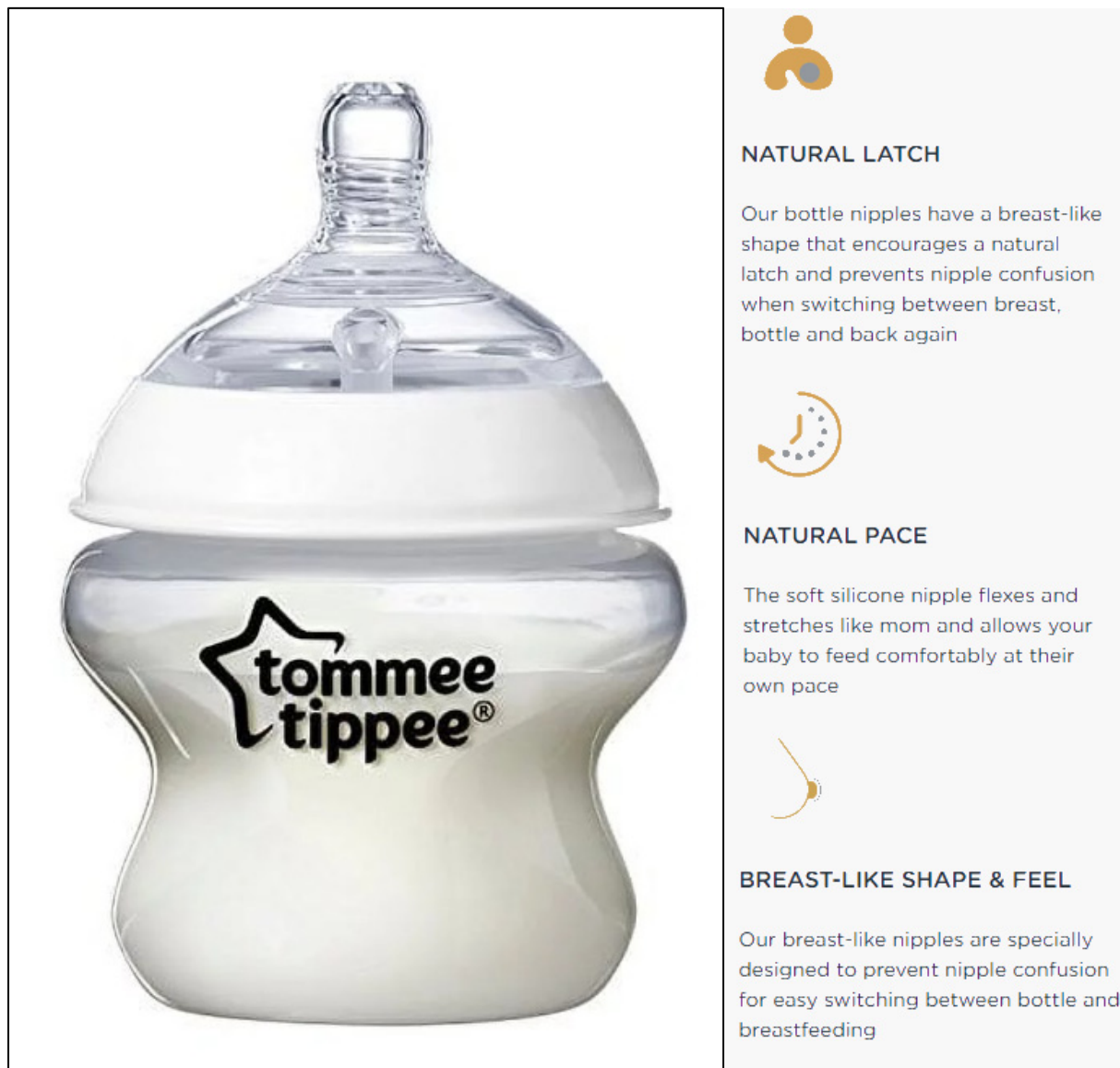
The '244 Patent's inventors sought to improve upon breast-like baby bottle designs in multiple innovative ways. *See, e.g.*, EX1003 ('244 Pat.), 1:29-48, 2:11-17. Relevant to this proceeding, the invention of the '244 Patent's independent claim 21 combines a “flex region” that promotes breast-like nipple flexing with a nipple-collar assembly having a “domed shape” that more closely matches the anatomical shape of a human breast than conventional baby bottle designs. *See id.*, 4:1-43, 8:1-20, Figure 4. In combination, these features create a drinking product that mimics the human breast and creates a more natural feeding experience for infants. *Id.*

21. A drinking vessel comprising:
a container comprising a varying internal circumference and an opening into the container; and
a cover assembly configured to couple to the container over the opening, the cover assembly comprising:
i. a nipple comprising a mouthpiece configured to allow liquid flow through the nipple to an aperture, a flex region configured to allow flex of the mouthpiece towards and away from a lower portion of the nipple, the mouthpiece defining a bite region, and a flange depending from the lower portion of the nipple defining the nipple circumference furthest from the aperture; and
ii. a collar configured to removably couple to the nipple to seal over the opening of the container; and
wherein the collar and the lower portion of the nipple together define a downward domed shape that extends outwardly and downwardly from the flex region of the nipple towards a widest circumferential edge of the collar.



EX1003 ('244 Pat.), 8:1-20, Figure 4 (annotated).

Patent Owner's Closer to Nature Baby Bottle (“the CTN Product”), marketed under the Tommee Tippee brand, reflects the innovations of the '244 Patent and embodies independent claim 21. *See generally* EX2042 (Fletcher Dec.), ¶¶130-156.



<https://www.tommeetippee.com/en-us/product/closer-to-nature-baby-bottles>

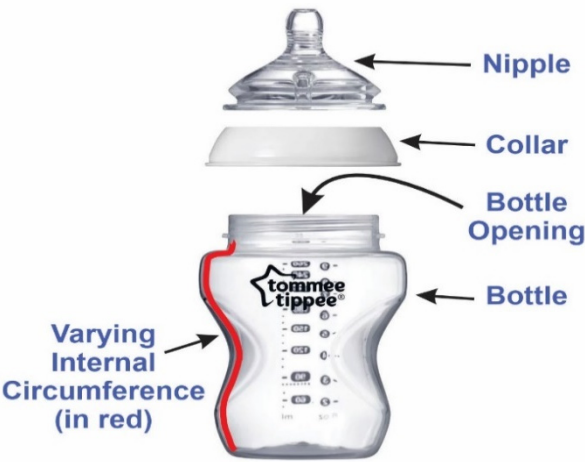
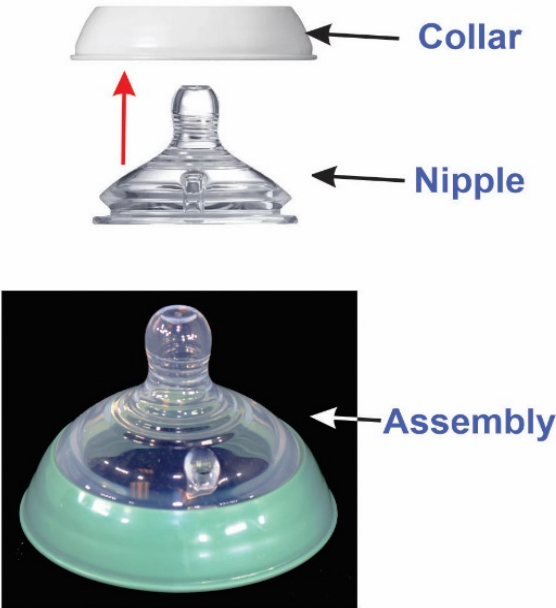
The CTN Product has been “inundated with awards since its launch in 2006” and revolutionized the baby bottle industry. EX2003, p1; *see also* EX2042 (Fletcher Dec.), ¶¶157-158; EX2032 (Parkin Dec.), ¶¶15-26. This extensive industry praise for a patent-practicing product is a key indicator of non-obviousness that “must be considered” when evaluating the ’244 Patent’s independent claim 21 in view of

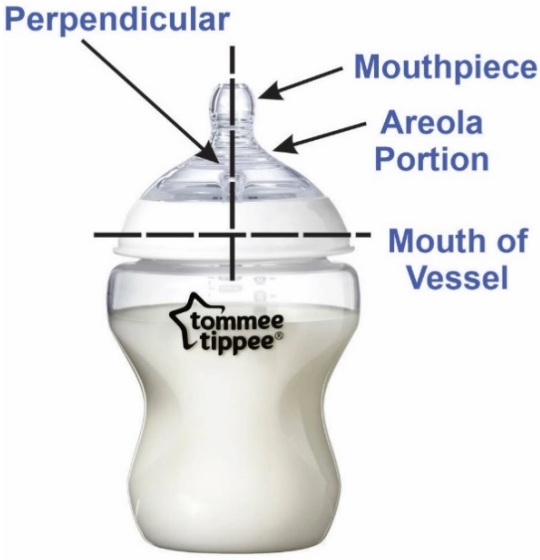
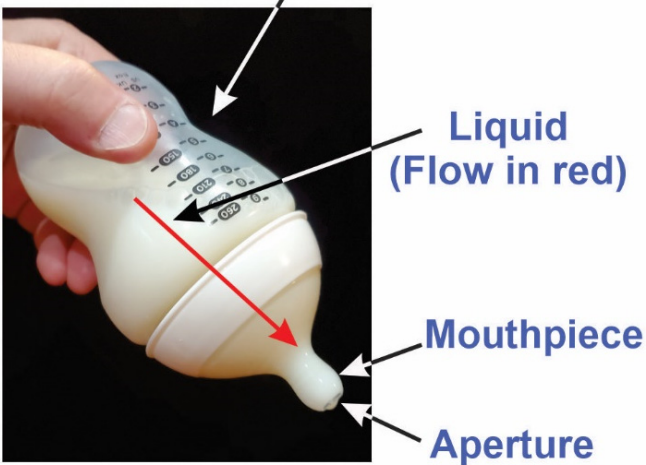
Petitioner’s prior art grounds. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc). Compared to Petitioner’s cursory and unsupported obviousness analysis, the countervailing industry praise for the patent-practicing CTN Product is “the most probative and cogent evidence in the record.” *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

A. Patent Owner’s Closer to Nature Baby Bottle Is a Patent-Practicing Product

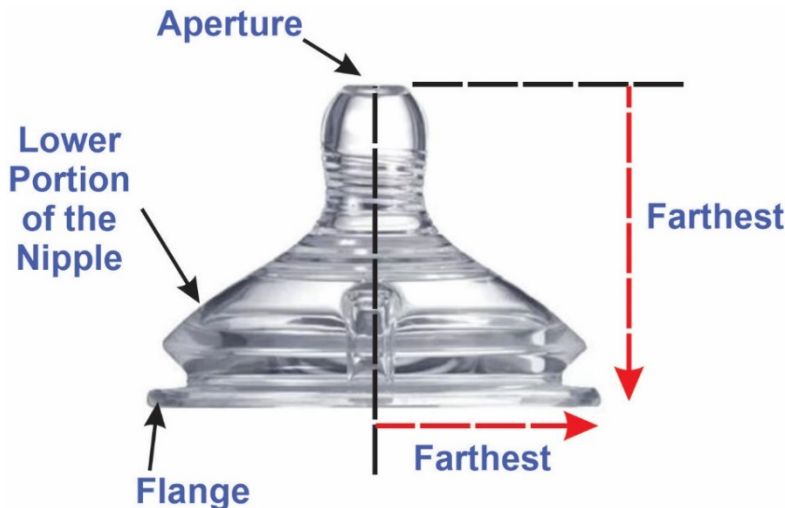
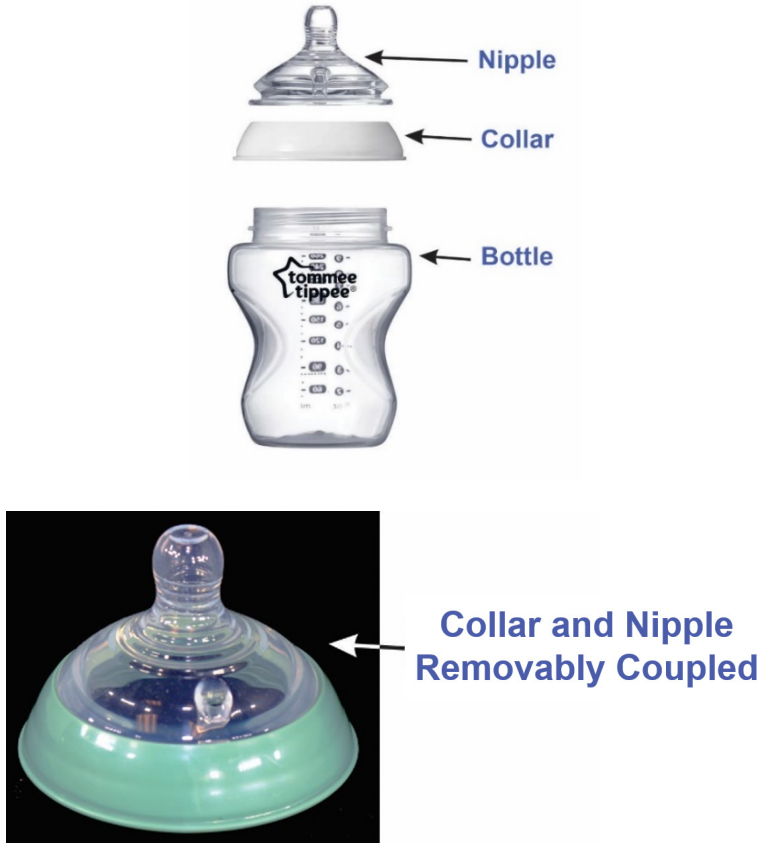
As shown in the claim chart below, the CTN Product satisfies each and every limitation of independent claim 21. Patent Owner’s expert, Mr. Fletcher, expounds on this analysis in his declaration. *See* EX2042 (Fletcher Dec.), ¶¶130-156.

Claim Language	CTN Product
[21.PRE]: A drinking vessel comprising:	 The diagram shows a baby bottle assembly. At the top is a clear plastic nipple. Below it is a white collar. At the bottom is a clear plastic bottle with the 'tommee tippee' logo. Arrows point from the labels 'Nipple', 'Collar', and 'Bottle' to their respective parts.

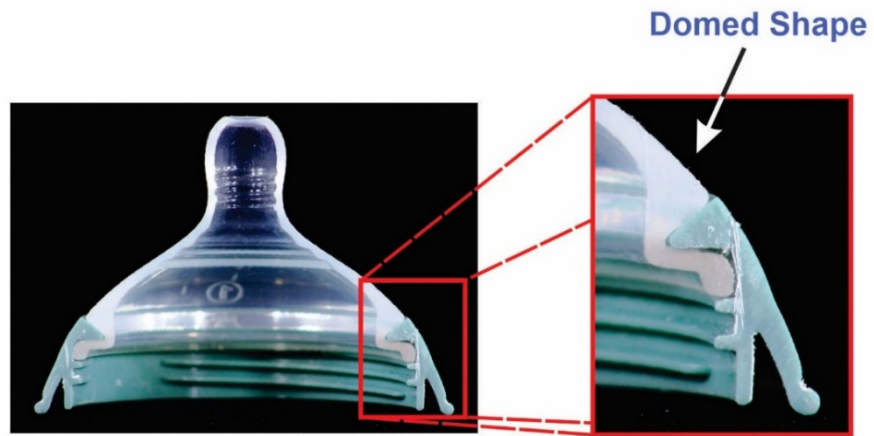
[21.A]: a container comprising a varying internal circumference and an opening into the container; and	 The diagram shows a baby bottle assembly. At the top is a clear plastic nipple. Below it is a white collar. An arrow points from the collar to the bottle's opening. The bottle itself is clear plastic with a red line along its inner wall, labeled 'Varying Internal Circumference (in red)'. The bottle has the 'tommee tippee' logo and measurement markings. Labels with arrows point to the 'Nipple', 'Collar', 'Bottle Opening', and 'Bottle'.
[21.B]: a cover assembly configured to couple to the container over the opening, the cover assembly comprising:	 The diagram shows a cover assembly. At the top is a white collar. Below it is a clear plastic nipple. A red arrow points upwards from the nipple towards the collar. Below this is a photograph of the assembled cover, which is green and has a clear plastic nipple on top. Labels with arrows point to the 'Collar', 'Nipple', and 'Assembly'.

[21.C]: i. a nipple comprising a mouthpiece configured to allow liquid flow through the nipple to an aperture,	 
[21.D]: a flex region configured to allow flex of the mouthpiece towards and away from a lower portion of the nipple	The CTN Product features “a flex region” comprising a series of three grooves. <i>See</i> EX2042 (Fletcher Dec.), ¶¶142-148.

	The grooves of the CTN Product’s “flex region” are “configured to allow flex of the mouthpiece towards and away from a lower portion of the nipple,” as claimed. For example, the grooves are designed to allow the CTN Product’s “flex region” to expand and contract as an infant sucks/suckles on the mouthpiece. <i>See</i> EX2042 (Fletcher Dec.), ¶¶145-147. The grooves of the “flex region” also allow the mouthpiece to bend relative to the lower portion of the nipple. <i>Id.</i>, ¶¶147-148.
[21.E]: the mouthpiece defining a bite region,	

[21.F]: and a flange depending from the lower portion of the nipple defining the nipple circumference furthest from the aperture; and,	 The diagram shows a cross-section of a nipple assembly. A vertical dashed line runs through the center. At the top, an arrow points to the opening, labeled 'Aperture'. Below it, the main body is labeled 'Lower Portion of the Nipple'. At the base, a horizontal flange is labeled 'Flange'. Two red dashed arrows indicate the extent of the assembly: one pointing downwards from the aperture area, labeled 'Farthest', and another pointing horizontally from the center line to the edge of the flange, also labeled 'Farthest'.
[21.G]: ii. a collar configured to removably couple to the nipple to seal over the opening of the container; and,	 The top part of the diagram shows three components: a clear 'Nipple' at the top, a white 'Collar' in the middle, and a clear 'Bottle' at the bottom. The bottom part is a close-up photograph of the 'Collar and Nipple Removably Coupled' to a green base, with an arrow pointing to the assembly.

[21.H]: wherein the collar and the lower portion of the nipple together define a downward domed shape that extends outwardly and downwardly from the flex region of the nipple towards a widest circumferential edge of the collar.



B. Patent Owner's Closer to Nature Baby Bottle Received Extensive Industry Praise

One of the problems with baby bottles on the market before the CTN Product is that they were “quite different from a mother’s breast in both shape and feeding action.” EX2032 (Parkin Dec.), ¶7. The stark differences between a human breast and existing baby bottles caused some infants “to have trouble latching and feeding when [they] switched from bottle to breast.” *Id.* This problem sparked the idea to produce a baby bottle product that “more closely approxim[es] the shape of a mother’s breast and mimic[s] the natural movement of a mother’s nipple during breastfeeding.” *Id.*, ¶8. The subsequent research and development project—dubbed “Most Natural Feeding”—spawned the claimed inventions of the ’244 Patent and the CTN Product. *Id.*, ¶¶6-12.

The CTN Product launched in the United Kingdom in 2006 and “became an instant success,” displacing competitors and ascending to “the top-selling baby bottle in [that market].” EX2032 (Parkin Dec.), ¶11. The CTN Product remains Patent Owner’s “best-selling baby product with sales topping 22 million bottles worldwide in 2022.” *Id.*, ¶12. Given its immense success in the marketplace, it is no surprise that the CTN Product has been “inundated with awards.” EX2003, p1. The CTN Product “has won numerous awards in multiple different countries,” including the UK, the United States, Australia, Malaysia, and Ireland. EX2032 (Parkin Dec.), ¶15. In fact, “[b]y the time of the official product launch in 2006, the Closer to Nature bottle had already won [the following UK] industry awards.”

Year	Industry Observer	Award Category
2005	Mother & Baby	Most Innovative Product – Gold
2005	Practical Parenting	Best Buy Award
2005	Prima Baby	Best Buy
2005	Pregnancy & Birth	Star Buy
2005	I’m Pregnant! Magazine	My Best Buy



EX2032 (Parkin Dec.), ¶¶17-18. Industry observers throughout the UK have continued to recognize the award-winning CTN Product ever since. Steve Parkin, CEO of Mayborn UK Limited, details *more than twenty* such awards in his declaration, a small sampling of which is shown below. *Id.*, ¶¶17-24.

Winners of the 2008 Mother & Baby Awards announced

By [Helen Kaye](#)

14 November 2008 10:49

The winners of the Mother & Baby awards were announced last night at a glitzy black-tie ceremony at the Park Lane Hilton Hotel in London.

Leading baby manufacturers and brands congregated for the biggest event in the industry's calendar, organised by the Number 1 parenting magazine – Mother & Baby.

All products at the independent awards were tested and rated by mums before their feedback decided which brands won the Gold, Silver and Bronze awards.

Gold Winners included Mamas and Papas Luna Mix for the Best Pushchair, McCann Erickson's Graco Contempo for the Best High Chair and Bumgenius All in One Nappy won the best Reusable Nappies.

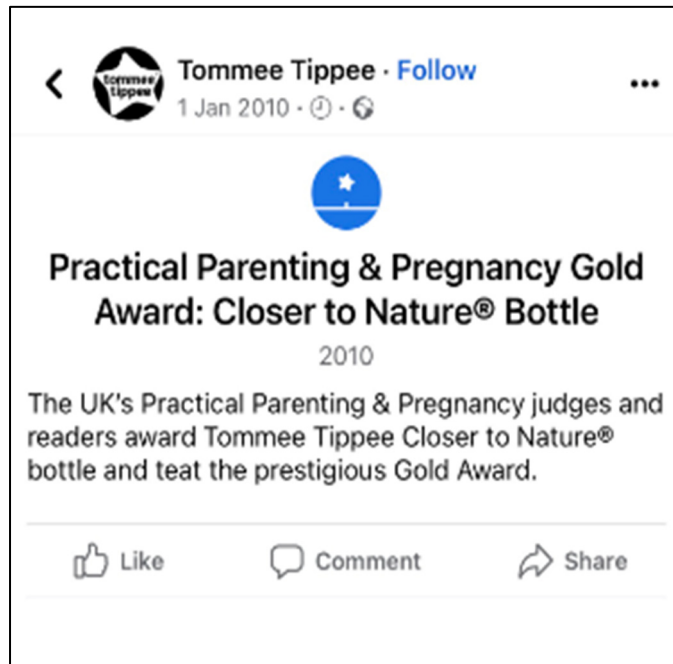
Other award winners included Asda who scooped the prestigious Retailer of the Year Award and the Brother Max 3 in 1 Thermometer which won Most Innovative Product.

Gold Product Winners from the night

Best Baby Bottle: Tommee Tippee Closer to Nature



EX2032 (Parkin Dec.), ¶20 (p.14) (Appendix C (excerpt with annotations)).



EX2032 (Parkin Dec.), ¶21 (p.18).



EX2032 (Parkin Dec.), ¶23 (p.21) (Appendix H (excerpt)).

Tommee Tippee Closer to Nature Feeding Bottle

Price: **From £6.49**
Category: **Feeding Bottle**
Website: **www.tommeetippee.co.uk**

Best Baby and Toddler Gear 2018 by mum*i*
CONSUMER CHOICE
Feeding Bottle

Best Baby and Toddler Gear 2018 by mum*i*
BRONZE
Feeding Bottle

Tommee Tippee's Closer to Nature bottles are inspired by what babies love most: mum. With the most breast-like teat ever made, this bottle flexes like mum and feels like mum because babies prefer it that way. In fact, the Closer to Nature bottle has guaranteed acceptance, with more than 92 percent of surveyed parents reporting that even babies who had never previously taken a bottle accepted in within three attempts.

The breast-like shape encourages a natural, easy latch, while the smooth silicone teat feels closer to skin. There is an anti-colic valve incorporated into the teat to reduce air ingestion.

Closer to Nature bottles are compatible with a range of Closer to Nature teats for the slow, medium, fast or vari-flow speed to suit your little one as they grow. The bottles come in a choice of sizes, pack sizes, colours and decorations for the best possible match for your family, budget and preferences.

Optimum venting valve with slow flow teat for less air intake and less discomfort for your baby

Easy latch-on teat for smooth transition between breast and bottle

Reviewer's thoughts

As a busy parent who looks for ease of use, the first thing that came to mind was how easy this bottle would be to wash, and I was not disappointed! . The shape also makes this product a pleasure to use during feeding

Page 69

Best baby & toddler gear 2018/19

EX2032 (Parkin Dec.), ¶24 (p.27) (Appendix O (excerpt with annotations)).

“Just as the industry lauded the Closer to Nature bottle in the United Kingdom, the same thing happened in the United States,” where the CTN Product is a three-time winner of the National Parenting Product Awards and has been recognized by multiple other industry observers as well. EX2032 (Parkin Dec.), ¶¶25-26.

Year	Excerpt
2016	 “The Closer to Nature bottle brings mom and baby together for a smooth transition from breast to bottle. <i>The original breast-like nipple mimics the ‘just like mom’ feel and reduces nipple confusion.</i>” EX2032, Appendix Q.

2019		“Evaluation comments: ‘I liked the shape of the nipple and bottle. It looks like a good shape to easily transition from breast to bottle. <i>Its curve and softness are very breast-like.</i> ” EX2032, Appendix R.
2023		“Evaluation comments: . . . ‘The design is made to <i>mimic a human nipple, which is ideal</i> if you have a baby who is primarily nursing.’” EX2032, Appendix S.

C. The Industry Praise for Patent Owner’s Closer to Nature Baby Bottle Has Nexus to the ’244 Patent’s Claim Features

“[T]o be accorded substantial weight in the obviousness analysis, the evidence of secondary considerations must have a ‘nexus’ to the claims, i.e., there must be a legally and factually sufficient connection between the evidence and the patented invention. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quotes omitted). One way to establish nexus is by “showing that the [industry praise] is the direct result of the unique characteristics of the claimed invention.” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1374 (Fed. Cir. 2019) (quotes omitted). The record here shows just that.

This record satisfies the direct-result test because the features recited in the ’244 Patent’s independent claim 21 are the main impetus behind the industry’s extensive praise of the award-winning CTN Product. *See* EX2042 (Fletcher Dec.), ¶¶158-162; EX2032 (Parkin Dec.), ¶¶13-14. Specifically, the industry’s effusive praise flows from the synergistic combination of the “flex region” and “domed shape” claim features. *Id.* The following three reasons support this conclusion.

First, as shown in the table below, there is extensive documentary evidence associating the '244 Patent's "domed shape" and "flex region" claim features with the awards won by the CTN Product. *See* EX2042 (Fletcher Dec.), ¶159. These documents repeatedly highlight the benefits of incorporating the '244 Patent's claim features—namely, the breast-like shape from the "domed shape" limitation and the breast-like movement from the "flex region" limitation. *Id.*

Award	Reference to Claim Features
2016: National Parenting Product Awards	"The Closer to Nature bottle brings mom and baby together for a smooth transition from breast to bottle. <i>The original breast-like nipple mimics the 'just like mom' feel and reduces nipple confusion.</i> " EX2032 (Appendix Q)
2018: Best Baby & Toddler Gear—Feeding Bottle, Bronze & Consumer's Choice	"Tommee Tippee's Closer to Nature bottles are inspired by what babies love most: mum. <i>With the most breast-like teat ever made, this bottles flexes like mum</i> and feels like mum because babies prefer it that way." EX2032 (Appendix O)
2019: Mom's Choice Awards	"Tommee Tippee's award-winning Closer to Nature bottle features an <i>easy-latch-on nipple that mimics the flex, stretch and shape of mom's breast for a natural latch</i> , because babies prefer it that way." EX2032 (Appendix T)
2019: National Parenting Product Awards	"Evaluation comments: 'I liked the shape of the nipple and bottle. It looks like a good shape to easily transition from breast to bottle. <i>Its curve and softness are very breast-like.</i> '" EX2032 (Appendix R)
2019: Daily Mom—Best Baby Essentials	"Tommee Tippee . . . has created the best baby bottle for breast milk, the Closer to Nature Baby Bottle. This baby bottle is shaped like a breast and feels like a breast which is what babies prefer. <i>The breast-like nipple of the Closer to Nature Bottle helps babies both breast and bottle feed without difficulty</i>

	<i>transitioning between the two.”</i> EX2032 (Appendix U)
2020: MadeForMums—Baby Bottles, Silver Award Winner	“ <i>Why it’s a winner:</i> “The Closer to Nature bottle from hugely trusted brand Tommee Tippee is <i>shaped to feel more like a breast</i> , making it easier for the baby to latch. The silicone nipple also <i>mimics the natural breast feeding action</i> [.]” EX2032 (Appendix J)
2021: MadeForMums—Baby Bottles, Silver Award Winner	“ <i>Why it’s a winner:</i> “Described by our mum testers as ‘comfortable to use’ and ‘good quality,’ this bottle impressed our testers with its smooth silicone teat and has <i>a breast-like shape</i> .” EX2032 (Appendix K)
2022: MadeForMums—Baby Bottles, Silver Award Winner	“ <i>Why it’s a winner:</i> “The squeezable soft-touch silicone is designed to feel warm and comforting, just like mum’s skin, and the teat itself is shaped to mimic a breast.” EX2032 (Appendix L)
2023: MadeForMums—Baby Bottles, Gold Award Winner	“ <i>Why it’s a winner:</i> “Marketed by Tommee Tippee as the ‘original breast-like bottle’ with a teat that is shaped like a breast, the Closer to Nature Baby Bottles proved to be a hit with our testers and their babies[.]” EX2032 (Appendix M)
2023: National Parenting Product Awards	“Evaluation comments: . . . ‘The design is made to <i>mimic a human nipple, which is ideal</i> if you have a baby who is primarily nursing.’” EX2032 (Appendix S)
2023: MomTrends—Best Bottle For Newborns	“Plus, [the Closer to Nature bottles] are <i>modeled [sic] after an actual breast so the bottle mimics the natural flex and movement of a mom’s breast</i> to achieve a comfortable feeding for baby. And the compact shape allows your baby to be closer to you too!” EX2032 (Appendix V)
2023: Today’s Parent—Best Bottles for Breastfed Babies	“It’s shaped like a boob, moves like a boob and stretches like a boob—what’s not to love?” “Pros: • <i>Designed to look and feel like a boob</i> • <i>Flexible soft silicone nipple that mimics your own</i>” EX2032 (Appendix W)

Second, the combination of the '244 Patent's "domed shape" and "flex region" claim features is what makes the CTN Product uniquely effective as an infant feeding device. *See* EX2042 (Fletcher Dec.), ¶¶160-161. These hallmark features produce the CTN Product's characteristic breast-like shape and movement, which set the CTN Product apart from other contemporary baby bottle products on the market. *See* EX2042 (Fletcher Dec.), ¶160 ("I am not aware of any other baby bottle products before the CTN Product launched in 2006 that combined these "domed shape" and "flex region" features in a similar way[.]"); EX2032 (Parkin Dec.), ¶14 ("This design was completely new when the product launched in 2006, and others have been attempting to copy these features ever since."). The industry would not have praised the CTN product as it did if the unique breast-like characteristics were commonplace in other products.

Third, the fact that the "domed shape" and "flex region" have remained constant in the CTN Product since its launch 17 years ago strongly suggests that these features are the main impetus of the extensive industry praise. *See* EX2042 (Fletcher Dec.), ¶162; EX2032 (Parkin Dec.), ¶14 ("Because these breast-like features of the Closer to Nature bottle have been so effective and favorably received by the industry, we have not changed them over the 17-year history of the product, including in the glass bottle and silicone bottle product variations."). While other aspects have varied over the years—e.g., different bottle sizes, bottles types, colic

valves, etc.—the breast-like shape and flex characteristics have remained the same throughout the CTN Product’s award-winning history. *Id.*

* * * *

The Petition’s strained obviousness grounds are not enough to carry Petitioner’s burden of proof in this proceeding. The discussion below in Section III proves as much. Still, to the extent there is any doubt, the industry’s high praise for the patent-practicing CTN Product tips the scales in favor of upholding the ’244 Patent. *See Henny Penny*, 938 F.3d at 1333 (affirming the Board’s final decision to uphold claims embodied by an award-winning patent-practicing product).

III. PETITIONER’S GROUNDS PROVE NO CLAIM UNPATENTABLE

A. Ground 1: The Ishimaru-Kurkjian Combination Lacks Multiple Claim Limitations and Falls Short on Motivation to Combine

Petitioner’s Ishimaru-Kurkjian combination lacks at least the following three limitations of the ’244 Patent’s independent claim 21:

- (1) a nipple having a “flex region”;
- (2) “a flange depending from the lower portion of the nipple defining the nipple circumference furthest from the aperture”; and
- (3) “wherein the collar and the lower portion of the nipple together define a downward domed shape.”

Instead of acknowledging and addressing these deficiencies, Petitioner and its expert, Mr. Silver, gloss over them with cursory analysis that the record in this case

does not support. The absence of elements in Petitioner's combination that satisfy these limitations provides multiple independent reasons to uphold the '244 Patent.

The '244 Patent also should be upheld because Petitioner fails to provide a credible motivation analysis that supports the Ishimaru-Kurkjian combination. As exposed below, Petitioner's combination features a radical modification of Ishimaru's nipple that Petitioner fails to address in its motivation-to-combine analysis and that has no basis in Kurkjian or any other prior art on this record. Just as the prior art does not support Petitioner's bizarre nipple design, neither does Mr. Silver. Mr. Silver's conclusory declaration testimony fails to explain why or how a skilled artisan would have reached such a design. Worse, his deposition testimony revealed that Mr. Silver had no hand in creating it. He simply gave a rubber-stamp approval. Had Mr. Silver carefully considered the matter, he would have seen that the design Petitioner holds out as the Ishimaru-Kurkjian combination is implausible.

1. Ishimaru lacks the claimed "flex region"

The '244 Patent's "flex region" limitation requires a nipple region with surface characteristics that control flexing of the nipple's mouthpiece towards and away from a lower portion of the nipple. EX1003 ('244 Pat.), 8:7-9. But that is not what Ishimaru discloses. *See generally* EX2042 (Fletcher Dec.), ¶¶38-57. Ishimaru's nipple is instead riddled with thin-walled portions arranged in a groove-like pattern that extends throughout the nipple. No particular region of the nipple

controls flexing in the manner required by the '244 Patent's claims. Unlike the '244 Patent, Ishimaru leaves the point of flexure undefined and unpredictable.

- i. *The “flex region” is the nipple region that controls flexing between the “mouthpiece” and the nipple’s “lower portion”*

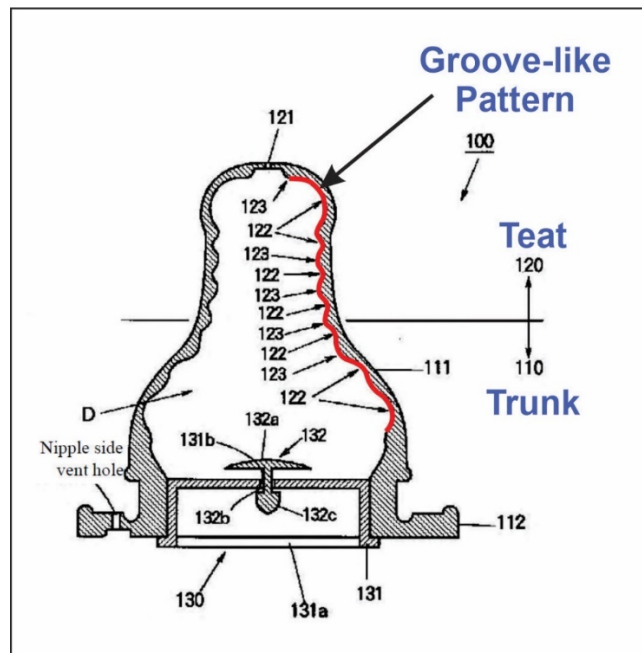
The Board's Institution Decision adopts the District Court's construction of “flex region” as “a region having surface characteristics that control flexing.” *See* Inst. Dec. at 13 (citing EX2008 (*Markman* Order) at 26). As the Board aptly observed, the District Court's *Markman* Order presents “a thorough and reasoned explanation of the construction, citing evidence and argument submitted by both parties.” *Id.* Patent Owner agrees and requests that the Board again adopt the District Court's construction in the upcoming Final Written Decision.

Throughout its explanation, the District Court emphasized the ample intrinsic evidence supporting that the claimed “flex region” improves on the prior art by ensuring that “the point of flexure is clearly defined” and “that the flexing is happening in a particular manner.” EX2008 (*Markman* Order) at 26 (citing EX1003 ('244 Pat.), 1:37-48, 2:15-17). The particular manner of flexing called for in the '244 Patent's claims is “flex[ing] of the mouthpiece towards and away from a lower portion of the nipple.” EX1003 ('244 Pat.), 8:7-10 (independent claim 21). Thus, the claimed “flex region” is the nipple region that controls flexing between the “mouthpiece” and the “lower portion of the nipple.”

- ii. *Far from a discrete “region,” Ishimaru’s “groove-like pattern” extends throughout the nipple, from teat to trunk*

According to Petitioner, “Ishimaru discloses that the nipple further includes a flex region, as shown by *the* thin-walled portions 122 and inner surfaces 123 of the nipple, which are designed to be flexible.” Pet., 36 (citing EX1008 (Ishimaru) at [0008], [0041]). Petitioner and Mr. Silver both emphasize that Ishimaru refers to the full collection of seven thin-walled portions as “*a groove-like pattern*” that causes “the teat portion 120 and nipple trunk 110 [to] be elongated in the mouth of the infant 200.” *Id.* (quoting EX1008 (Ishimaru) at [0041], [0046]); *see also* EX1005 (Silver Dec.) ¶388 (same). Thus, Ishimaru’s groove-like pattern of seven thin-walled portions constitutes Petitioner’s mapping to the claimed “flex region.”

But Ishimaru’s groove-like pattern is not a distinct “region” at all, much less a “flex region,” as the Court and the Board have construed the term. *See* EX2042 (Fletcher Dec.), ¶¶45-49. As shown below, Ishimaru’s groove-like pattern extends “*across the teat portion 120 and the nipple trunk 110*,” so that all “seven thin-walled portions 122 [can] elongate,” allowing “the teat portion 120 and the nipple trunk 110 [to be] elongated more evenly.” EX1008 (Ishimaru) at [0046].



EX1008 (Ishimaru) at Figure 1 (with annotations). Ishimaru’s goal of achieving “even” elongation throughout the nipple stems from a criticism of “the conventional artificial nipple,” which “does not elongate the teat portion . . . or the portion corresponding to the mammary areola.” *Id.*, [0004].

Logically, from the perspective of a skilled artisan, Ishimaru’s groove-like pattern differs materially from a “region”—i.e., a defined section or area—because it runs throughout the nipple, from teat to trunk. *See* EX1008 (Ishimaru) at [0046] (“the thin-walled portions 122 are placed at 7 locations **across** the teat portion 120 and the nipple trunk 110”); EX2042 (Fletcher Dec.), ¶47 (“Ishimaru’s approach is logically divorced from the notion of a ‘region.’”). The ’244 Patent reinforces this distinction. Unlike Ishimaru’s groove-like pattern, the ’244 Patent’s “flex region” is spatially distinct from certain other portions of the nipple. For example, the claims

juxtapose the “flex region” against a “bite region” of the “mouthpiece.” EX1003 (’244 Pat.), 8:6-13; *see also id.*, 3:56-58 (“the flex region [is] in a non-bite area”); EX2042 (Fletcher Dec.), ¶48.

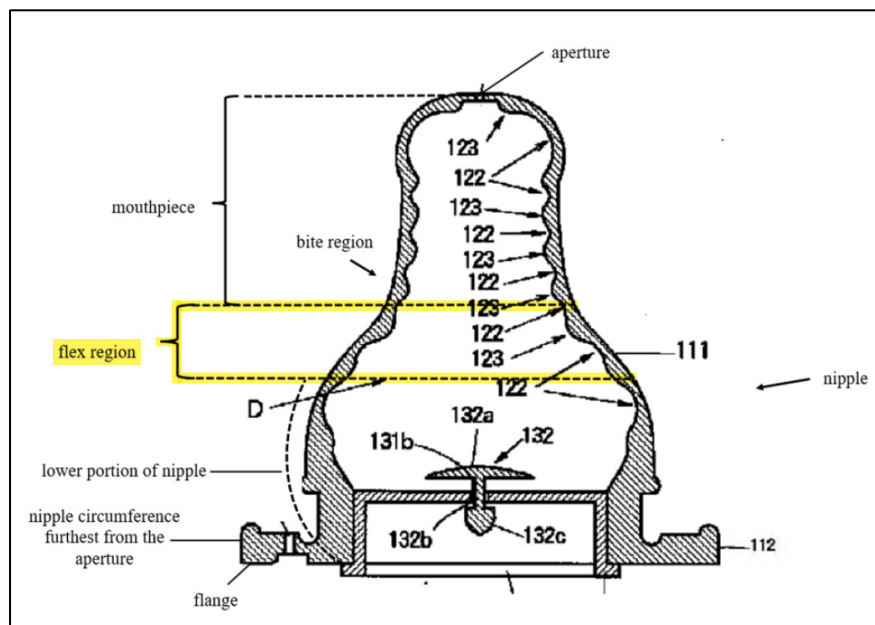
Ishimaru’s groove-like pattern also does not control flexing to occur within any particular “region” because all seven of the thin-walled portions distributed across the nipple are designed to elongate, such that “the teat portion 120 and the nipple trunk 110 will also be elongated in the mouth of the infant 200.” EX1008 (Ishimaru) at [0046] (“peristaltic movement of the tongue 230 of the infant 200 described above *will cause these seven thin-walled portions 122 to elongate*”); *see also* EX2042 (Fletcher Dec.), ¶50. Promoting elongation across the groove-like pattern of thin-walled portions is all part of Ishimaru’s design goal of making the nipple elongate “more evenly.” *Id.*

The ’244 Patent’s inventors took a different approach, one that is counterintuitive when juxtaposed against Ishimaru and other prior art. *See* EX2042 (Fletcher Dec.), ¶50 (“[E]longating ‘evenly’ is not what the ’244 Patent’s flex region is about.”). Just like the prior art distinguished in the ’244 Patent and addressed in the District Court’s *Markman* Order, Ishimaru’s groove-like pattern leaves the point of flexure “undefined and unpredictable.” EX1003 (’244 Patent), 1:40-43 (“the point at which flexing takes place is undefined and unpredictable”); *see also* EX2008 (*Markman* Order) at 28-29 (“The specification describes how the invention was

designed to improve upon prior inventions . . .”). The ’244 Patent’s flex region resolves this problem and, as a result, provides “a more natural feeding action” that has garnered extensive praise from industry observers. *See supra*, §II.

iii. *Petitioner cannot create a “flex region” in Ishimaru with arbitrary dotted lines and annotations*

As discussed, Petitioner’s analysis of the “flex region” limitation (Element 21[D] in the Petition) calls out all seven of the thin-walled portions that constitute the entirety of Ishimaru’s groove-like pattern. *See Pet.*, 35-37. Elsewhere, though, while addressing an unrelated claim limitation about the claimed “flange” (Element 21[F] in the Petition), Petitioner appears to change course by using dotted-line annotations to prescribe an arbitrary portion of Ishimaru’s groove-like pattern as the “flex region.” *See Pet.*, 38-39 (annotated drawing reproduced below).



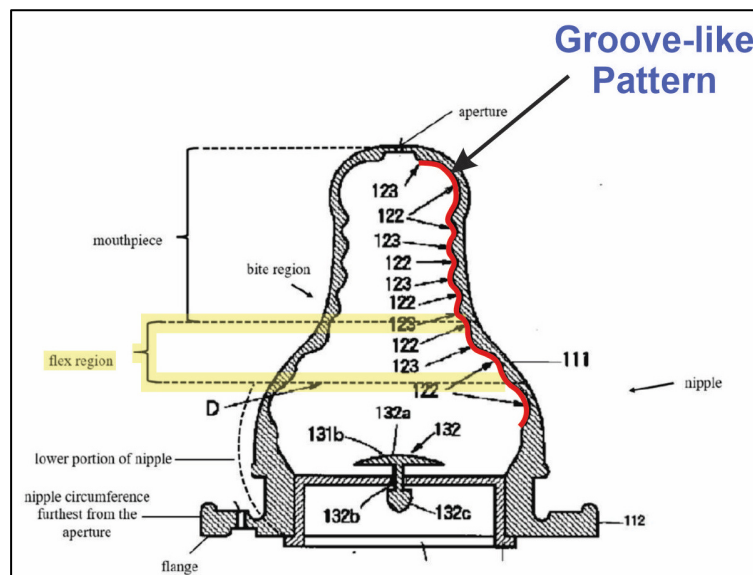
Pet., 39 (with added yellow highlighting).

Confusingly, Petitioner’s dotted-line annotations prescribe just one and one-half of Ishimaru’s thin-walled portions as the “flex region.” While Petitioner does not bother to explain why it chose to draw its dotted lines at these odd locations, the answer is apparent: hindsight. Petitioner is viewing Ishimaru through the lens of a party that wishes Ishimaru would satisfy the ’244 Patent’s claims, “read[ing] into [Ishimaru] the teachings of the invention in issue,” *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966). Petitioner cannot square its arbitrary and unrealistic dotted lines with Ishimaru’s actual disclosure. Those lines only make sense from the distorted perspective of improper hindsight bias. *See generally* EX2042 (Fletcher Dec.), ¶¶52-57. Hindsight aside, the Board should not adopt Petitioner’s annotations for at least four important reasons.

First, Petitioner’s unexplained annotations are inconsistent with its initial analysis on the “flex region” limitation. Designating just one and one-half thin-walled portions as the “flex region” is a material change from relying on the entire groove-like pattern of seven thin-walled regions. *Compare* Pet., 36, *with id.*, 39. Vacillating between inconsistent positions without warning or explanation flouts the codified requirements of particularity and specificity in IPR petitions. *See* 35 U.S.C. § 312(a)(3) (“with particularity”); 37 C.F.R. § 42.22(a)(2) (“a detailed explanation”), 37 C.F.R. §§ 104(b)(4)-(5) (“must specify”); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“It is of the utmost

importance that petitioners in the IPR proceedings adhere to the requirement [of 35 U.S.C. § 312(a)(3)] that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim’ . . .”).

Second, calling one and one-half—about 21.5%—of Ishimaru’s seven thin-walled portions a “flex region” just doesn’t make sense. A skilled artisan would not partition Ishimaru’s groove-like pattern this way, particularly when Ishimaru gives no hint or guidance to do so. *See* EX2042 (Fletcher Dec.), ¶56 (“[M]arking an alleged ‘flex region,’ by drawing a dotted line through the middle of one of Ishimaru’s thin-walled portions is dubious on its face.”). Petitioner’s shoehorning only accentuates the problem with Ishimaru—the groove-like pattern is not limited to any particular “region” of the nipple. It extends through what Petitioner labeled a “flex region,” a “mouthpiece” and “bite region,” **and** a “lower [nipple] portion.”



Pet., 39 (with added yellow highlighting and annotations).

Third, Ishimaru's disclosure makes clear that Petitioner's identified one and one-half thin-walled portions would not control nipple flexing like the '244 Patent's claimed (and construed) "flex region." The subset of thin-walled portions (mis)identified as the "flex region" in Petitioner's drawing are no different from the remaining five and one-half thin-walled portions across the remainder of the nipple. None of them defines a specific point of flex. Instead, all seven of Ishimaru's thin-walled portions elongate so the nipple teat and trunk will "elongate more evenly." EX2008 (Ishimaru) at [0046]; *see also* EX2042 (Fletcher Dec.), ¶57 ("It is the groove-like pattern as a whole that dictates how the nipple flexes[.]").

Fourth, Petitioner's hindsight-laden annotations are pure attorney argument. The annotations are not explained, endorsed, or even replicated in the declaration of Petitioner's expert, Mr. Silver. Attorney argument is not evidence at all, much less substantial evidence that could support the Board's adoption of Petitioner's dotted lines. *See Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017) (reiterating that "[a]ttorney argument is not evidence" and vacating the Board's decision for relying on the same).

For all these reasons, Petitioner should be held to its original position that maps the entirety of Ishimaru's groove-like pattern, all seven thin-walled portions, to the claimed "flex region." The unexplained assertion that just one and one-half of Ishimaru's thin-walled portions constitute a "flex region" is inadequately pled,

dubious on its face, and unsupported by substantial evidence.

2. The Ishimaru-Kurkjian combination's flange does not define the "circumference furthest from the aperture," as claimed

Just as Petitioner has no credible case on the '244 Patent's "flex region," Petitioner also fails to show how the Ishimaru-Kurkjian combination provides the claimed "flange" depending from the lower portion of the nipple that defines the "circumference *furthest* from the [mouthpiece] aperture." EX1003 ('244 Pat.), 8:10-13 (the "flange" limitation); *see generally* EX2042 (Fletcher Dec.), ¶¶58-66. Here, again, the problem is twofold: Petitioner does not explain its mapping adequately, and the mapping is flawed on its face.

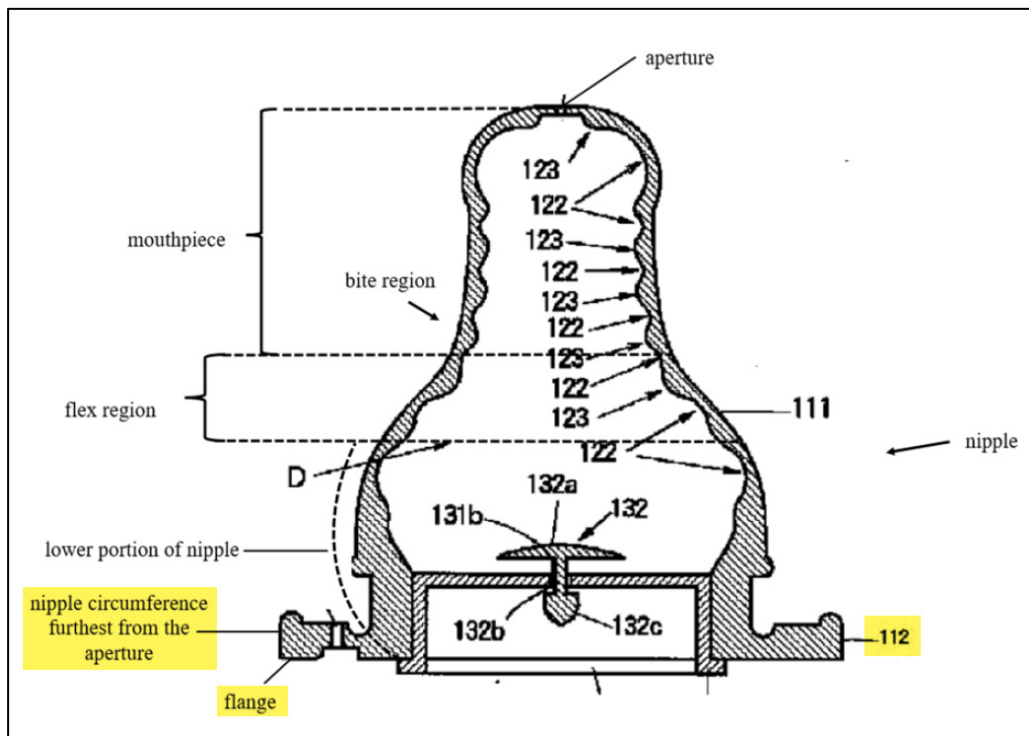
While Petitioner contends Ishimaru's Figure 1 illustrates the '244 Patent's "flange" limitation, it fails to explain this position or reveal the underlying rationale for it. *See* Pet., 38-39 ("As illustrated in annotated Fig. 1..."); EX1005 (Silver Dec.) ¶398. The Petition presents the mapping in a conclusory fashion as if its meaning and sufficiency are self-evident, which they are not. *See Dominion Energy, Inc. v. Alstom Grid LLC*, 725 F. App'x 980, 986 (Fed. Cir. 2018) ("just saying that something is so does not make it true"); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."); *accord KSR*

Intl Co. v. Teleflex Inc., 550 U.S. 398, 418, 127 S. Ct. 1727, 1741 (2007).

The entirety of the Petition’s written analysis takes place in a single paragraph. This paragraph does not explain how Petitioner interprets the “flange” limitation or how it is satisfied by Ishimaru’s Figure 1. Beyond the opening statement that says Ishimaru “discloses or renders obviousness” this limitation, the Petition provides just the following three sentences of pseudo-substantive analysis:

Ishimaru discloses “a flange portion for connecting to a feeding bottle main body” which is part of the “base portion 112.” Ex[1008],[0037],[0050]. The base portion would include the lower portion of the nipple. As illustrated in annotated Fig. 1 below, base portion 112 at the lower portion of the nipple furthest from the hole at the tip, which defines the nipple circumference. Ex[1008],Fig.1; Ex[1005],¶399.

Pet., 38-39 (with added highlighting). The first sentence (in pink) says Ishimaru discloses a flange portion that is part of a base portion 112. The second sentence (in blue) says the base portion 112 includes the lower portion of the nipple. The third sentence (in yellow) is difficult to parse due to grammatical and/or typographical errors. However, it seems to suggest that the base portion 112 is furthest from the hole at the tip of the nipple and, thus, defines the furthest nipple circumference. The Petition provides the following annotated version of Ishimaru’s Figure 1 to reflect its written analysis:



Pet., 39 (Petitioner's annotated figure with added yellow highlighting).

As a result of Petitioner's conclusory approach, Patent Owner and the Board do not even know what Petitioner thinks the "nipple circumference furthest from the aperture" language means, let alone why Petitioner thinks Ishimaru's Figure 1 satisfies this aspect of the "flange" limitation. Because it merely parrots back the same insufficient analysis, Mr. Silver's declaration does not clarify the Petition at all. *See* EX1005 (Silver Dec.) ¶398. Nor was Mr. Silver himself able to expound on the matter during deposition. There, with the relevant passage of his declaration before him, Mr. Silver testified that the claim language is "unclear," could be interpreted multiple different ways, and a skilled artisan "wouldn't know" which interpretation should apply. *See generally* EX2033 (Silver Tr.), 195:2-202:1.

Transcript of Brian Silver Deposition Taken October 12, 2023	
A. I'm saying it's unclear in that the flange depending from the lower portion of the nipple defining the nipple circumference farthest from the aperture, I would take a diameter to be the circumference, to be the circumference of the flange. And how you -- how do you define "furthest" can be along the path of the nipple. It could be from the centerline and could be from the tip of the nipple directly to the edge. All three of which would be furthest from the aperture.	Q. Okay. Of those three, which do you think is how a skilled artisan would understand this claim term -- this claim term here? MR. WILLIAMS: Objection to form and scope. A. I think a skilled artisan wouldn't know.
EX2033 (Silver Tr.), 200:8-19	EX2033 (Silver Tr.), 201:17-202:1

Mr. Silver also confirmed that his declaration does not indicate which of these multiple meanings he relied on and confessed that he was unable to recall this critical information. *See* EX2033 (Silver Tr.), 202:14-203:4.

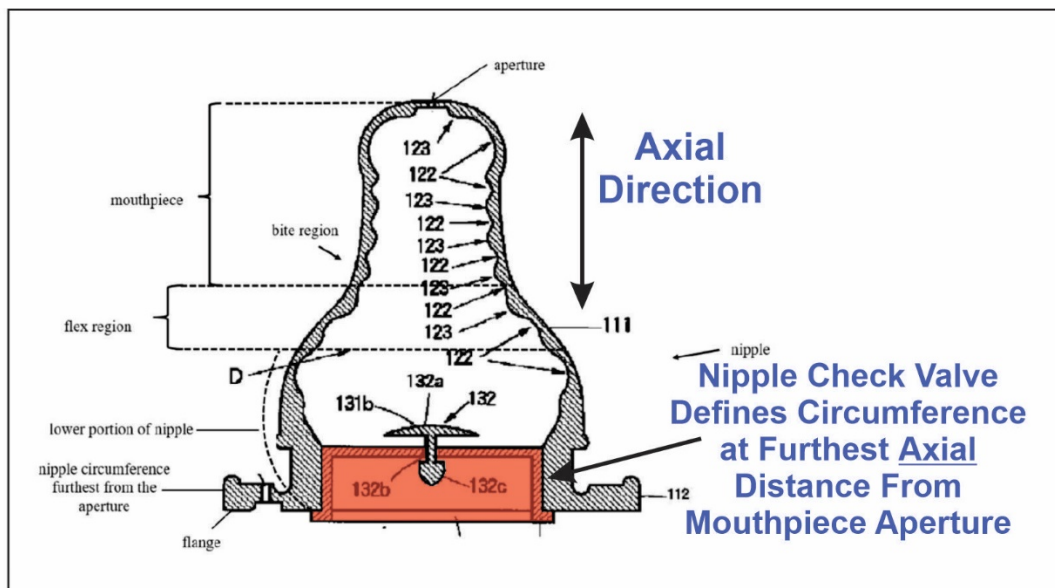
Transcript of Brian Silver Deposition Taken October 12, 2023	
Q. What did you have in mind when you wrote your declaration at Pages 188 and 189? MR. WILLIAMS: Objection to form. A. I don't recall which one of the three I was thinking of at the time.	Q. In any event, we can agree that you didn't explain which one you were using in your declaration; is that fair? A. Yes.
EX2033 (Silver Tr.), 202:14-18	EX2033 (Silver Tr.), 203:1-4

Petitioner cannot be said to have carried its burden of proof when the Petition's written analysis is so conclusory that it cannot even refresh the recollection of Petitioner's own expert on the most rudimentary aspects of the case-in-chief. If Petitioner's expert is "unclear" and "do[es]n't recall" what the Petition (or his own declaration) means, how should anyone else know? It is Petitioner's burden to explain "[h]ow the challenged claim is to be construed" and "[h]ow the construed claim is unpatentable." 37 C.F.R. §§ 104(b)(3)-(4). It is not Patent Owner's burden to guess what the Petition might mean and respond by "shoot[ing] at a moving target." *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2154 (2016). For this reason alone, the Board should find the Petition deficient. But there's more.

Petitioner could not have prevailed on the "flange" limitation even if the Petition had articulated a clear claim interpretation and prior art rationale. No matter how the "nipple circumference furthest from the aperture" language is interpreted—e.g., furthest radially or furthest axially—Petitioner's case comes up short. *See* EX2042 (Fletcher Dec.), ¶¶62-66.

From an axial perspective, Ishimaru's Figure 1 shows that the flange is not the furthest circumference from the teat ("mouthpiece") aperture. Ishimaru's nipple features an additional component—a *check valve 130*—that seals against the lower surface of the flange. *See* EX1008 (Ishimaru) at [0037] (describing Figure 1's "schematic cross-sectional view of the artificial nipple 100" and noting that "[a]

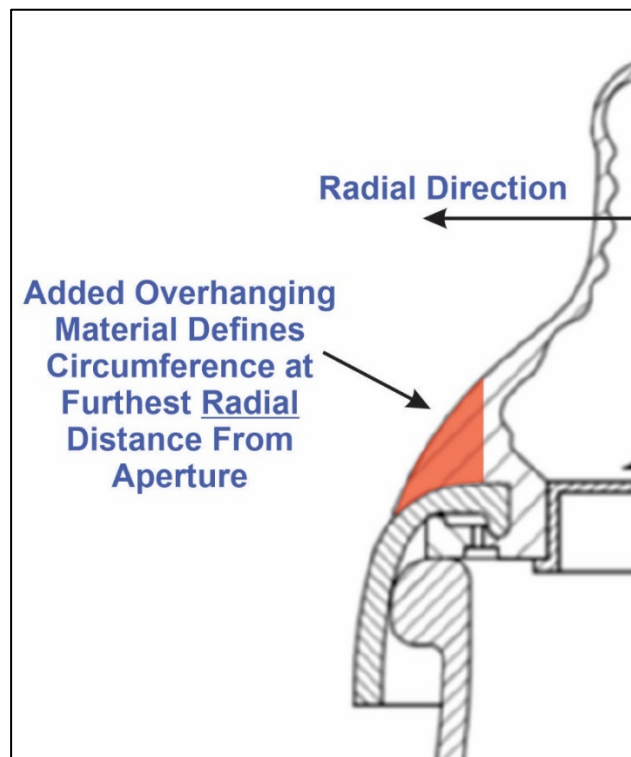
check valve 130 is provided near the base portion 112”); *see also id.*, [0008] (“an artificial nipple . . . wherein the aforesaid internal pressure adjusting means is formed by a check valve”), EX2042 (Fletcher Dec.), ¶63 (“Ishimaru repeatedly refers to the check valve 130 as a component of the nipple 100, which is how a POSITA would have interpreted the design shown in Ishimaru’s figures.”), ¶64 (explaining “why the check valve must seal against the lower surface of the flange”). As shown below, it is Ishimaru’s check valve, not the flange, that provides the nipple circumference furthest from the aperture in the axial direction. EX2042 (Fletcher Dec.), ¶63.



Pet., 39 (Petitioner’s annotated figure with additional annotations in red).

Given Ishimaru’s clear deficiency from the axial perspective, perhaps Petitioner’s intent was to rely on the fact that Ishimaru’s Figure 1 shows the flange as the largest nipple diameter. Because the flange is the largest diameter and the teat

(“mouthpiece”) is the narrowest diameter, Petitioner might reasonably assert that the flange is the nipple circumference that is furthest *radially* from the teat aperture. But even this theory fails. After all, Petitioner’s combination of Ishimaru and Kurkjian changes the shape of Ishimaru’s nipple. As a result of Petitioner’s modifications in the Ishimaru-Kurkjian combination, the flange is no longer the largest diameter, and it does not define a circumference that is furthest radially from the teat aperture. Instead, as shown below, the overhanging material Petitioner added to Ishimaru’s nipple defines the radially furthest circumference. *See* EX2042 (Fletcher Dec.), ¶65.



Pet., 30 (Petitioner’s combination drawing with added annotations). Petitioner cannot have it both ways. It cannot rely on Ishimaru’s unmodified nipple to satisfy the “flange” limitation of the ’244 Patent’s claim 21, only to modify the nipple later

in an attempt to reach the “domed shape” limitation of the very same claim.

To sum up, the Petition’s cursory one-paragraph analysis and annotated figure are not enough to carry its burden of proof on the “flange” limitation. Even Petitioner’s expert, Mr. Silver, could not put the pieces together in deposition while staring at a virtually identical paragraph of his declaration. What’s more, even if the Petition had articulated a reasonably clear position, that hypothetical position would not withstand scrutiny. The flange in Petitioner’s Ishimaru-Kurkjian combination does not in any way “defin[e] the nipple circumference furthest from the [mouthpiece] aperture.”

3. Ishimaru and Kurkjian both lack a nipple-collar assembly defining a “domed shape”

Yet another limitation missing from Petitioner’s prior art is a collar and lower portion of the nipple that “together define a downward *domed shape*.” EX1003 (’244 Pat.), 8:16-17; *see generally* EX2042 (Fletcher Dec.), ¶¶67-89. The Board’s Institution Decision adopts the District Court’s construction of “domed shape” as “wide circular bottom with an arc-shaped cross-sectional profile.” *See* Inst. Dec. at 15 (citing EX2008 (*Markman* Order) at 15). As the Board aptly observed, the District Court’s “*Markman* Order provided a thorough and reasoned explanation of the construction, citing evidence and argument submitted by both parties.” *Id.* Patent Owner agrees and requests that the Board again adopt the District Court’s

construction in the upcoming Final Written Decision. Petitioner was well aware of this construction but glossed over it in the Petition. Specifically, Petitioner failed to address the “**wide** circular bottom” aspect of the construction, which is entitled to patentable weight and distinguishes prior art like Ishimaru and Kurkjian.

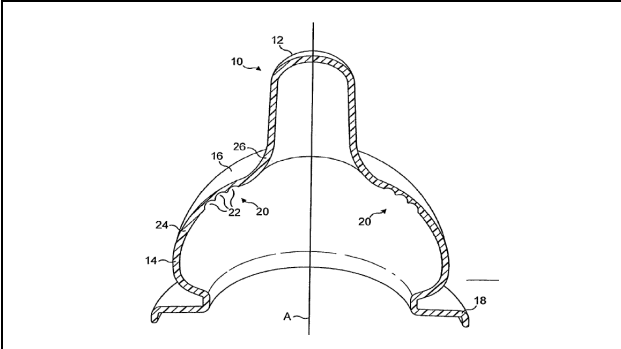
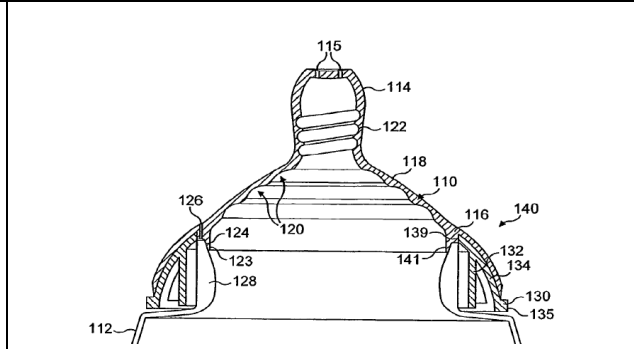
i. The word “wide” in the adopted “domed shape” construction distinguishes conventional nipple shapes

The District Court’s claim construction analysis is drawn from the ’244 Patent’s specification, which describes the base/lower portion of the nipple as “being shaped like a breast and having a **wide**, domed configuration.” EX1003 (’244 Pat.), 4:3-5. Thus, “the specification supports the use of ‘wide’” in the construction of “domed shape.” EX2008 (*Markman* Order) at 13. The specification also shows that “wide” carries an important meaning that distinguishes the ’244 Patent’s “domed shape” from conventional nipple shapes. *See* EX2042 (Fletcher Dec.), ¶¶69-78.

In common parlance, “wide” means having a greater than typical lateral extent or width. EX2029, p.3 (defining “wide” as “of great or more than average width”). And that’s how the term is used in the specification. By describing the nipple shown in the ’244 Patent’s Figure 4 as having a domed base that is “wide,” the specification is saying that the wide base has a larger diameter than a typical baby bottle nipple, one that more closely replicates the characteristic anatomical shape of a human breast. *See* EX1003 (’244 Pat.), 4:3-5 (“shaped like a breast”); EX2042 (Fletcher

Dec.), ¶¶70-71 (explaining that a breast-like shape in this context refers to a shape that approximates the anatomy of a typical human breast). A skilled artisan familiar with the landscape of pre-existing nipples would have appreciated that the Figure 4 embodiment matches this description and understanding of “wide.” *See* EX2042 (Fletcher Dec.), ¶70.

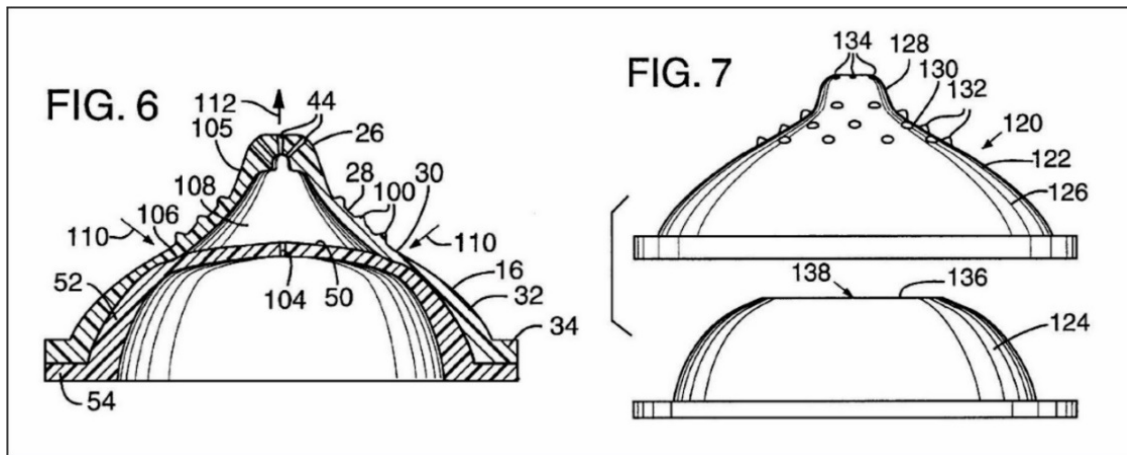
The ’244 Patent further solidifies the skilled artisan’s understanding of “wide” by juxtaposing a conventional nipple shape in Figure 1 (and also Figures 2a-2b) against a domed configuration in Figure 4. Only the Figure 4 embodiment is described as “domed” and “wide.” EX1003 (’244 Pat.), 4:3-5. The Figure 1 embodiment, by contrast, carries no such description because the nipple shown there has a conventional shape that resembles popular products on the market before the ’244 Patent. *See* EX2042 (Fletcher Dec.), ¶72-73 (“[T]he Figure 1 nipple looks quite similar to known products on the market made by major manufacturers, such as the AVENT Classic baby bottle nipple[.]”).

Conventional Nipple Shape '244 Patent (Figure 1)	Breast-Like Nipple Having a Base With a Wide, Domed Shape '244 Patent (Figure 4)
	

Just as a skilled artisan would have appreciated the distinction between Figure 1's conventional nipple shape and the wide, domed shape and configuration of Figure 4, so too did Petitioner's counsel. During the District Court's *Markman* hearing, Petitioner's counsel emphasized that Figure 4 is "the breast-shaped wide embodiment" while "the other embodiment, this figure 1 embodiment," has "a different type of shape." EX2043 (*Markman* Tr.), 80:15-81:5; *see also id.*, 142:3-15 ("So, figure 4 is what we're talking about here, because that's what discloses the specific [domed] structure that's claimed here. That's what's relevant."); *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1376 (Fed. Cir. 2022) ("party admissions . . . are permissible evidence in an *inter partes* review"); *Hanson v. Waller*, 888 F.2d 806, 814 (11th Cir. 1989) (finding litigation-related admissions by counsel admissible).

The distinction between the conventional nipple shape of Figure 1 and the "wide," "domed" nipple shape of Figure 4 is no coincidence. They are two different embodiments. *See* EX1003 ('244 Pat.), 2:31-32 ("FIG. 1 is a cross-sectional side view of a teat according to the present invention[.]"), 2:39-40 ("FIG. 4 is a cross-sectional side view of a teat and vessel according to ***another aspect*** of the present invention[.]"). And these different embodiments were disclosed in different priority applications. The Figure 1 embodiment traces back to GB 0414560.3 filed June 29, 2004, while the Figure 4 embodiment traces back to GB 0502599.4 filed February 8, 2005. *Compare* EX2022, *with* EX2023.

Prior art cited on the face of the '244 Patent provides even further intrinsic evidence¹ that the meaning of “wide” in the “domed shape” construction connotes a base or lower portion of the nipple that is wider than a conventional nipple design. See EX2042 (Fletcher Dec.), ¶¶74-78. For example, U.S. Pat. No. 6,161,710, which issued on December 19, 2000 to Dieringer, et al. and bears the title “Natural Nipple Baby Feeding Apparatus,” touts the superiority of a “wide” nipple design—e.g., one “having a width approximately double that of the height of the nipple apparatus.” EX2024, 1:10-17, 5:38-50 (“[D]ue to the *wide diameter*, color, texture pliancy, stretchability and shape of the outer membrane, an infant will recognize and be comfortable with the nipple apparatus of the present invention.”), Figures 6-7 (pictured below); see also EX1003 ('244 Pat.), [56] (listing the Dieringer Patent).



¹ *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (“[P]rior art . . . cited in the prosecution history . . . constitutes intrinsic evidence.”).

By contrast, older nipples like those pictured below “do not look or feel like a natural breast” because they have “a width much narrower than a natural breast.” EX2024, 2:28-41; *see also* EX2042 (Fletcher Dec.), ¶¶77-78 (“[N]one of these nipples has a wide base with a domed shape that resembles the anatomical shape of a human breast like the ’244 Patent’s Figure 4 or the nipples in the Dieringer Patent.”). Unlike a “wide” breast-like nipple, “once the infant is comfortable with bottle feeding [using these older, narrower nipples] the infant will often encounter ‘nipple confusion’ upon returning to breastfeeding.” EX2024, 2:28-41; *see also* EX2031 (discussing “nipple confusion”).



Accordingly, the intrinsic and extrinsic evidence not only supports inclusion of “wide” in the construction of “domed shape,” just as the District Court concluded and the Board affirmed, but the evidence also supports an understanding of “wide” as requiring a diameter larger than that of a conventional baby bottle nipple, such that the nipple approximates the anatomical shape of the part of a typical human breast with which the infant interacts during feeding.

ii. *The word “wide” in the adopted “domed shape” construction deserves patentable weight*

In its discussion of the word “wide” from the “domed shape” construction, the Board’s Institution Decision cites *In re Rose*, 220 F.2d 459, 463 (C.C.P.A. 1955), for the proposition that “[c]hanges in the size and proportion do not render a product patentable unless it performs differently.” Inst. Dec. at 25. That case involved claims to “a lumber package,” and the Court rejected the patent applicant’s attempt to overcome prior art disclosing lumber packages that “can be lifted by hand” based on the claims’ requirement “that the package is of appreciable size and weight so as to require handling by a lift truck.” 220 F.2d at 460, 463. The present case before the Board is distinguishable from *In re Rose* in multiple important respects.

First, “wide” in this case is distinguishable from “the size of the article” in *In re Rose*. 220 F.2d at 463. Instead of a mere change in *size*, the word “wide” in the adopted construction is used to describe the “domed *shape*” of a baby bottle nipple—i.e., a shape comprised of a “wide circular bottom with an arc-shaped cross-section profile.”

Second, in the context of defining the ’244 Patent’s nipple shape, “wide” is a performance-enhancing feature. See EX2042 (Fletcher Dec.), ¶71. As the specification explains, a nipple with a base/lower portion “having a wide, domed configuration” is “shaped [more] like a breast” than conventional designs. EX1003

(’244 Pat.), 4:3-5; *compare id.*, Figure 4, with Figure 1. Accordingly, “the experience of the infant is as similar as possible to the natural experience of breast feeding.” *Id.*, 4:10-12. This similarity between the baby bottle nipple and the anatomy of a human breast encourages a natural latch and prevents nipple confusion when switching between bottle and breast. *See* EX2042 (Fletcher Dec.), ¶71.

Notably, Petitioner’s expert, Mr. Silver, obtained a United States patent that critiqued the “specific shape” of a “conventional artificial nipple” and sought an improved design “that more closely mimics that of a natural breast.” EX2020, 1:52-2:5. Accordingly, when asked whether “it [is] fair to say that the nipple shape can be important to how a nipple functions,” Mr. Silver answered unequivocally, “Yes.” EX2033 (Silver Tr.), 72:13-16.

Finally, *In re Rose* was an appeal from a decision by the Board to uphold an examiner’s rejection during *ex parte* prosecution. The posture of this case is different. This case is an adversarial *inter partes* review proceeding, where the petitioner owns the burden of proof. *See* 35 U.S.C. § 316(e) (“the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence”). To the extent Petitioner relies on a theory that the construed “domed shape” limitation—specifically, the word “wide”—deserves no patentable weight due to a lack of performance utility, it is Petitioner who must prove the lack-of-utility premise; Patent Owner is not burdened with disproving it. *See In re Magnum Oil*

Tools Int'l, Ltd., 829 F.3d 1364, 1376 (Fed. Cir. 2016) (“[I]t is inappropriate to shift the burden to the patentee after institution to prove that the patent is patentable.”); *see also Gardner v. TEC Sys.*, 725 F.2d 1338, 1345 (Fed. Cir. 1984) (en banc) (explaining that whether the limitations at issue have “no effect on [] performance” is “of course, a fact which [the patent challenger] had the burden of proving”).

Petitioner was well acquainted with Patent Owner’s proposed, and now adopted, “domed shape” construction when it filed its Petition. Indeed, the Petition acknowledges and cites Patent Owner’s claim construction briefs, which emphasize the word “wide”. *See* Pet., 15-16; EX1017 (Mayborn’s Claim Construction Brief), 8-9; EX1019 (Mayborn’s Claim Construction Reply). Despite its knowledge of the construction and statutory burden of proof, Petitioner did not argue in the Petition that “wide” in the “domed shape” construction lacks patentable weight. Instead, the Petition states “whether the terms of the ’244 Patent are afforded Patent Owner’s or Petitioner’s construction, the grounds render the claims obvious,” (Pet., 16), and argues the “domed shape” limitation is “explicitly taught by Kurkjian,” (*id.*, 40).

It is now too late for Petitioner to raise and support a new theory that the “wide” aspect of the adopted “domed shape” construction lacks patentable weight due to a lack of utility. *See, e.g., Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369-1370 (affirming the Board’s refusal to consider a new obviousness theory “raised for the first time in [the petitioner’s] reply brief and

expert declaration”); *GN Hearing A/S v. Oticon A/S*, IPR2017-01926, Paper 39 at 37 (PTAB Mar. 4, 2019) (“We observe that Petitioner has argued in its Reply for the first time that language recited in claim 7 amounts only to aspirational intended use entitled to no patentable weight. This construction was not argued in the Petition. Petitioner cannot introduce a new argument in a reply.” (cites omitted)).

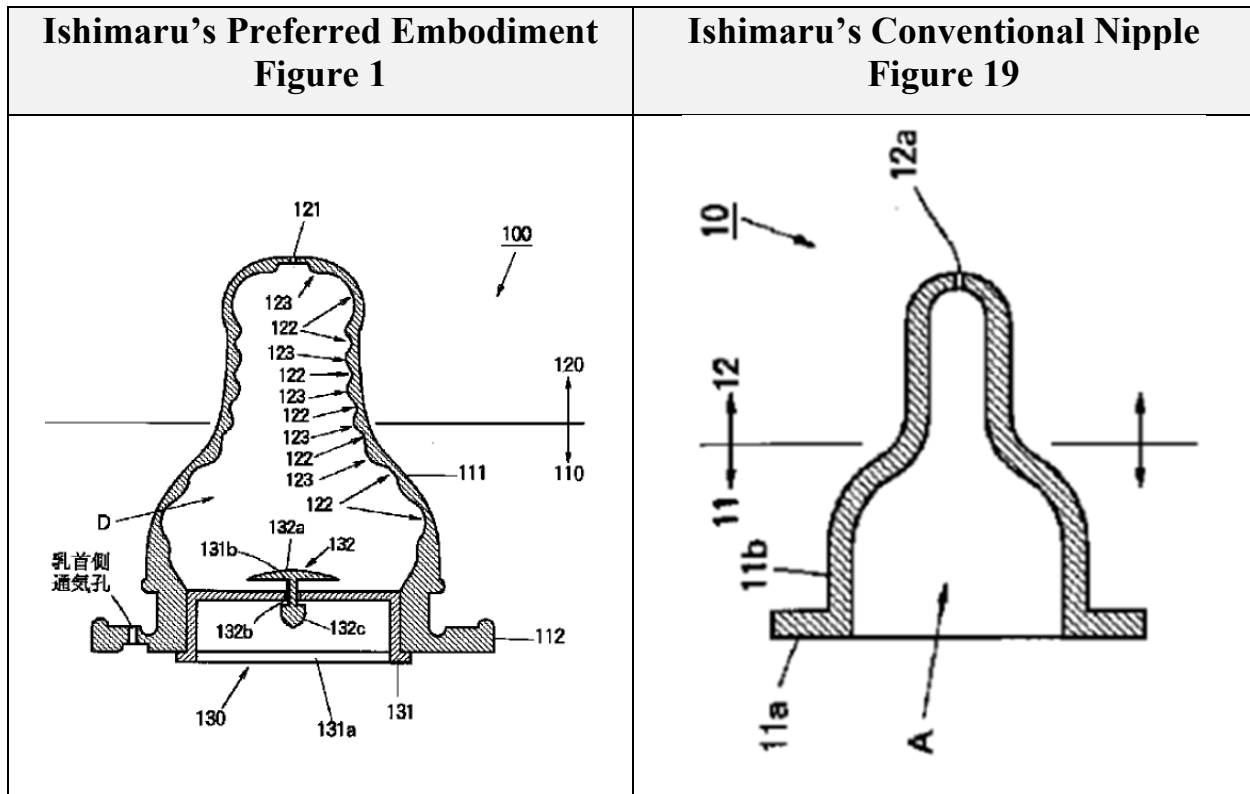
Given the substance and posture of this case, the word “wide” in the adopted “domed shape” construction deserves patentable weight.

iii. Petitioner concedes that Ishimaru fails to provide the “domed shape” limitation

Everyone agrees “Ishimaru does not explicitly disclose” the ’244 Patent’s “domed shape” limitation. Pet., 40. The Petition concedes this point outright. And while the Petition does not itemize Ishimaru’s conceded deficiencies, they are readily apparent. EX2042 (Fletcher Dec.), ¶¶79-81.

For one, Ishimaru cannot disclose a collar and lower nipple portion that “**together** define a downward domed shape” because Ishimaru does not provide any meaningful details regarding a collar. See EX2042 (Fletcher Dec.), ¶80. All Ishimaru says is that the nipple can be “fixed using a detachable feeding mounting cap (now shown in the figure), which is used when mounting the artificial nipple to the feeding bottle.” EX1008 (Ishimaru), [0054] (reference numbers omitted).

Ishimaru also does not teach a nipple-collar assembly with a “domed shape” because the lower portion of Ishimaru’s nipple is not “wide” in the manner of the ’244 Patent. *See* EX2042 (Fletcher Dec.), ¶81. The crux of Ishimaru’s disclosure is providing a nipple that flexes “more evenly” throughout the nipple teat and trunk. EX1008 (Ishimaru) at [0046]; *see also id.*, [0004]. In other words, Ishimaru set out to change the flexing/elongation pattern of the nipple, not its shape. *See* EX2042 (Fletcher Dec.), ¶81. This understanding of Ishimaru is confirmed by observing that the nipple of Ishimaru’s preferred embodiment in Figure 1 (*see id.*, [0037]) has a substantially similar shape to the “conventional” nipple depicted in Ishimaru’s Figure 19 (*see id.*, [0002]).



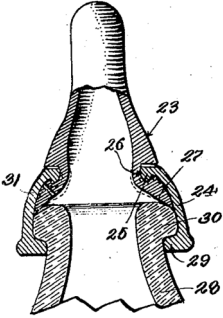
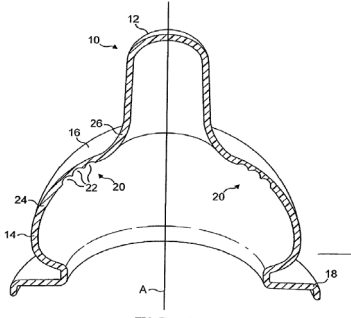
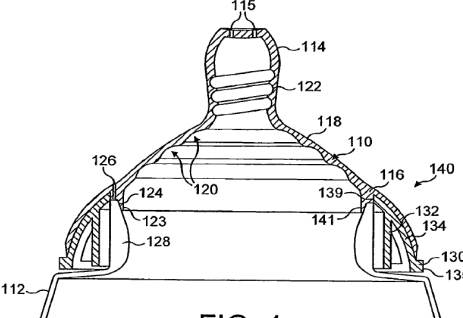
- iv. *Kurkjian's nipple-collar assembly cannot be "domed" because it is far narrower than conventional nipples*

Given Ishimaru's conceded deficiency on the "domed shape" limitation, Petitioner turns to Kurkjian. *See* Pet., 40-41 ("Such a modification is explicitly taught by Kurkjian[.]"); Inst. Dec. at 23 ("Petitioner relies on Kurkjian . . ."). But the Petition's analysis of Kurkjian gives no substantive consideration to the word "wide" in the now-adopted construction of "domed shape." *See* Pet., 40-41; EX1005 (Silver Dec.) ¶¶411-412 (same). The Petition does not address the "domed shape" construction at all, which is remarkable because Petitioner knew about the construction from the district court litigation and attempted to address other such constructions throughout the Petition.

Ignoring the construction entirely, the Petition quotes Kurkjian's disclosure that the contour of the collar "conforms to the contour of the nipple" and concludes from there that Kurkjian's "Fig. 6 illustrates to a POSA a collar and lower portion of the nipple in a downward domed shape." Pet., 40-41. Nothing could be further from the truth. Kurkjian's nipple is not "domed" in any sense of the word. The base portion of Kurkjian's nipple and the collar have the shape of a relatively narrow cone rather than a dome, which is why Kurkjian describes the collar as "conical." EX1009 (Kurkjian), 3:29-37. To be clear, no skilled artisan could reasonably view the nipple-collar shape in Kurkjian's Figure 6 as a "dome." *See* EX2042 (Fletcher Dec.), ¶84

(“A POSITA would immediately see that Kurkjian’s nipple is not ‘domed[.]’”), ¶¶85-86 (explaining the context and history behind Kurkjian’s design).

Kurkjian’s shortcoming is even more apparent when viewed through the lens of the adopted construction. *See* EX2042 (Fletcher Dec.), ¶¶87-89. A “domed shape” requires a “**wide** circular bottom,” which Kurkjian does not disclose. Indeed, the bottom of Kurkjian’s nipple-collar assembly is exceedingly narrow, far more so than (A) Ishimaru’s conventional nipple shape; and (B) the conventional nipple shape depicted in the ’244 Patent’s Figure 1, which is **not** wide or domed. *See* EX2042 (Fletcher Dec.), ¶87; *see also* EX2043 (Markman Tr.), 80:15-81:5 (Petitioner’s counsel admitting Figure 4 is “the breast-shaped wide embodiment” while the Figure 1 embodiment has “a different type of shape”), 142 (Petitioner’s counsel admitting Figure 4 is “what’s relevant” to the “domed shape” limitation).

Kurkjian—Figure 6 Not Wide or Domed	'244 Patent—Figure 1 Not Wide or Domed	'244 Patent—Figure 1 Wide and Domed
	 FIG. 1	 FIG. 4

Kurkjian’s nipple from the 1930s fits the description of what the Dieringer Patent characterized as an older nipple that is “much narrower” than a “wide” design and

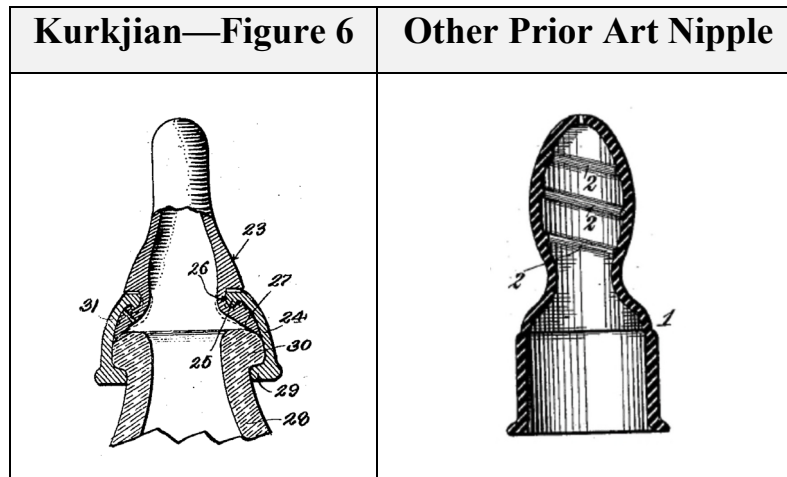
likely to cause nipple confusion. EX2024, 2:28-41; *see also* EX2042 (Fletcher Dec.), ¶86.

The best Petitioner might argue is that the Kurkjian’s nipple-collar assembly is wider than the teat. But that view is wrong for multiple reasons. First, it relies on an interpretation of “wide”—i.e., wider than any other portion of the nipple—that finds no support in the specification and defies a skilled artisan’s understanding of the ’244 Patent. *See* EX2042 (Fletcher Dec.), ¶89.

Second, this analytical framework breaks down when put to the test. For example, Mr. Silver attempted to employ a wider-than-the-teat framework under cross-examination, and it led him to a dead-end. When asked “how much wider does the base need to be from the teat portion for it to be a nipple with a wide base,” Mr. Silver said, “I don’t have an exact dimension.” EX2033 (Silver Tr.), 139:5-14. When asked more simply for “any sort of metric at all by which we could understand how to make that [wide] determination in your review,” Mr. Silver said, “I don’t have a definitive answer.” *Id.*, 139:15-21. When given yet another opportunity to provide “any other words . . . that would help someone understand how you make that [wide] determination,” Mr. Silver said, “Not at this time.” *Id.*, 140:3-7.

Making matters worse, it is clear that Mr. Silver’s wider-than-the-teat framework would force him to adopt conflicting positions. On the one hand, Mr.

Silver must say Kurkjian’s nipple below on the left *is* wide², but on the other hand, he said during deposition that the similar prior art nipple below on the right *is not* wide. See EX2033 (Silver Tr.), 179:17-180:22.



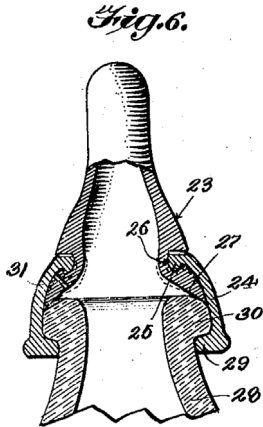
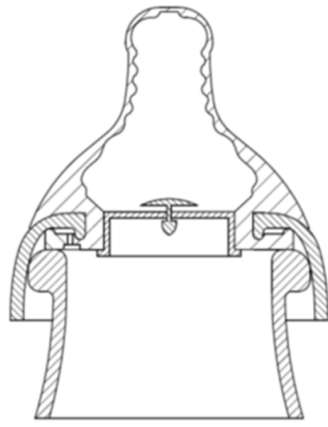
In each case, the base of the nipple is “just slightly bigger than the . . . teat portion of the nipple,” (*id.*), yet Mr. Silver could call only one of them “wide” in the manner of the “domed shape” limitation.

Third, if a nipple base with a “domed shape” were simply wider than the teat/areola and nothing more, then the ’244 Patent’s Figure 1 would have been described as such, but it is not. In fact, virtually every 21st century nipple would be described as having a “wide,” “domed” shape, and those terms would carry no meaning at all. See EX2042 (Fletcher Dec.), ¶89. But words like “wide” and

² Mr. Silver’s declaration does not actually say that Kurkjian’s nipple is wide. EX1005 (Silver Dec.) ¶¶411-412. This argument is addressing a hypothetical.

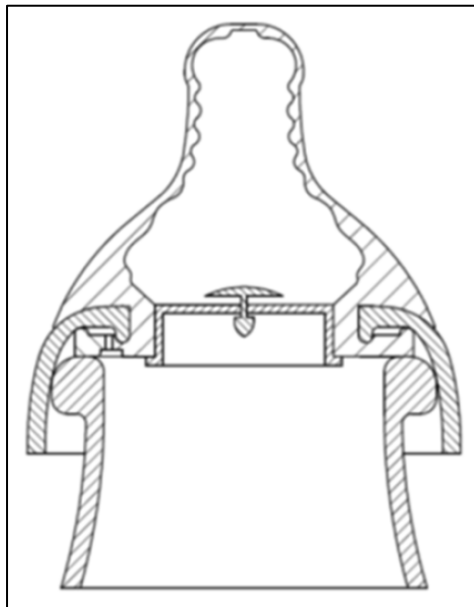
“domed” *do* carry meaning in the art, and skilled artisans use them selectively, just as Mr. Silver did in his own patent. *See* EX2020, 6:45-54 (describing the nipple of Figure 3 as having a “dome-shaped body”), 8:23-24 (describing the nipple of Figure 10 as having “a dome-like structure”), 5:11-6:30 (describing the nipple of Figure 1 with no mention of any “dome” or “domed” aspects).

Finally, if all these reasons were not enough, Petitioner undercuts its own assertion that the “domed shape” limitation is “explicitly taught by Kurkjian,” Pet., 40, via its fabricated drawing of the Ishimaru-Kurkjian combination. As shown below, Petitioner’s combination drawing is much wider in the lower portion of the nipple and collar than what Kurkjian discloses. If Petitioner really thought Kurkjian disclosed a nipple-collar assembly that defines a “domed shape,” then Petitioner’s combination drawing would have employed the shape Kurkjian actually taught. The fact that Petitioner diverged from Kurkjian’s shape is telling.

Kurkjian—Figure 6	Petitioner’s Combination Figure
	

4. Petitioner draws its Ishimaru-Kurkjian combination from impermissible hindsight with no legally sustainable motivation

As discussed, Petitioner concedes that Ishimaru fails to provide the claimed “domed shape” limitation (*supra*, §III.A.3.iii), and Kurkjian’s even narrower nipple-collar design also does not fit the bill (*supra*, §III.A.3.iv). Yet, somehow, Petitioner purports to have combined two references without a domed nipple-collar assembly and arrived at an Ishimaru-Kurkjian combination drawing that the Board’s Institution Decision describes as “a [nipple-collar] structure that has a wide bottom with an arc-shaped profile.” Inst. Dec. at 28; Pet., 30.



Pet., 30 (Petitioner’s combination drawing). The peculiar nature of this combination drawing—which incorporates a “domed shape” feature that the constituent prior art references lack—warrants scrutiny. As revealed below, however, Petitioner’s explanation just doesn’t add up. *See generally* EX2042 (Fletcher Dec.), ¶¶90-106.

i. Kurkjian's "streamline type connection" does not support Petitioner's combination drawing

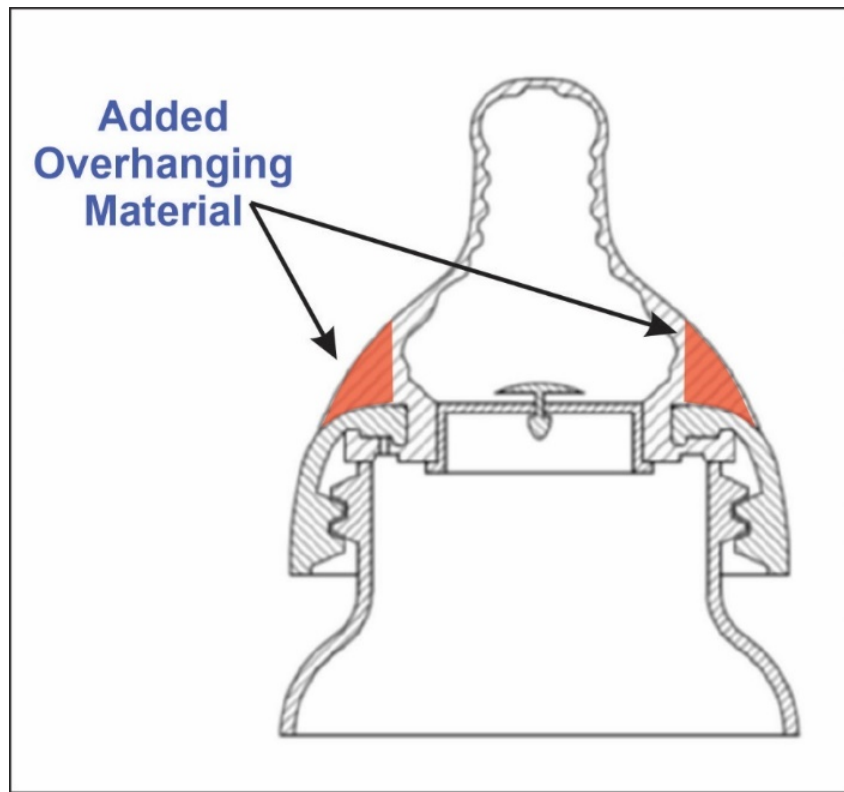
Petitioner's discussion of the Ishimaru-Kurkjian combination relies chiefly on the following description of Kurkjian's Figure 6:

The outer face of the 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.

EX1009 (3:42-46); *see also* Pet., 21 (quoting the above excerpt), 26 (same), 40 (same). Recognizing as much, the Board's Institution Decision observed that Petitioner's combination drawing provides "a streamlined transition" between the nipple and collar, which abides Kurkjian's teaching of a "streamline type connection." Inst. Dec. at 28-29 (quoting EX1009 (Kurkjian), 3:41-46).

That said, the "streamlined" nature of the nipple-collar assembly only pertains to the '244 Patent's claim language that requires the nipple and collar to "**together** define" a shape. "Streamlined," however, does not mean the defined shape formed by the nipple-collar assembly is a "**domed** shape," which neither Ishimaru nor Kurkjian disclose. *See* EX2042 (Fletcher Dec.), ¶92. As for the remainder of the Kurkjian quote that the "cap 24 preferably conforms to the contour of the nipple 23," (EX1009 (Kurkjian), 3:41-46), applying this teaching to Ishimaru would not change the shape of Ishimaru's **nipple**. To wit, Kurkjian instructs the POSITA to conform the **collar** ("cap 24") contour "to the contour of the nipple," which means the collar

shape conforms to the nipple shape, not the other way around. *See* EX2042 (Fletcher Dec.), ¶92 (“[T]hat teaching has nothing to do with the nipple. It is about the collar.”). Kurkjian’s teaching about the shape of the *collar* lends no support to Petitioner’s modification of Ishimaru’s *nipple*, which adds a thick, downwardly sloping mass of material overhanging the flange to make the base appear “domed.”



Pet., 30 (Petitioner’s combination drawing with added annotations).

Mr. Silver confirmed this disconnect between Kurkjian’s “streamline” disclosure and Petitioner’s combination drawing during deposition. There, Mr. Silver testified that Kurkjian’s figures, the subject of the “streamline” disclosure, lack the overhanging material introduced in Petitioner’s combination drawing.

Q. Okay. That sort of overhang isn't contemplated by Kurkjian, fair?

A. Kurkjian doesn't show an overhang in Figure 6.

Q. It doesn't show it in Figure 7 either, right?

A. Or in Figure 7.

Q. Right. In fact, it isn't in any of the figures, isn't that fair, sir?

A. Yes.

See EX2033 (Silver Tr.), 211:12-21; *see also generally id.*, 208:14-211:21.

A faithful application of Kurkjian's "streamline" teaching would have left Ishimaru's conventional nipple shape in place and changed the shape of the collar to match it. See EX2042 (Fletcher Dec.), ¶92. The Petition unwittingly concedes this point by stating that Kurkjian's teachings would have motivated a skilled artisan "to modify the shape of the *collar* in Ishimaru." Pet., 28. But just applying Kurkjian's collar to Ishimaru's nipple would not have served Petitioner's purpose of meeting the "domed shape" limitation, so Petitioner did something different. Petitioner *radically* changed the shape of Ishimaru's nipple, which neither reference suggests. See EX2042 (Fletcher Dec.), ¶93 ("To be clear, I am not using hyperbole when I say that Petitioner and Mr. Silver made a 'radical' change to Ishimaru's nipple. I have never seen a nipple that looks anything like Petitioner and Mr. Silver's combination drawing.").

ii. *Ishimaru's pursuit of a breast-like nipple does not support Petitioner's combination drawing*

Just as Petitioner's radical change to Ishimaru's nipple lacks support from Kurkjian, it likewise finds no support in Ishimaru's stated objective of providing a more breast-like nipple. *See* EX2042 (Fletcher Dec.), ¶¶94-96.

The Board's Institution Decision cites Mr. Silver's testimony that "[a] POSA would understand *this* to include a wide, domed-shaped [sic] that would appear to a baby or child to imitate a human breast." EX1005 (Silver Dec.) ¶413; *see also* Inst. Dec. at 27-28 (quoting the same). By "*this*," Mr. Silver refers to his interpretation of Ishimaru's "primary objective . . . to create a nipple that is more human and breast-like," as summarized in Section XIII.A of his declaration. EX1005 (Silver Dec.) ¶413. In Section XIII.A, Mr. Silver's declaration explains that Ishimaru's view of breast-like includes "a shape similar to a mother's breast and nipple as shown in Fig. 1" and "elongat[ion] in the same way as the mother's nipple" by adding "thin-walled portions . . . in a groove-like pattern." EX1005 (Silver Dec.) ¶356 (quoting EX1008 (Ishimaru) at [0041], [0048]). These aspects of Ishimaru do not support Petitioner's modification of Ishimaru's nipple.

To start, Petitioner's reasoning is circular. It makes no sense to rely on Ishimaru's nipple "as shown in Fig. 1" to support Petitioner's modification of that same nipple shape. As discussed, the "shape" of the nipple in Ishimaru's Figure 1

is not materially different from the conventional nipple shape that Ishimaru shows in Figure 19. *See* EX2042 (Fletcher Dec.), ¶96 (“Ishimaru does not give any reason to depart from that shape[.]”). The addition of thin-walled portions on the interior of the nipple likewise has no impact on the conventional shape of Ishimaru’s nipple. *See id.* (“A POSITA would understand that the addition of thin-walled portions on the *interior* of the Ishimaru’s nipple has no impact on the nipple’s conventional *outer* shape.”). Petitioner’s failure to provide a legitimate explanation for why Ishimaru’s teaching of a conventional nipple shape with thin-walled portions would inspire a skilled artisan to employ “a wide, dome-shaped” nipple-collar design is hardly a surprise. No such explanation exists.

iii. Petitioner’s remaining motivation arguments are equally deficient

None of the remaining arguments in the Petition’s motivation-to-combine discussion fare any better than Petitioner’s misapplication of statements from Kurkjian and Ishimaru.

First, the fact that “[a] POSA would have considered Ishimaru and Kurkjian in the same field of endeavor,” (Pet., 24, 27), is not a legally sustainable motivation for Petitioner’s combination. Petitioner’s Ishimaru-Kurkjian combination is not a simple arrangement of known elements according to their established functions. Rather, Petitioner’s combination includes modifications—namely, the sloping mass

of material overhanging the nipple flange—that neither Ishimaru nor Kurkjian contemplate. In this case, the mere existence of Ishimaru and Kurkjian in the same field of endeavor is not insufficient.

“[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) (original emphasis). That is why the Supreme Court emphasized how “it 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.” *KSR*, 550 U.S. at 418. Petitioner’s same-field-of-endeavor theory does not answer the critical question of *why* a skilled artisan would have arrived at the specific design shown in Petitioner’s combination drawing. 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 skilled artisan would have modified Ishimaru's nipple design.

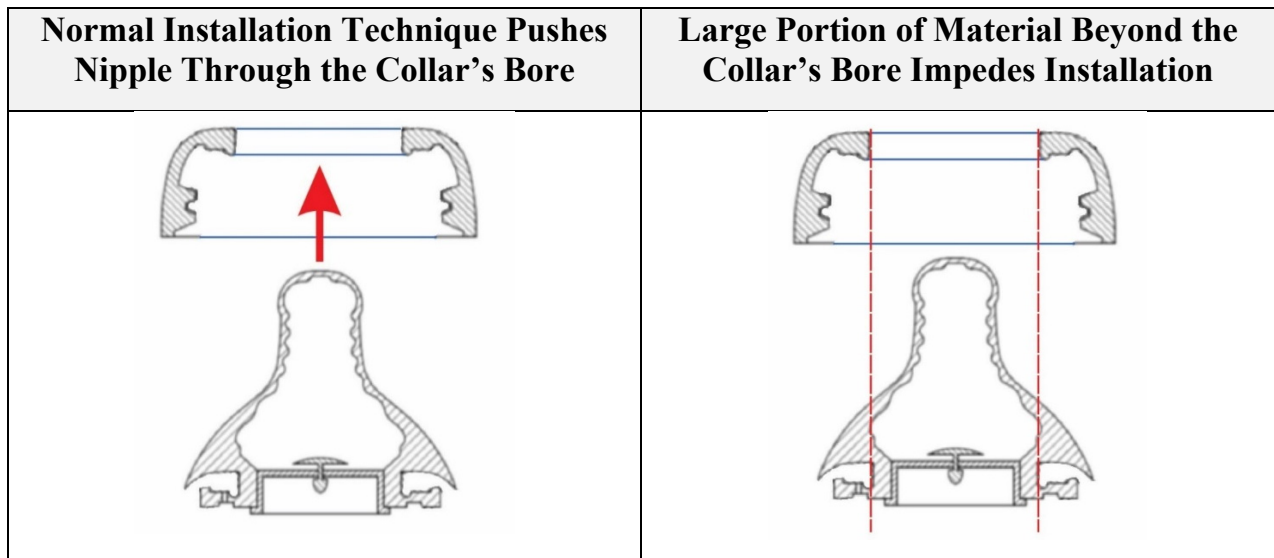
Finally, Petitioner argues that Ishimaru and Kurkjian provide "predictable solutions to solve the problem of designing a realistic, breast-like nipple," and a POSITA "would be motivated to combine and substitute these familiar elements according to known methods to yield predictable results." Pet., 28-29. 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 collar shape with Ishimaru's nipple would not result in a "domed" nipple-collar assembly. *See* EX2042 (Fletcher Dec.), ¶¶85-86, 92.

iv. *The nipple-collar assembly in Petitioner's combination drawing is implausible*

A skilled artisan would not have arrived at the nipple-collar arrangement in Petitioner's drawing because it is implausible and would not work properly compared to conventional designs. Specifically, the mass of material overhanging the flange—which Petitioner added to make the nipple-collar assembly appear “domed”—impedes proper installation of the collar on the nipple.³ See EX2042 (Fletcher Dec.), ¶¶97-106. This fact is perhaps the strongest indicator of Petitioner's improper hindsight bias.

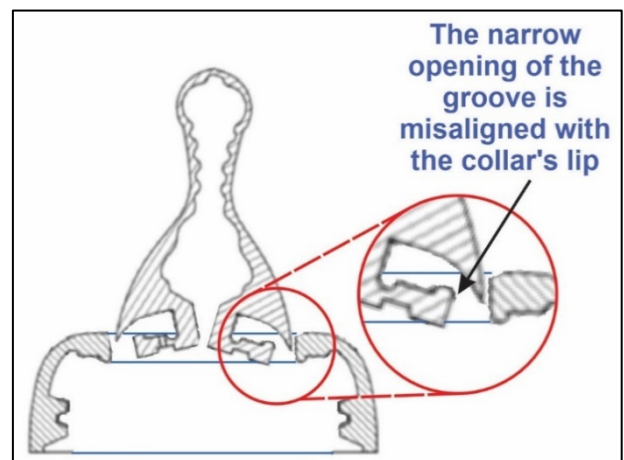
The odd shape of Petitioner's modified nipple frustrates any plausible assembly method that could seat the lip of the collar against the flange of the nipple in the manner shown in Petitioner's combination drawing. As Patent Owner's expert, Mr. Fletcher, explains, Petitioner's design hampers a normal assembly method because it has “a very large portion of the nipple material [that] extends radially beyond the diameter of the collar's central bore,” and “[i]t would be difficult (if possible at all) for the thick mass of added material to compress enough to allow the nipple to pass through[.]” See EX2042 (Fletcher Dec.), ¶¶98-104.

³ Installation is required by the claim language that says the collar is “configured to removably couple to the nipple to seal over the opening of the container.”



Even if Ishimaru's check valve were removed (something Petitioner has not proposed), such that the material could be compressed far enough to fit the nipple through the collar (itself a dubious proposition, EX2042 (Fletcher Dec.), ¶103), installation would still be a challenge. Mr. Fletcher explains why:

Thanks to the thick mass, the opening to the groove is very narrow and oriented at an odd angle that does not align with the upper lip of the collar, as demonstrated in the modified diagram [at right] (blue horizontal lines added to complete the sectional view), where I have magnified the interaction between the collar and nipple.



EX2042 (Fletcher Dec.), ¶104.

Unlike *KSR*'s combination of familiar elements yielding predictable results, Petitioner's combination is improper because it misrepresents and misapplies the teachings ("elements") in the relied-upon prior art to create a quintessentially unpredictable result—a design that likely doesn't work. *See* Inst. Dec. at 27.

While it may seem strange that an experienced artisan like Mr. Silver would produce such an odd and implausible design, that mystery is now solved. Mr. Silver had no hand in creating it. EX2033 (Silver Tr.), 204:15-205:14. He merely "approved it." *Id.* When asked, "[w]ho made that design," Mr. Silver answered "I believe an outside draftsman did the drawing based on input from – from Baker Botts and with my review." *Id.* And when asked "whose idea was it," Mr. Silver confessed he was "uncertain." *Id.* Petitioner's Ishimaru-Kurkjian combination drawing does not reflect how a skilled artisan would have combined the teachings of those references because the drawing was not produced by a skilled artisan.

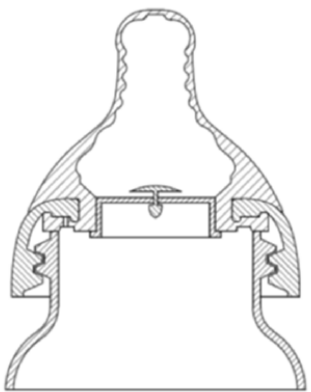
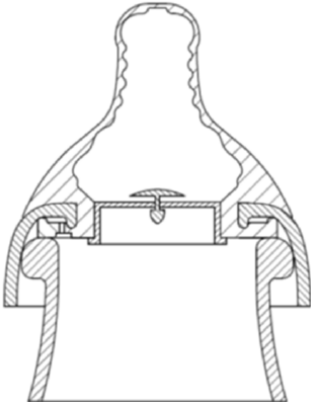
B. Ground 2: The Ishimaru-Atkin Combination's Flaws Are Even More Severe Than Those of Ishimaru-Kurkjian

As with the Ishimaru-Kurkjian combination in Ground 1, the Petition gives no plausible explanation in Ground 2 for *why* a skilled artisan would have created a nipple-collar assembly with a "dome shape" based on the teachings of Ishimaru and Atkin. Ishimaru does not disclose a collar at all, and Atkin's collar is not "domed" because its cross-sectional profile is vertical rather than arc-shaped. Ground 2 also

falls short on the “flex region” and “flange” limitations for all the same reasons as Ground 1. As in Ground 1, Petitioner relies on Ishimaru alone to address these limitations, and Ishimaru is deficient.

1. Petitioner fails to explain why a skilled artisan would have combined Ishimaru and Atkin to achieve a “domed shape”

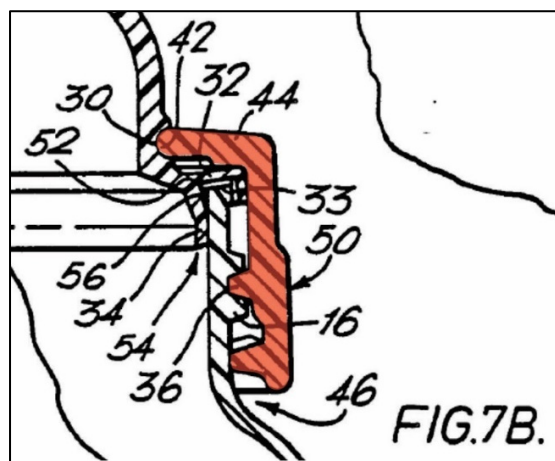
Despite the fact that Ground 1 and Ground 2 pair Ishimaru with totally different secondary references in Kurkjian and Atkin, Petitioner contends a skilled artisan would have arrived at a substantially similar design for both combinations. As shown below, the only material difference between Petitioner’s combination drawings is that the Ground 2 drawing has threads and the Ground 1 drawing does not. These dubious mirror image drawings are yet another telltale sign that Petitioner’s view is distorted by hindsight. An even bigger clue is that, yet again, Petitioner’s motivation rationales fail to support the changes to Atkin’s collar and Ishimaru’s nipple that Petitioner employs for the “domed shape” limitation.

Ishimaru-Atkin Drawing Ground 2, Pet., 51	Ishimaru-Kurkjian Drawing Ground 1, Pet., 30
	

i. Petitioner's modifications of Atkin's collar are unjustified

Petitioner's Ishimaru-Atkin combination diverges from what both references teach regarding the “domed shape” limitation. As discussed, Ishimaru cannot possibly disclose a collar and lower nipple portion that “**together** define a downward domed shape” because Ishimaru does not illustrate or provide any meaningful details regarding a collar. EX1008 (Ishimaru), [0054] (briefly mentioning “a detachable feeding mounting cap (now shown in the figure)”). All parties agree on this point. *See* Pet., 55 (“Ishimaru does not explicitly disclose this limitation.”).

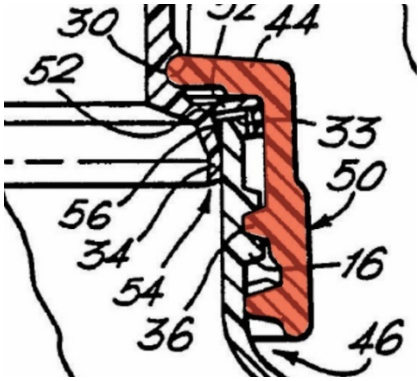
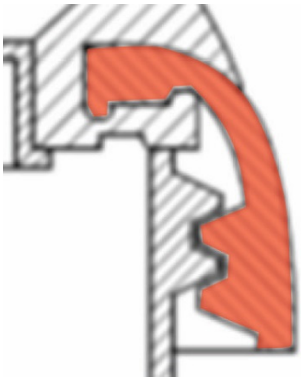
Worse than Ishimaru's silence, Atkin affirmatively teaches a collar design that diverges from the claimed “domed shape.” *See* EX2042 (Fletcher Dec.), ¶122. As shown below, Atkin's collar has a vertical cross-sectional profile that is not even remotely “arc-shaped,” as the District Court's construction requires. *Id.*



EX1010 (Atkin), Figure 7B (collar colored red). Equally problematic, Atkin's assembly has an abrupt change in slope between the nipple and the collar, precluding

any suggestion that the nipple and collar “together” define any particular shape. *See* EX2042 (Fletcher Dec.), ¶115 (“Atkin’s nipple-collar assembly has a curved nipple mated to a vertical collar, with an abrupt change in slope between them.”).

None of Petitioner’s purported reasons for the Ishimaru-Atkin combination explain how or why a skilled artisan would convert Atkin’s collar with a vertical profile into the arced profile shown in Petitioner’s combination drawing. *See* EX2042 (Fletcher Dec.), ¶¶121-125. The Board’s Institution Decision identified this flaw in Petitioner’s case, and the following discussion confirms that the Board was correct. Inst. Dec. at 36.

Atkin, Figure 7B Vertical Collar	Petitioner’s Combination Drawing Downwardly Sloping Collar
	

As in the Ishimaru-Kurkjian combination, the first point in Petitioner’s motivation-to-combine discussion is that “[a] POSA would have considered Ishimaru and Atkin in the same field of endeavor” and “analogous solutions for . . . realistic human-like nipples.” Pet., 45. But, again, these theories answer the wrong

question. They only suggest a skilled artisan *could have* achieved some combination of Ishimaru and Atkin. They do not, however, explain *why* the skilled artisan would have reached the specific design shown in Petitioner’s combination drawing. The Board said it best: “What is not clear to us . . . is why a skilled artisan would have made the particular modification of Atkin’s collar.” Inst. Dec. at 36.

Next, as before, Petitioner touts Ishimaru’s pursuit of a more breast-like nipple as a reason “to modify the nipple design of Ishimaru as taught by Atkin.” Pet., 48-49. Notwithstanding that Petitioner’s logic is circular—it points to Ishimaru’s Figure 1 as a motivation to alter the shape of the nipple shown in Figure 1—it is irrelevant as to the key question of why a skilled artisan would have modified Atkin’s *collar* in the manner Petitioner’s combination drawing shows. See EX2042 (Fletcher Dec.), ¶123-125. Ishimaru does not disclose any details about a collar, and Ishimaru’s discussion of a nipple design provides no reason to change Atkin’s collar.

Petitioner further argues that a skilled artisan “would be motivated to incorporate the domed collar in Atkin in order to modify the shape of the collar in Ishimaru” for the purpose of “improv[ing] the aesthetics of the nipple to provide a realistic, breast-like shape, as taught by Ishimaru.” Pet., 49. This argument falls flat with its premise. As discussed, Atkin does not disclose a “domed collar.” See EX2042 (Fletcher Dec.), ¶122. Nor has Petitioner explained how or why the abstract notion of “aesthetics” would have prompted a skilled artisan to make Atkin’s collar

with vertical sides “domed.” *See* EX2042 (Fletcher Dec.), ¶123. To be clear, the Petition does not allege or suggest that a POSITA would have been motivated to change the shape of Atkin’s collar. Instead, Petitioner wrongly assumes that Atkin’s collar *is* domed. Any attempt by Petitioner to change course by promoting a modification of Atkin’s collar would constitute an impermissible new theory of obviousness.

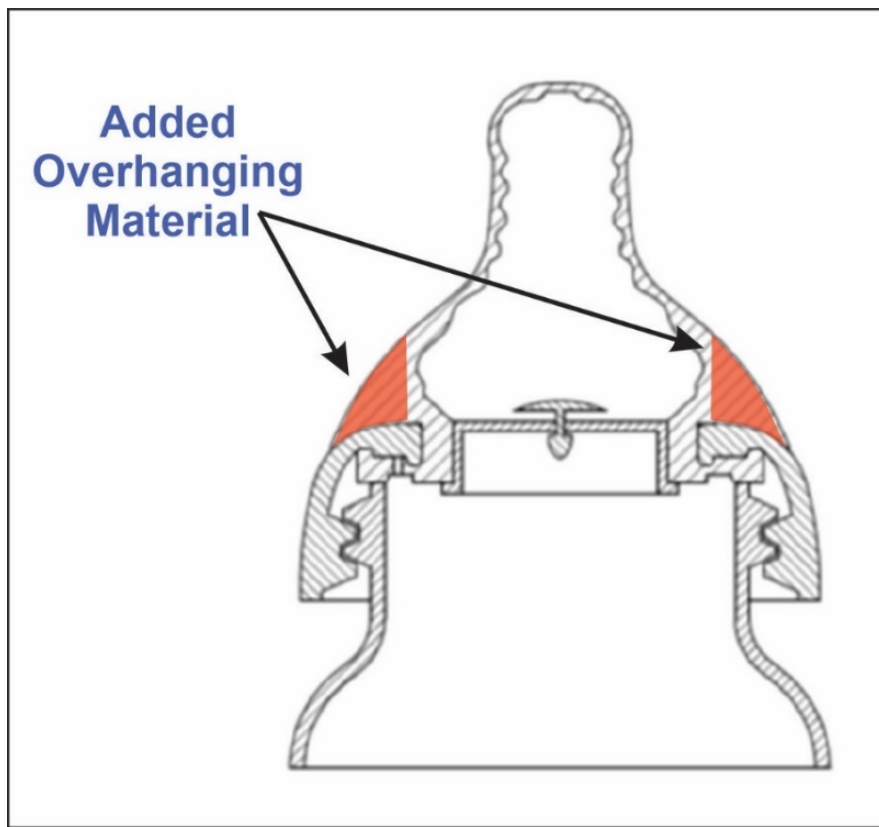
The Board was certainly correct when it said that Petitioner failed to provide the necessary factual predicate for a “design choice” theory. *See* Inst. Dec. at 36 (citing Pet., 57); *see also* Pet., 50. For one, Petitioner and Mr. Silver do not actually identify the alleged “finite number of identified predicable solutions to solve the problem of designing a realistic, breast-like nipple[.]” Pet., 50. Nor do Petitioner and Mr. Silver explain *why* a skilled artisan would have arrived at the specific nipple design shown in their combination drawing. *See Cutsforth, Inc. v. Motivepower, Inc.*, 636 F. App’x 575, 578 (Fed. Cir. 2016) (“The Board must offer a reason for why a person of ordinary skill in the art would have made the specific design choice[.]”).

Besides, even if its design choice assertions were not utterly conclusory (which they are), Petitioner has not even attempted to enlighten the Board as to how the problem of “designing a realistic, breast-like *nipple*” pertains to the all-important question of why a skilled artisan would have departed from Atkin’s teaching of a

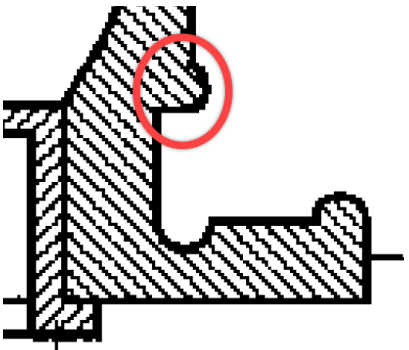
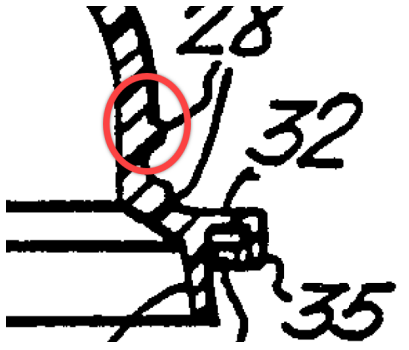
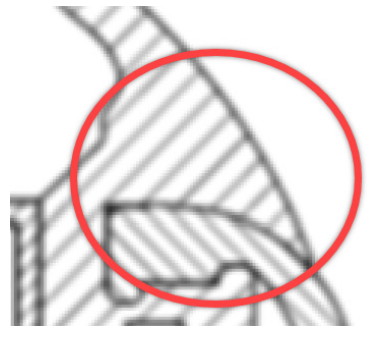
collar with vertical sides and pursued a domed collar. *See AviaGames, Inc. v. Skillz Platform, Inc.*, IPR2022-00531, Paper 13 at 24 (PTAB Aug. 4, 2022) (“KSR buzzwords . . . do not establish “**why** a POSITA would have made this particular change.” (original emphasis)). It is axiomatic, that an alleged problem relating to a nipple does not motivate a change to a collar.

ii. *Petitioner’s modifications of Ishimaru’s nipple are unjustified*

As in Ground 1, Petitioner has no legitimate justification for its radical modification to Ishimaru’s nipple, which, again, frustrates installation with the collar. *See* EX2042 (Fletcher Dec.), ¶¶114-120; EX2033 (Silver Tr.), 211:22-213:2.



Pet., 51 (Ishimaru-Atkin combination drawing with annotations). The added thick, downwardly sloping mass of material overhanging the flange in Petitioner’s combination drawing has no basis in either Atkins or Ishimaru, both of which employ the conventional approach of a small overhanging rim. *See* EX2042 (Fletcher Dec.), ¶¶117-120.

Ishimaru, Figure 1 Small Rim	Atkin, Figure 4A Small Rim	Petitioner’s Combination Drawing Thick Downwardly Sloping Mass
		

Petitioner’s motivation analysis points to Atkins’s use of a “larger teat” to promote “natural feeding.” Pet., 56 (quoting EX1010 (Atkin), 3:10-27; citing EX1005 (Silver Dec.) ¶444). But it does not follow that simply making Ishimaru’s nipple larger like Atkins’s would yield the peculiar shape in the combination drawing. *See* EX2042 (Fletcher Dec.), ¶118 (“There is not a single aspect of Atkins’s nipple that even remotely resembles Petitioner and Mr. Silver’s added thick mass overhanging the flange.”). Petitioner’s motivation analysis also points to Ishimaru’s objective to create a breast-like nipple “as shown in Fig. 1.” *See* Pet., 49 (quoting

EX1008 (Ishimaru) at [0040]⁴); EX1005 (Silver Dec) ¶443 (quoting EX1008 (Ishimaru) at [0041]). But that argument fails here in Ground 2 for the same reasons as in Ground 1—it does not make sense to rely on Ishimaru’s conventional nipple shape in Figure 1 as support for radically changing that very same shape. *See* EX2042 (Fletcher Dec.), ¶¶119-120.

2. Petitioner does not contend that Atkin resolves Ishimaru’s “flex region” and “flange” deficiencies

As discussed regarding Ground 1—*see supra*, §§III(A)(1) and (2)—Ishimaru fails to satisfy the “flex region” and “flange” limitations. *See* EX2042 (Fletcher Dec.), ¶107 (cross-referencing *id.* ¶¶38-57 regarding the “flex region” limitation), ¶108 (cross-referencing *id.* ¶¶58-66 regarding the “flange” limitation). This discussion applies equally to Ground 2 because Petitioner relies on the exact same analysis and does not propose that Atkin is relevant to these limitations in any way. *See* Pet., 54-55.

IV. CONCLUSION

For the foregoing reasons, the Board should confirm the patentability of the ’244 Patent’s claims.

⁴ There is a citation error in the Petition. The quoted language appears at [0041] of Ishimaru, not [0040].

Respectfully submitted,

Date: October 27, 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 Response to Petition totals 12,487, which is less than the 14,000 allowed under C.F.R. §42.24(b)(1).

Respectfully submitted,

Date: October 27, 2023

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e), the undersigned certifies that on October 27, 2023, a complete and entire copy of this Patent Owner's 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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