

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOM ENTERPRISES, LLC,
Petitioner,

v.

ELAINE AND REINHOLD W. VIETH,
Patent Owner

IPR2023-00726
Patent 9,066,958 B2

Record of Oral Hearing
Held: June 18, 2024

Before JOHN G. NEW, SHERIDAN K. SNEDDEN, and CYNTHIA M.
HARDMAN, *Administrative Patent Judges*.

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The above-entitled matter came on for hearing on June 18, 2024, commencing at 10:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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JUDGE HARDMAN: So welcome, everybody. I am Judge Hardman and with me are Judges Snedden and New. This is the final oral hearing in IPR2023-00726, MOM Enterprises, LLC v. Elaine and Reinhold W. Vieth. We have a court reporter present, and the Board will file the transcript in the record in due course.

Let's start with appearances. Counsel for petitioner, please identify yourself and if you have anyone with you.

MR. CONRAD: Good morning. David Conrad on behalf of petitioner.

JUDGE HARDMAN: Good morning, and welcome, Mr. Conrad. Counsel for patent owner?

MR. ANDERSON: Good morning, Your Honors. Alan M. Anderson on behalf of patent owners, Elaine and Reinhold Vieth. And with me is Mr. Mark Ungerman.

JUDGE HARDMAN: Welcome, counsel. There are some pending motions. We don't expect to decide those today. And you're welcome to argue those motions during your portion if you wish. But that's not required. As set forth in our hearing order, each side has 60 minutes to present its case.

At this time, the hearing is open to the public currently. As we discussed last week, we will reserve a portion of the hearing for confidential presentations if the parties elect to do so.

But let's set that aside for the moment. First, I want to discuss

1 whether each side intends to reserve time for rebuttal during the open
2 portion of the hearing. Mr. Conrad, as petitioner, you'll be presenting first.
3 Would you like to reserve any portion of your time for rebuttal?

4 MR. CONRAD: Yes, Your Honor. We'll reserve 30 minutes
5 for rebuttal.

6 JUDGE HARDMAN: And Mr. Anderson, would you like to
7 reserve time?

8 MR. ANDERSON: Yes, we'd like to reserve 10 minutes or
9 whatever the balance is for surrebuttal. Also, Your Honor, the parties did
10 confer and we -- I believe Mr. Conrad can confirm this. There is nothing --
11 there will be nothing confidential. So this can be -- we don't have to worry
12 about the confidential section.

13 JUDGE HARDMAN: Okay, great. Thanks. And do we have
14 your confirmation on that?

15 MR. CONRAD: That's correct, Your Honor. According to the
16 parties' demonstratives, it appears we're not going to be discussing it. If that
17 comes up during the hearing, of course we'll let the Board know.

18 JUDGE HARDMAN: Okay. Thank you, counsel. Okay. So
19 the panel has access to the entire record here today. So when you're
20 referring to a demonstrative, a paper, an exhibit, what have you, please give
21 us the specific citation so that we can pull it up on our side and also so that
22 we have a clear record.

23 Our expectation is that when the other side is giving its
24 presentation that the opponent does not interrupt, no objections, no
25 interruptions. If you have something to object to, please save it for your
26 presentation and bring it up at that time. So with that, are we ready to go?

1 MR. CONRAD: Ready to proceed.

2 JUDGE HARDMAN: Okay. Thank you, counsel. Let me put
3 30 minutes on the clock. And I'll start when you're ready, Mr. Conrad.

4 MR. CONRAD: Good morning. David Conrad on behalf of
5 petitioner. May it please the Board. This patent claims an old method for
6 using a very old product. It's a very simple patent too. If you look at the
7 abstract and look at the claims, it's really as simple as taking one drop of that
8 product and putting it on the surface and getting that to a human like an
9 infant.

10 That's it. There's really nothing more to the patent than that.
11 Like I said, the Vitamin D supplement in question here was not new. It was
12 available for prescription -- under prescription in Germany for many, many
13 years. It was even known to patent owners, Dr. Vieth in particular. He
14 wrote about it in articles that he published before filing this patent, pointing
15 out that it was the most popular Vitamin D supplement in Europe.

16 In fact, Dr. Vieth also obtained samples of it. He made
17 solutions with it for use in studies. He worked with it for years in his lab,
18 sometimes personally, sometimes using his assistants. He even tested -- if
19 you look at his notebook and his deposition, he even tested his own
20 compositions against it and compared. So this was not an obscure product.
21 It was not a rare find that we happened across.

22 It wasn't distributed in North America, though. And I think
23 that's really the crux of what patent owner's case is trying to rely on. That
24 doesn't matter. What matters is what's in the publications, what it teaches us
25 about this product, and what it teaches us about how to use it. Vigantol in its
26 commercial form provided a daily recommended dose of Vitamin D in one

1 drop.

2 This was described in part on slide 13. Harder is a textbook by
3 a major German publisher. And it was cataloged in the United States
4 Library of Medicine. Harder is a textbook on Postpartum Care in the
5 Hospital and at Home. It's self-described as a comprehensive textbook that
6 is supposed to fill in the gap on the postpartum period that otherwise isn't
7 typically covered in obstetric textbooks.

8 Harder has a section on how to prevent rickets. It talks about
9 what rickets is. It talks about why Vitamin D is important to treating it and
10 preventing it. And it gives some options on how to take care of an infant in
11 order to avoid rickets. One of those options was Vigantol. It notes that it's a
12 good option, especially if there's allergies or maybe there's some bloating
13 that might be -- that one might encounter when using some of the other
14 tablet forms.

15 Harder points out that Vigantol oil contains 500 IU of Vitamin
16 D in one drop. There's only one excipient it says, and that's medium-chain
17 triglycerides. I think there's some hay that's been made about the fact that
18 Harder puts in parenthesis vegetable oil. But medium-chain triglycerides are
19 simply just a subset of vegetable oils. We'll see that they are derived from
20 plants. And that's all Harder is doing here is explaining for the layperson
21 that this is nothing scary as the rest of the paragraph is pointing out of other
22 products that have scary sounding ingredients.

23 It's a simple ingredient. It's just a kind of vegetable oil,
24 specifically MCT. Now the Harder textbook also gives an explanation of
25 use on how to administer the oil to an infant. It says the use is simple. One
26 drop of Vigantol oil is given to the baby to be licked off from the tip of a

1 spoon once a day before breastfeed or a meal. That's it. This is the claimed
2 inventio of claim 1. There's nothing more to it than that.

3 Put one drop of this composition on the surface of an object and
4 give that to an infant. So Harder discloses the method. We provided several
5 different translations in German as the Board is aware of. And it doesn't
6 really matter which one you use. We relied upon Sherman in the petition.
7 But the point of all of these translations is that Harder teaches putting one
8 drop on the exterior of a surface and then giving that to a baby.

9 Without getting too much into the details of the translation back
10 and forth that the parties encountered, if you look at Tinworth, she doesn't
11 mention the words to be licked off, of course. That was a big dispute. But
12 does it really matter? What the evidence shows in the record, this is
13 according to Dr. Reid's declaration and deposition, is that when you put on
14 drop of this composition on a spoon, it doesn't roll off.

15 It doesn't fall off. It doesn't drip off like water may. And so if
16 you're going to put one drop of this substance on a spoon and give that to a
17 baby, the natural outcome of that is that you're going to put it in the baby's
18 mouth and the baby is going to get the substance. So whether it's licked off,
19 whether it says licked off, whether it doesn't say it, it doesn't matter because
20 it's the natural result of what Harder teaches. It's obvious.

21 JUDGE HARDMAN: Counsel, can I ask you if you are limited
22 to the Tinworth translation, is that argument you just made in your paper
23 somewhere? Could you point me to where in your paper that even if you're
24 limited to Tinworth, the claims are still obvious?

25 MR. CONRAD: Your Honor, I don't have that ready. I can get
26 that for the Board on the rebuttal. But Dr. Raj does testify to this. And I

1 believe we point at it on the reply. I'll make a note of that to provide that for
2 the Board.

3 Harder also discloses the composition of Claim 1, Vigantol oil.
4 Now it doesn't have all the details, of course. It's just a textbook. It's not
5 providing all the details about what Vigantol oil is.

6 But that's where the other references come into play. Wolf is a
7 journal article that discloses several different types of treatment for rickets
8 and different products. One of them is Vigantol oil. It discloses the
9 composition and dosage of Vigantol.

10 The European Pharmacopoeia also contains a monograph for
11 what medium-chain triglycerides are. There's a well-accepted definition for
12 that. Wolf makes sense to look at. Just like Harder was teaching, it's the
13 prophylaxis of rickets in babies as its subject.

14 It points out that one example of the product, Vigantol, contains
15 20,000 IU of Vitamin D3 which is about 30 drops or 0.5 milligrams. And
16 that is equivalent to one milliliter. It identifies the daily dose as one drop for
17 treatment of rickets.

18 From that calculation -- from that information, we can calculate
19 how many micrograms per milliliter would be in the one drop taught by
20 Harder. And that is well within the range of Claim 1. And unsurprisingly in
21 the specification since Dr. Vieth was familiar with Vigantol, he didn't
22 identify it but he does identify that it is essentially the same product that was
23 described in Wolf, 20,000 IU, which is 50 micrograms per milliliter of oil.

24 The European Pharmacopoeia, Supplement 4.3, describes the
25 content of medium-chain triglycerides that's set forth in Claim 1 which is 6
26 to 12 carbon chain links. In fact, it says, specifically minimum 95 percent of

1 8 and 10 carbon atom length saturated fatty acids. And that is unsurprisingly
2 one of the dependent claims that's being challenged here.

3 It is more specifically a length that comes directly from either
4 this pharmacopoeia or maybe perhaps the United States version. The
5 definition set forth in the patent for medium-chain triglycerides appears to
6 have come directly from this pharmacopoeia or something similar to it.

7 The remainder of the claim are just properties of the
8 composition. First, there's the -- whether there is a nutritional or therapeutic
9 amount of Vitamin D in the one drop that's being applied, and then second,
10 whether it adheres to a surface of an object. I'll talk about adherence first.
11 Dr. Williams pointed out that medium-chain triglycerides possess the
12 properties of adherence needed to satisfy what the '958 patent is talking
13 about.

14 The patent itself, I think the Board noted this in the institution
15 decision. The patent itself really describes nothing more about adherence
16 other than medium-chain triglycerides are good enough. It compares it to
17 water-based solutions, ethanol-based solutions, other kinds of oil. And it
18 says, you know what. Some of these are not sticky enough, like water.

19 That's not good enough. Some of them may be too sticky like
20 canola oil, olive oil, or sesame oil. But -- and this is at column 7 at the top --
21 we found that medium-chain triglyceride oil was particularly desirable.

22 So the adherence in the claims is just the property of the
23 medium-chain triglycerides. Now Harder also discloses the rest of the
24 properties which is that one drop contains a nutritional or therapeutic amount
25 of Vitamin D.

26 It explains that Vigantol oil satisfies the minimum daily

1 requirement of 400 IU. This is explained even further in Harder about
2 treatments in prophylaxis of rickets of pointing out in Harder itself what the
3 daily recommended amount is which is 400 IU.

4 And for the purposes of today, what matters for the claim is not
5 whether Harder conducted experimental tests to satisfy that the blood levels
6 of the children she's teaching moms and pediatricians and dads how to take
7 care of their kids. And nurses and midwives, these are all the audiences of
8 Harder. She's not trying to teach them the science beyond Vigantol.

9 She's not required to. All she needs to do is teach a person of
10 ordinary skill in the art that there's a reasonable expectation of success that
11 following this method is going to treat -- or I'm sorry, prevent rickets. And
12 she says this. She says the oil has proved to be successful over many years.
13 She says the method for doing that is simple. That's a reasonable
14 expectation of success. I think the patent owner trying to hold us to a level
15 of success that's not required by the law.

16 So, for example, I'll give the Board a case cite. OSI
17 Pharmaceuticals v. Apotex, 939 F.3d 1375 points out that there is no
18 efficacy data that is always required for a reasonable expectation of success.
19 And we don't require absolute predictability of success. The point is that
20 we're not trying to cure cancer here. And I mean that literally. We're not
21 taking the disclosures of Harder and using Vigantol oil and saying doing that
22 is going to cure cancer. What we're doing is saying follow the instructions
23 in Harder and it will do as she says it will do which is to treat rickets. She
24 points out it's successful. And there's no reason that a POSITA would have
25 reasonably otherwise.

26 So I'll talk about a few of the arguments that patent owner has.

1 And I'm happy to entertain any questions of the Board that may not have
2 been answered yet. First off, Harder is not prior art. I think they've raised
3 hearsay objections.

4 They've raised arguments that a person of ordinary skill would
5 not use it or that just cannot be the case. It's a textbook on the exact same
6 subject matter, postpartum care in the U.S. National Library of Medicine by
7 the National Institutes of Health. It is absolutely kind of textbook that a
8 person of ordinary skill in the art looking for how to use compositions to
9 treat diseases would look to.

10 I think the argument that patent owner is going for here is that,
11 well, a person of ordinary skill in the art is really educated, really trained.
12 And therefore, they wouldn't look to a textbook by someone that is not
13 educated or not trained.

14 And the law does not say that. You don't lose your common
15 sense, your lay experience just because you become more educated and the
16 POSITA level is higher.

17 You gain more by a higher level of POSITA. In fact, the co-
18 inventor, Dr. Vieth's wife, Ms. Vieth, she's not a doctorate in pharmacology
19 or pharmaceuticals. She was a registered nurse. And yet she is claimed as a
20 co-inventor here. So Harder is from the same field of endeavor, directed to
21 the same problem, and reasonably pertinent to the problem with which Dr.
22 Vieth was trying to solve which is how do you deliver Vitamin D to infants
23 to treat or to prevent rickets.

24 Briefly on the translation issue, I think this has played out well in
25 the briefing. I don't think there's much more to say to that other than if there
26 really was something there, there that mattered for this case, patent owner

1 would have provided a translation of their own with their own independent
2 translator that contradicted the Sherman translation and Benyunes translation
3 that we provided to show that the fact that licked off is not actually there.

4 But they did engage their own translator. And they had this
5 person translate the front matter of the textbook. But they didn't have this
6 person translate the line in question, the sentence in question.

7 I think that tells us everything. We point out the reason why
8 the Sherman translation was a correction to the Tinworth translation. And
9 that's because the words in German, zum ablecken, means to lick. It's what
10 the dictionaries say. Dr. Sherman's supplemental declaration in his
11 deposition at Exhibit 1039, for example.

12 I'm sorry. His declaration at Exhibit 1021, paragraph 3, he
13 explains why adding that phrase made it a more correct translation. It's
14 because that's what --

15 JUDGE HARDMAN: Mr. Conrad?

16 MR. CONRAD: Yes?

17 JUDGE HARDMAN: Can I ask you? You submitted some
18 dictionaries, German to English, German dictionaries. There is a motion to
19 exclude pending on those on the grounds of hearsay.

20 And I believe in your opposition, your rebuttal to that is that
21 you're not offering them for the truth of the matter but rather for their effect
22 on the translator. But I don't see that your translator used or looked at these
23 particular exhibits that are being challenged.

24 So it seems to me that you are, in fact, offering them for the
25 truth of the matter -- that this German phrase does mean to lick off. Could
26 you respond to that, please?

1 MR. CONRAD: Sure. Two things on that, one, the evidence in
2 the record is that Exhibit 1022 which is Mr. Sherman's supplemental -- or
3 amended declaration, he points out the Cambridge dictionary.

4 And that's what he relies on. And Exhibit 1022 at Exhibit C, I
5 don't think this is objected to. Their copy of that is provided in 1022. And
6 here it says to lick off.

7 JUDGE HARDMAN: And 1022 is not subject to a motion to
8 exclude. Is that correct?

9 MR. CONRAD: I don't believe so, Your Honor. I think it was
10 just the later exhibits that we added.

11 JUDGE HARDMAN: Okay.

12 MR. CONRAD: But regardless of whether these actual
13 dictionaries are in evidence or not, Mr. Sherman testified as to why he did
14 what he did. That's in his declaration.

15 We provided another translator. And he came up with almost
16 exactly the same phrase. It wasn't perfectly exact, but he did what he felt
17 was appropriate. And it essentially means to lick of or to be licked off.
18 That's Mr. Benyunes, Exhibit 2024.

19 So the clear story here is not this conspiracy about Fish &
20 Richardson using one of the larger translation services to manufacture
21 evidence. It's obviously just trying to get it right. And the first go around
22 under circumstances of time crunch with a preliminary injunction hearing
23 and prior litigation unrelated to this petitioner meant that there was a
24 mistake.

25 It was corrected. And that's why the evidence is the way it is.
26 The Board has the full record to be able to examine whether it looks like a

1 mistake or it looks like conspiracy. The other -- I think one of the biggest
2 things that patent owner hangs their hat on is their argument that somehow
3 Harder doesn't work, that you wouldn't expect to succeed by putting a drop
4 on the top of a spoon.

5 First off, she says it succeeds. She says for many years it had
6 been successful. So that's not true. Second off, the argument that you can't
7 use a spoon to provide a drop of something to an infant is -- it can't be
8 correct.

9 As a matter of personal experience, common sense, and the
10 evidence we have for the Board, I think the best example of that is patent
11 owner's exclusive licensee themselves, that's one of their instructions on how
12 to use the product that they allege is an embodiment of the patent. Put one
13 drop onto a clean surface. And an example they provide is a spoon.

14 Now they don't say a tip of the -- they don't put it right at the
15 tip. They actually point to putting it in a bowl. It doesn't matter if you put
16 one drop of it on the spoon and put that in the mouth of a baby. No, it
17 doesn't because the natural instinct of a baby is going to suck on whatever it
18 is that it puts into its mouth.

19 There's no evidence to the contrary of that. And again, on
20 Exhibit 1032, we point out a more recent product that's not Vitamin D. But
21 it is a one drop product in oil intended for newborns. And there they put one
22 drop on a product. And actually, they say one drop can be licked off a clean
23 surface such as a clean spoon.

24 JUDGE HARDMAN: Mr. Conrad, is there evidence in the
25 record that the small spoons being shown on, for example, petitioner's
26 demonstrative 48 were, in fact, available before the priority date?

1 MR. CONRAD: No, those are the Munchkin brand spoons. I
2 don't think we put evidence into the record.

3 I think patent owner tries to argue that they weren't in fact. I
4 don't think it's conclusive.

5 But it doesn't matter. The patent doesn't require putting one
6 drop on a Munchkin spoon.

7 It requires putting one drop on a spoon that you can give to a
8 baby.

9 And if Harder says you can successfully do that, then clearly a
10 person of ordinary skill in the art is going to use a spoon.

11 That makes sense which would be a small spoon. In fact, I
12 think it's interesting.

13 If you look at Dr. Raj's declaration and testimony, what we did
14 was we sent her some samples of spoons for her to test.

15 Go test. See if what Harder says you can do. And she
16 actually -- I was hoping she would use larger metal spoons like Dr. Reid
17 used in his test for patent owner.

18 But she actually wouldn't. She said, this doesn't make sense.
19 No one would use this because they're too large.

20 So she used the smaller spoon. And in her declaration, she
21 points out that that's the property that makes sense.

22 It's just small, maybe plastic. It doesn't have to be a Munchkin
23 spoon.

24 That's not relevant to the claim here. They point out that Wolf,
25 they argue, teaches away because it suggests using some liquid.

26 But Wolf doesn't criticize. Harder actually comes I think about

1 two decades, maybe three decades after Wolf anyways.

2 So it would be able to criticize Harder. But something that's an
3 alternative is not a teaching away. It's just an alternative.

4 I mentioned earlier already adherence. The testimony -- the
5 declaration of Dr. Reid, patent owner's expert in Exhibit 2072 -- paragraph
6 72, points out that medium-chain triglycerides as an excipient is all you
7 need, just like Dr. Vieth and Mrs. Vieth and their patent confirmed.

8 It wasn't possible for the drop to fall off the spoon. That's
9 adhering.

10 I think your question about whether the Munchkin spoon is
11 necessary to have existed, no.

12 When I mentioned Dr. Raj, it was paragraph 23 of her
13 declaration, Exhibit 1040.

14 She says the small plastic spoon is suitable, and that's it. That's
15 all it takes, just something small and plastic. It doesn't have to be a certain
16 brand.

17 JUDGE HARDMAN: I guess, counsel, to put a finer point on
18 it, what evidence in the record is there that small plastic spoons existed as of
19 the priority date, Munchkin brand or otherwise?

20 MR. CONRAD: Well, I'll have to get the Board that. So it
21 doesn't have to be plastic, right?

22 I mean, the whole point of what Dr. Raj was testifying to and
23 this is what my story about her that shows up in the record is that she
24 wouldn't use the large spoon.

25 She just used the small spoon because it fit in the baby's mouth.
26 And if you look at her declaration, paragraph 23, point c, she says,

1 alternately, the entire spoon could be placed in the baby's mouth for the baby
2 to lick and/or suck the drop off.

3 So she is explaining that, look, no matter what happens to the
4 drop on the spoon, there's no evidence in the record that it would ever fall
5 off.

6 In fact, there's evidence that it will not fall off. And then once
7 it's on the small spoon, you can put it in the baby's mouth and the baby will
8 lick and/or suck the drop off.

9 JUDGE HARDMAN: Did petitioner have a specific response
10 to patent owner's argument that the tongue would be under the bowl of the
11 spoon and therefore you can't lick off something that's on top of the spoon?

12 MR. CONRAD: Well, there's a couple things to that. And I
13 think the first is common sense.

14 Nothing in the claim requires that the tongue actually come into
15 contact with the drop.

16 That's not part of the claim. The claim just says to lick or suck
17 the drop off.

18 It doesn't mean it has to come into contact with it. If you put a
19 small spoon in a baby's mouth and it starts to suck on it, it will remove
20 what's on the object.

21 And the tongue doesn't have to be under or over or whatever.
22 That action is licking and/or sucking.

23 That's just a natural human experience. And here Dr. Raj
24 confirms that that would be the case with the small spoon.

25 So I touched on claim 1. Unless there are any more specific
26 questions about claim 1, I wanted to briefly address claim 3.

1 Claim 3 is a dependent claim. And it says specifically that the
2 human is an infant and that the object that the drop is placed onto is a
3 woman's nipple or the external surface of a pacifier.

4 So this is not a huge leap from the Independent Claim 1.
5 There's only so many surfaces that you can put into an infant's mouth.

6 So if your goal is to use an object to provide a drop to an infant,
7 there's not many things that you're going to want to use.

8 Harder teaches a spoon just like patent owner does -- what a
9 patent owner's licensee does.

10 But Harder -- the record shows that a spoon is not the most
11 natural surface for an infant.

12 So even though you can use it, it's not the most natural surface.
13 The most natural surface for -- especially for a newborn is a nipple or a
14 nipple-like shape.

15 That's why we primarily feed babies with nipples or nipple-like
16 shapes.

17 So that is a natural motivation to find an alternative surface.
18 And Dr. Vieth himself noted that was actually the case in the prior art, that
19 there were other methods that were considered on how to deliver Vitamin D.

20 In Exhibit 2008, his declaration, paragraph 14, he pointed out
21 that Scanlon which is one of the prior art references that he located and
22 submitted to the patent office explains that a solution in Germany is to put
23 an oral Vitamin D preparation on the mother's nipple once a day before the
24 baby breastfeeds.

25 Now that sounds familiar. In Germany, it doesn't say
26 what that preparation is. But it does note that others had other methods of

1 how to deliver that Vitamin D preparation. And nipples make sense.

2 Pacifiers are common alternative to nipples. That's what Dr.

3 Vieth testified on page 83, lines 14 to 23.

4 That's why he thought of a pacifier. Well, it's just a reasonable
5 parental alternative for people who give a baby a common item, he says.

6 And he also confirmed, why was nipples even in the question
7 for what he was coming up with for his patent.

8 And he says, well, that's just how babies breastfeed. It just
9 makes sense. It's common sense.

10 Dr. Horowitz, Exhibit 1036, page 14, lines 12 to 23, he testified
11 further to this motivation.

12 He says, I think a person of ordinary skill in the art would know
13 that a baby is more likely to suck on a pacifier than off of a spoon.

14 Blass is a publication that teaches putting a substance on the
15 surface of a pacifier and delivering that to the baby.

16 In Blass, they were trying to analyze whether providing sucrose
17 to a baby, whether just water or a pacifier dipped in water or dipped in
18 sucrose, whether any of these combinations or alternatives are more
19 effective for baby than -- in preventing pain in procedures.

20 They would -- their method was to dip a pacifier in sucrose and
21 give that to the baby or water if that were the case.

22 And their conclusion was, again, not surprising that sweet
23 solutions can be readily given to infants on a pacifier. That's it.

24 Now, of course, they dip it in sucrose and the claim here is put
25 one drop on it.

26 But that's not a huge leap. Both prior art references, they're

1 providing a solution to an infant by putting the solution on the surface of the
2 pacifier.

3 I think the patent owner tries to argue that during prosecution
4 that the examiner distinguished Blass because they successfully argued
5 around Blass.

6 But the problem with the prosecution which we point out in the
7 petition is that the examiner did not consider Blass in light of the Vitamin D
8 drop composition in the claim itself.

9 Of course, the composition of Vigantol never made its way to
10 the prosecution.

11 So that was not in front of the examiner. So the first point the
12 examiner makes and their reasons for allowance is that the cited references
13 in the combination fail to teach, motivate, or suggest the Vitamin D
14 composition consisting of a Vitamin D and liquid triglyceride of 6 to 12
15 carbon chain link.

16 With that, Your Honors, I'm happy to turn over the time to
17 patent owners.

18 JUDGE HARDMAN: Okay. Thank you, counsel. You have
19 approximately 27 minutes left for your rebuttal.

20 MR. CONRAD: Thank you.

21 JUDGE HARDMAN: Okay. Mr. Anderson. We have 50
22 minutes on the clock, and you can start when you're ready.

23 MR. ANDERSON: Thank you, Your Honor. May it please the
24 Court.

25 Alan Anderson on behalf of the patent owners. To paraphrase
26 the well-known and old saying, copying is the sincerest form of flattery.

1 And if that's true, the '958 patent and the inventions claimed in
2 it is one of the most flattered inventions.

3 The claimed inventions have consistently been copied by
4 entities wanting to capitalize on the patent owner's innovative solution to an
5 age-old problem.

6 And that includes the petitioner which is only the latest in a
7 long series of copies.

8 But unlike the other knock off artists who quickly realize the
9 error of their ways and agreed to stop sales of their copycat products,
10 petitioner now tries to invalidate claims 1 and 3 to 5 of the '958 patent by
11 presenting the Board with a weak and convoluted mélange of prior art.

12 Petitioner picks and chooses from disparate prior art fields,
13 ignores the absence of key limitations in the claims, mischaracterizes patent
14 owner's arguments of the evidence, and then shouts voila, the claimed
15 invention would've been obvious to a person of ordinary skill in the art in
16 2006.

17 However, the law does not allow claims of a patent be held
18 invalidated as obvious on the bases presented by the petitioner.

19 Petitioner is engaging in nothing more than hindsight
20 reconstruction.

21 It uses the claimed inventions as a roadmap because without the
22 roadmap of the patent, it has no way to get to where it says it's obvious.

23 It doesn't provide any explanation of why a person of ordinary
24 skill in the art would have been motivated to combine the bits and pieces
25 from the prior art to create the claimed inventions.

26 Indeed, you heard nothing in petitioner's presentation about

1 motivation to combine.

2 The petitioner admits that the prior art does not disclose at least
3 two limitations.

4 First, the nutritional or therapeutic amount of Vitamin D
5 requirement and second, the wherein said drop adheres requirement.

6 It therefore resorts to arguing that these elements are inherent, a
7 concept drawn from its dismissed, belated, and unsuccessful attempt to
8 argue anticipation and one that simply does not withstand minimal scrutiny.

9 JUDGE NEW: Mr. Anderson?

10 MR. ANDERSON: Yes, sir.

11 JUDGE NEW: Excuse me. Are you arguing that the
12 requirement that you are saying is a nutritional or therapeutic amount is
13 limiting in this claim?

14 Are you arguing that the preamble is limiting on this claim?
15 Because I don't see that anywhere in your arguments.

16 MR. ANDERSON: It is not in the preamble, Your Honor. If
17 you look at claim 1, column 9 beginning at line 38, the first subsection of the
18 claim says consisting of a nutritional or therapeutic effective amount.

19 That is a mischaracterization, one of the mischaracterizations
20 by petitioner.

21 We aren't arguing that we have to incorporate something from
22 the preamble into the claim because it's in the claim. Nutritional or
23 therapeutic effective amount of Vitamin D.

24 JUDGE NEW: Right. But given that, doesn't that limitation
25 very clearly define what a nutritional or therapeutic effective amount is that
26 is 99,000 MCD per ML of Vitamin D.

1 In other words, anything that provides that amount in its drop is
2 by the definition provided in the limitation under nutritional or therapeutic
3 effective amount.

4 MR. ANDERSON: But you have to have a means of providing
5 that consistently in one drop, one drop alone, not mixed with some other
6 aqueous solution which is what Wolf and Harder in effect teach.

7 But one drop has to be the nutritional and effective therapeutic
8 amount and it has to then provide that in a way that it doesn't drip or run off.
9 It has to adhere. Did I answer Your Honor's question?

10 JUDGE NEW: I think so. Please continue.

11 MR. ANDERSON: Thank you. Now Judge Hardman raised
12 the question to petitioner, what if you only have Tinworth? Then what?

13 And counsel for the petitioner said, well, I'll have to look that
14 up because I will tell you it's not in their briefs.

15 It is not in their papers. And the reason for that is because their
16 expert, Dr. Williams, testified. He admitted in his deposition that if he's
17 limited to Tinworth, he can't render his obviousness opinions. He's got
18 nothing.

19 And that's why when they discover this, they went off and
20 decided, I've got to fix this.

21 We've got to get translations until we get one that we want.
22 And that's what they did.

23 And as I will argue subsequently, no POSITA, no researcher in
24 this field with any integrity or any honesty would say, well, assuming they're
25 going to rely on Harder, I'll get a translation because it's German.

26 Oh, I don't like that translation. I'm going to go get another

1 one. Oh, I'm going to get another one. Oh, I'm going to get another one.

2 Indeed, I think it's ludicrous for petitioner to suggest, well,
3 patent owner should've got their own translation. Why?

4 Do you want to have another translation, a fifth translation. A,
5 it's not our job. They have the burden throughout.

6 But B, Tinworth is the only unsullied, untainted translation.
7 She is a qualified, certified translator.

8 She's testified. She's gave a declaration under oath that it was
9 true, complete, and accurate. And nobody has contradicted that. Nobody
10 has.

11 JUDGE NEW: Mr. Anderson, I'm a little confused here
12 because if I understand correctly, and please correct me if I'm
13 misunderstanding, the real crux of the argument about the translations is the
14 Tinworth translation does not use the term lick off and the others do.

15 However, I don't think there's any dispute whatsoever that the
16 German version of Harder uses the verb ablecken which means to lick off.

17 And I don't see any dispute about that because even Dr. Vieth,
18 the patent owner, has admitted that as a German speaker that that's what that
19 term means.

20 So in other words, there's no dispute that the copies term lick
21 off is actually in Harder.

22 And the Tinworth translation doesn't use that but the others do.
23 So I'm a little puzzled about the nature of the dispute here that you're
24 proposing to us.

25 MR. ANDERSON: Well, first off, I disagree that Dr. Vieth
26 admitted that zum ablecken means to lick off.

1 If you look at Dr. Vieth's deposition as well as his errata sheet,
2 what he was saying is I only understood household German as an infant.

3 I've never used the word or heard the phrase zum ablecken.
4 And in the context of the questions, he was agreeing that what Sherman says
5 is that zum ablecken means to lick off.

6 The other thing is you would see in the deposition of Mr.
7 Sherman, he agreed that it is improper to simply pick on sentence out of a
8 foreign language document and translate it because context matters.

9 Context matters particularly in German. And what he was
10 asked to do after petitioner's counsel discovered the defect in the Tinworth
11 translation was look at this one sentence and add these four words.

12 I mean, petitioner's counsel drafted his declaration that he
13 signed adding those four words.

14 Now one went back and asked Tinworth, hey, did you make a
15 mistake here? Did you miss something?

16 Tinworth is the translation. And I don't believe that the Board
17 should in effect accept or create a policy for foreign language prior art to get
18 as many translations as you want until you get one that you like.

19 I mean, that's not what a person of ordinary skill in the art
20 would do.

21 A person of ordinary skill in the art would receive Tinworth,
22 look at it. And as Dr. Williams testified, I don't have a basis for obviousness
23 based on Tinworth.

24 JUDGE HARDMAN: Do you think, though -- I think that
25 mischaracterized the record a little bit.

26 We don't have a bunch of differing translations. We have

1 Tinworth and then we have a series of additional translations that says that
2 was an error.

3 And it seems to me that the weight of the translations agree that
4 this phrase was missing from Tinworth.

5 I don't see how that petitioner kept getting a series of
6 translations until they got one they liked.

7 It seems like they got one in error and then rectified that error in
8 a consistent manner.

9 MR. ANDERSON: First off, none of the other translations say
10 Tinworth was in error.

11 Nobody says it's in error. Even Sherman in his declaration
12 drafted by the petitioner's counsel says I'm making this change to make it
13 more -- what he calls more accurate.

14 It doesn't mean that the first one was inaccurate and context
15 matters.

16 And I think if you look at Tinworth who is a woman and was
17 reading this in context and the fact that you don't put a spoon in an infant --
18 in a baby's mouth. You just don't.

19 I mean, there's all sorts of evidence in the record that that's not
20 something that you do with newborns is put a -- or with infants is put a
21 spoon in their mouth.

22 Even Dr. Raj says, you'd never spoon -- metal spoon. She says,
23 well, you've got to have, as Judge Hardman, as you pointed out, a small
24 plastic spoon.

25 But there's no evidence in the record that small plastic spoons
26 existed prior to the priority date.

1 She uses small plastic spoons that weren't available until 2012.

2 And there's no dispute over that.

3 JUDGE NEW: Doesn't the '958 patent define an infant as a
4 baby or a small child?

5 MR. ANDERSON: Yes.

6 JUDGE NEW: And is there any problem with putting a spoon
7 in a small child's mouth?

8 MR. ANDERSON: You're still going to have the problem that
9 it depends on how they accept it.

10 As the various research articles that we presented point out, the
11 infant, their reaction is to spit it out.

12 Their tongue is underneath the bowl so they're not going to
13 have anything to -- it's not going to be possible for them to suck or lick
14 because that's not their natural way of doing it.

15 Maybe if they get to an age of, like, 6 months or more, then
16 they might -- you might be able to put something in.

17 But again, you're missing then the requirement that they are
18 able to take off a nutritional or therapeutic effective amount because some of
19 it is going to the surface.

20 JUDGE HARDMAN: Let me just interrupt you right there.
21 Where in the claim is the requirement that the drop be removed?

22 It says apply a therapeutic or a nutritionally -- a nutritional or
23 therapeutically effective amount to the object such as a spoon.

24 But I don't see anywhere where the person who is receiving the
25 drop has to actually remove it.

26 MR. ANDERSON: Well, first off, there's nothing in the claim

1 that says a spoon.

2 That's something that the petitioners refer to instructions in the
3 product.

4 But that's not in the claim. Second, in the claim construction
5 which the parties have agreed on and which was accepted or ruled by the
6 district court and I believe there's no issue here.

7 The claim construction talks about it here and that requirement.
8 And you have to have it adhere because if you have something that doesn't
9 adhere so that you can get off a nutritional and therapeutic amount. You're
10 not able to get it in one drop.

11 JUDGE HARDMAN: The claim construction doesn't require
12 actual removal.

13 It just requires that the drop not be so sticky as to be difficult to
14 remove.

15 MR. ANDERSON: Well, I think it's implicit that if you're
16 going to get a nutritional and therapeutic effective amount, you've got to be
17 able to get off a nutritional and therapeutic amount.

18 It's kind of like a Goldilocks solution. You've got to have it
19 here enough to be able to get it off but not adhere too much that you can't get
20 it off and not have it not adhere enough so it just runs off.

21 JUDGE HARDMAN: But the claim construction says the drop
22 does not coat or adhere to the object so as to prevent efficient removal from
23 the object.

24 But it doesn't say that the recipient -- there's no active step of
25 the recipient needing to actually remove it.

26 MR. ANDERSON: Well, I think that's in the claim where it

1 says that the human being sucks or licks that composition directly from said
2 object.

3 The whole purpose of the invention is delivering a nutritional
4 and therapeutic amount in one drop.

5 That's what nobody had before. Nobody had for years after
6 because the state of the art was a product that required multiple drops and
7 was something other than MCT. It was an emulsified product -- a D-Vi-Sol
8 product.

9 JUDGE HARDMAN: And when you say the state of the art,
10 are you referring to just in the U.S. because there was the Vigantol product
11 at least in Harder was taught to be -- and Wolf taught to be a single drop.

12 MR. ANDERSON: Well, there was the Vigantol product
13 which was a special case. It was not for -- necessarily for infants.

14 And there was no evidence of exactly what it was, whether it
15 would work.

16 There was no evidence that the Vigantol product, whatever its
17 composition was, would deliver nutritional or therapeutic amount in one
18 dose -- one drop, excuse me, one drop.

19 He talked about one drop, but there was no evidence. And it
20 was out there, readily can see that whatever it was -- we don't know the
21 composition for certain.

22 Whatever it was, was out there for decades. And nobody put
23 this combination, this method together.

24 JUDGE HARDMAN: Let me ask you, counsel. Why does the
25 composition of the actual product in terms of what was available in
26 Germany or wherever, why does that matter because Harder tells us what the

1 composition is, doesn't she?

2 MR. ANDERSON: She speculates. There's no -- I mean, first
3 off, it's inadmissible hearsay because they're now taking Harder to -- they're
4 asserting it for the truth of the matter asserted that this is the actual
5 composition.

6 And there's no evidence that is accurate. In fact, what she says
7 suggests that it's not because vegetable oil has long-chain triglycerides, not
8 medium-chain triglycerides.

9 She's not a chemist. She has no training in chemical analysis.
10 And there is nothing that says that Vigantol is a medium-chain triglyceride.

11 JUDGE HARDMAN: Did you make this argument in your
12 patent owner response?

13 I saw you raise the question in your surreply. But I didn't see it
14 in your patent owner response in terms of saying that Harder is ambiguous
15 for the use of the term vegetable oil.

16 MR. ANDERSON: Thought we did. Yes, page 17 of our
17 response, it says, Harder provides no information regarding the composition
18 of the oil. She used Vigantol oil.

19 JUDGE HARDMAN: Thank you.

20 MR. ANDERSON: Thank you. And as we just said, what
21 petitioner is --

22 JUDGE NEW: Mr. Anderson, before you go on, one more
23 question --

24 MR. ANDERSON: Yes, sir.

25 JUDGE NEW: -- for you if I may. What about Wolf? I mean,
26 Wolf teaches the amount of D3 that is in one drop of -- excuse me, correct

1 myself on that.

2 It gives us the concentration of D3 that is found in 30 drops.

3 And therefore, it's a fairly easy conversion to convert that into a value falling
4 within the effective range recited in the claims.

5 So basically, one drop is going to contain that therapeutic
6 effective amount that's recited in the claims.

7 So I'm not sure why your position is that the prior art is not
8 telling us what Vigantol is, at least in terms of the therapeutic and effective
9 amount.

10 MR. ANDERSON: Two responses there, if I may, Your
11 Honor.

12 First off, the claim says, consisting of, so you've got to have it
13 all.

14 Second, Wolf teaches away because Wolf says -- if you read
15 Wolf, it says, put the drop or a crushed tablet in a spoon with water or some
16 other aqueous solution.

17 That is teaching away from the one-drop solution that is
18 claimed in the patent.

19 JUDGE NEW: Is it teaching away? Or is it just providing an
20 alternative method here?

21 Teaching away requires an active discouragement. If I were to
22 look for teaching away, I would expect it to say something like don't put it in
23 one drop of medium-chain triglyceride.

24 MR. ANDERSON: I would have to respectfully disagree, Your
25 Honor, because if you look at what Wolf says -- and this is at page 7 of the
26 translation that's part of Exhibit 1009.

1 It says drops or tablets should not be added to the bottle but
2 administered to the baby on a spoon with some liquid.

3 That, I think, is about as clear of a teaching away as you can get
4 that says don't just put a drop in, you know, a bottle or something or any
5 other.

6 Just put it on a surface and then have them suck off it. It says,
7 administer to the baby on a spoon with some liquid.

8 JUDGE NEW: I thought that a reasonable interpretation of that
9 is saying the dose is also toxic when the baby formula used contains 3,000
10 drops, should not be added to the bottle.

11 I take that to mean the bottle of baby formula. And rather it
12 says it should be administered to the baby on a spoon with the liquid.

13 I'm not sure that rises to an actual teaching away in
14 discouraging you from actually putting it on a spoon. It's saying don't put it
15 in the bottle with the formula.

16 MR. ANDERSON: But it's telling you -- it says, but. It says,
17 drops or a tablet should not be added to the bottle.

18 Don't add it to the bottle. The way you administer this is on a
19 spoon with some liquid which means you crush a tablet or you put a drop on
20 there with liquid.

21 It's not teaching or suggesting or even giving the hint, well,
22 come up with a one drop solution that provides a nutritional and therapeutic
23 effective amount.

24 And that the one drop will have the right adherence so that you
25 can suck it off or lick it off and get a nutritional and therapeutic amount.

26 JUDGE NEW: Right. And this brings me back to my point is

1 that it's teaching perhaps an alternative but it doesn't arise to a level of
2 teaching away because it's not actively discouraging the process.

3 MR. ANDERSON: Well, I guess I think it does. I think that a
4 person of ordinary skill in the art looking at it would read that and say, well,
5 this is again putting -- adding it into stuff.

6 Just as option 1, the primary option of Harder, teaches crushing
7 a tablet and adding it to water.

8 Now the other thing that I would say that petitioner ignores is
9 the considerable evidence of secondary indicia which establishes non-
10 obviousness.

11 JUDGE HARDMAN: Sorry, counsel. Before we move off
12 Harder, you said that it's hearsay. Do you have a motion to exclude on
13 Harder?

14 MR. ANDERSON: We don't have a motion to -- well, we
15 actually have to look at it.

16 JUDGE HARDMAN: On hearsay grounds.

17 MR. ANDERSON: Yes, I don't know. But regardless, the fact
18 is they have no admissible evidence that what Vigantol contained is the
19 actual composition.

20 Now we've gone over most of what I'm going to say in the
21 outline.

22 But as I said, I'm going to address these here individually.
23 They're using hindsight reconstruction.

24 They say nothing about a motivation to combine. They admit
25 that there's no reference that teaches the nutritional or therapeutic effective
26 amount or the adheres requirement.

1 There's no admissible evidence of the composition of Vigantol.

2 As I said, Tinworth is the only untainted translation of Harder.

3 And our argument is the POSITA would not rely on Harder.

4 And we talked about the deficiencies in the main references, Harder, Wolf,
5 and Blass.

6 And then the secondary indicia which the petitioner does not
7 even consider even though it's out there and they know it.

8 Now this is a problem to be solved, and it's a complex problem.
9 It involves interrelated variables.

10 They wanted to say, well, if you get a single drop of something
11 and blah, blah, blah. You put this together and voila.

12 But you can't. This is a complex problem and one that nobody
13 had come up with.

14 And I think the examiner's state of reasons for allowance is
15 instructive here.

16 Obviously, it's not binding by any stretch of the imagination.
17 But what petitioner highlighted was the Vitamin D composition consisting
18 Vitamin D and a liquid triglyceride of 6 to 12 carbon chain length.

19 They stop there. What they ignored and didn't highlight was
20 the and a method of delivering the Vitamin D concentration which goes on
21 there.

22 As the examiner concluded, one skilled in the art would not be
23 motivated to apply a single drop of Vitamin D composition to the exterior
24 surface of an object because it may drip off or get contaminated.

25 Thus, the claimed invention is novel and non-obvious. They
26 want to either just take -- well, look at the composition.

1 They talk all about composition, composition, composition.

2 But the claim is a method claim and you got to have both.

3 And that's what's missing here. Now there's a lot in the record
4 of the problem that existed and how long it's been there.

5 I'm not going to go over that because it's all been discussed in
6 the record.

7 But what they are missing is a motivation to combine. They
8 said one thing about the problem, that Vitamin D is not like curing cancer.

9 Well, no, it's pretty important because it's preventing and curing
10 rickets, a debilitating disease that has lasted for centuries.

11 And I think it's important to step back and use a little common
12 sense. Given how important and critical preventing and curing rickets has
13 been, no one came up with this particular combination until Dr. Vieth and
14 his spouse, no one.

15 If this was so obvious, if this was such a big -- and this clearly
16 is a big deal, as we'll get to it, the commercial success.

17 Why didn't Merck come up with it? Why didn't Merck who
18 makes Vigantol?

19 Why didn't they come up with it? Why didn't Mead Johnson
20 who makes the D-Vi-Sol product?

21 They didn't come up with it. There's all these big huge
22 companies and yet it is a tiny startup Canadian company and two inventors
23 that came up with it.

24 And that, I think, is often the example of a non-obvious
25 invention because it takes someone who in this case Dr. Vieth was primarily
26 researching other areas.

1 And he just said, oh, maybe I can look at this. And he comes
2 up -- he and his wife come up with a solution to an age-old problem.

3 And it's really a big success. People just copy it. They don't try
4 to come up with something.

5 They just copy it. Now we talked about the motivation to
6 combine.

7 And they don't address it. I think a really instructive case is the
8 TQ Delta case which I would commend to the panel.

9 What the petitioner does is they ignore motivation to combine.
10 They use -- when you read particularly Dr. Williams' declaration, he refers
11 to, well, this aspect of the patent.

12 And then he goes here. They're using the patent as a roadmap
13 for hindsight reconstruction.

14 And you can't do that. We all know that. You've got to forget
15 about the patent.

16 Look at just the prior art. Put these things on the desk in front
17 of you and then say, okay, put it together.

18 And there's no motivation to combine because you've got
19 disparate references from different fields.

20 They can't just leave it -- petitioner can't leave it to Your
21 Honors to explain why a POSITA would be motivated to combine the
22 numerous references they cite here.

23 All Dr. Williams offers is conclusory assertions. It says, in my
24 opinion, a POSITA would be motivated to combine followed by a recitation
25 of the claims he references -- what he claims the references disclose.

26 Simply -- and the only thing he came close to was saying, well,

1 I've been told that the marketplace can provide a motivation to combine.

2 But when I try to ask, what were you told about the
3 marketplace, he was instructed not to answer.

4 And just seeing, well, marketplace, you can do that anytime.
5 You got to say, what is it in the marketplace that would provide the
6 motivation to combine?

7 And if it is a big deal in the marketplace, I would argue that
8 there ought to be a lot of other examples of people coming up with this
9 solution.

10 All Dr. Williams says is his ipse dixit. Just here's my
11 conclusion and therefore it's it without referring to the claims of the '958
12 patent because as I said, he references what's in the specification throughout
13 his declaration to say here's what to look for in the prior art.

14 He's not working from a clean slate. And he acknowledges
15 that.

16 But you've got to use the '958 patent to guide him as to what
17 elements need to be combined.

18 This is just classic hindsight reconstruction, Your Honors, no
19 motivation to combine.

20 And without a motivation to combine, evidence on motivation
21 to combine, they don't get anywhere.

22 Now beyond the failure of the motivation to combine, they
23 recognize that there's nothing to suggest delivering a nutritional therapeutic
24 effective amount of Vitamin D.

25 They mischaracterize their arguments. As Judge New, as you
26 mentioned, they said, oh, we're relying on a preamble.

1 No, that's not true. It's in the claim. They say, oh, yeah, we're
2 saying you have to suck on it for 30 seconds.

3 No, that's not in their arguments anywhere. We don't make
4 those arguments.

5 They say, now, well, it's a natural motivation to provide the
6 alternative surfaces. But that's not in their papers. They don't make that
7 argument.

8 And they don't -- they say, well, the nutritional therapeutic
9 effective amount limitation is inherent. They go to inherency. But that
10 doctrine is from their dismissed efforts to belatedly add in anticipation.

11 And I would suggest that their belated and dismissed effort to
12 change this entire case from obviousness and inherent to anticipation shows
13 that they realize that they don't have a good case on obviousness.

14 Because if you had a good case on obviousness, why bother?
15 But they didn't.

16 And for inherency to exist, the claim -- the limitation must be
17 necessarily present.

18 That's the pharma case which we cite in our papers. And while
19 a nutritional therapeutic amount may be delivered using the Harder spoon
20 method, there's no evidence that it actually is the natural result of that
21 method.

22 As patent owner's experts and Dr. Vieth testified, an infant will
23 not naturally suck on or lick a spoon inserted into its mouth.

24 The infant's tongue as Judge Hardman -- as Your Honor pointed
25 out was going to be below the bowl of a spoon.

26 And for anyone who's been a parent of a young child, you're not

1 going to stick a metal spoon into an infant's mouth.

2 That's just not anything that anyone would do. And indeed, I
3 would suggest that Harder recognizes that's not the way to go because it's
4 option 3.

5 JUDGE NEW: Since you're going there, Mr. Anderson, as a
6 parent myself, I've fed infants with spoons numerous times and they're pretty
7 capable of getting everything off of them.

8 And because we're defining infant here in the '958 patent as a
9 small child, which I think we could reasonably interpret to be a two-year-
10 old, they're entirely capable of cleaning off a spoon that you stick in their
11 mouth.

12 MR. ANDERSON: I would respectfully disagree, Your Honor.
13 If you were to put something in the bowl of a spoon as Harder suggests, it's
14 going to roll toward the bottom of the concave surface. It's not going to
15 stick on the tip and they're not going to be able to lick or suck that off and
16 get a nutritional and effective therapeutic amount.

17 JUDGE NEW: A two-year-old couldn't do that?

18 (CROSSTALK).

19 JUDGE NEW: That's a small child. Can we reasonably agree
20 that a two-year-old is a small child?

21 MR. ANDERSON: But I don't know that there's any evidence
22 that a two-year-old would get a nutritional and therapeutic effective amount.

23 JUDGE NEW: Well, now we're arguing a different thing.

24 MR. ANDERSON: Yes.

25 JUDGE NEW: But I'd like to stay on the question which is
26 you're saying an infant could not remove the substance from a spoon

1 because the bowl would be above the tongue.

2 But since the '958 patent defines an infant as a small child, it
3 seems to be entirely possible that a small child could suck the contents of a
4 spoon that is delivered to it in its mouth on a spoon.

5 MR. ANDERSON: Inherency requires more than it's a
6 possibility, Your Honor.

7 It has to be the natural result. It's not just a possibility. I mean,
8 I always like to say to folks it's possible the sun exploded seven minutes ago
9 and we're about to go dark.

10 Anything is possible. And that's not the test or sufficient to
11 establish inherency.

12 JUDGE HARDMAN: Counsel, is it your position that an infant
13 or small child couldn't get something off a spoon?

14 Isn't that inconsistent with DDrops advertisement that says use
15 a spoon?

16 MR. ANDERSON: So, what I guess is my initial response. I
17 mean, what's the claim that we're relying on?

18 What they say in advertising and marketing is neither here nor
19 there.

20 As long as their product is covered by the claims which it
21 clearly is because you're looking at a tertiary or a part of the instructions.

22 And indeed, the petitioner puts up instructions for a product
23 other than the baby Vitamin D product.

24 And that's part of our -- one of our motions to -- part of our
25 motion to exclude.

26 The fact that if you're old enough -- oh, here, try a spoon -- the

1 instruction and the way to use it consistent with the patent claims is to put
2 one drop on a mother's nipple or a pacifier.

3 JUDGE HARDMAN: That is true for claim 3. But claim 1 is
4 much broader and says object --

5 MR. ANDERSON: Yes.

6 JUDGE HARDMAN: -- which encompasses a spoon.

7 MR. ANDERSON: Object may encompass a spoon. But
8 again, there's nothing in the prior art that shows you can get a nutritional and
9 therapeutic effective amount from a spoon or that whatever the composition
10 is will have the special adhere characteristic to permit the person to obtain a
11 nutritional and therapeutic effective amount.

12 And again, petitioner does not disagree that those two
13 limitations are not explicitly taught in the prior art.

14 They resort to inherency. And a probability doesn't establish
15 inherency.

16 JUDGE HARDMAN: Can I ask you about in column 6 of the
17 patent starting around line 34, it teaches right there that medium-chain
18 triglycerides will adhere.

19 And then basically -- I won't read it. But it quotes what we
20 have as the claim construction for adhere.

21 So doesn't the patent tell us that medium-chain triglycerides
22 will always meet this limitation?

23 MR. ANDERSON: No, it says medium-chain triglycerides
24 within this invention are liquids that are sufficiently viscous so that one drop
25 does not immediately drip or roll, blah, blah, blah.

26 And it goes on from there. It doesn't say that any medium-

1 chain triglyceride will do that.

2 And indeed, the Vieths disclosed in the various test results and
3 examples, they try a number of different vehicles for Vitamin D to do it.

4 Claim 6 -- column 6 is speaking about -- if you go down a little
5 bit farther to line 49, one drop was applied to a nipple to determine. Now --

6 JUDGE HARDMAN: Wait. Just let me see if I understand.

7 So are you saying that there are only certain types of medium-chain
8 triglycerides that fall within the claims?

9 MR. ANDERSON: Obviously, it's got to be a medium chain
10 triglyceride that has the 6 to 12 carbon chain length in terms of what they're
11 made out of.

12 Now as I said, we've talked about the lack of the adhere
13 limitation.

14 And we talked about -- I don't want to go over it again unless
15 Your Honors have more questions about it.

16 There's no actual evidence of the composition of Vigantol.
17 They take out of context those statements from Dr. Reid about his tests
18 because he was talking about the way he conducted the test.

19 You couldn't put the drop on the tip. It would roll into the
20 bowl.

21 So I mean, if you read his declaration in context and not just
22 take out a snippet, he's not saying what they claim it does. And we point
23 that out in our surreply.

24 JUDGE HARDMAN: What is patent owner's response -- I
25 think Dr. Raj had the opinion that if you are going to put a drop on the tip of
26 a spoon and it rolls, you would simply hold the spoon at an appropriate angle

1 so that it doesn't roll.

2 MR. ANDERSON: Well, first off, she never tested any metal
3 spoons.

4 As we've established, she tested some small plastic spoons that
5 didn't even exist.

6 And there's nothing in the record that a small plastic spoon
7 exists.

8 But she didn't test that aspect of it. She never said, okay, I'm
9 now going to see if I can hold it on the tip.

10 That's not on the record. There's nothing in there. That's just
11 her -- at best, an assumption of her part which as we've said in our motion to
12 exclude her entire declaration and opinion should be excluded because she's
13 not qualified to give her opinions.

14 JUDGE HARDMAN: How was Dr. Horowitz who's a
15 pediatrician -- how is he qualified to give opinions on the meaning of Harder
16 whereas you're saying Dr. Raj is not?

17 MR. ANDERSON: He doesn't give an opinion on Harder.
18 He's -- if you look -- go back and read his declaration.

19 He's not trying to say this is what Harder says. He's talking
20 about Tinworth.

21 He's not trying to interpret it. He's not trying to do what Dr. Raj
22 does because Raj, if you look at his declaration, says, I was asked to give an
23 opinion as to how a pediatrician would understand Harder.

24 Well, she's got no qualifications for that. And Dr. Horowitz
25 doesn't say this is it.

26 I mean, if you look at Dr. Horowitz's report, he's opining on

1 why you would not put a spoon in an infant's mouth or why it's not possible
2 for an infant to get a nutritional and therapeutic effective amount because
3 Raj says in effect when you look at her report and then at her deposition
4 transcript, she was told -- or she picked Sherman.

5 She picked the Sherman declaration because she said, well,
6 that's the most recent.

7 That's wrong and added words. Okay. She never looks at
8 anything else.

9 And she says, well, if you take the Sherman translation, a
10 pediatrician at some unspecified time -- she doesn't even know when the
11 priority date is -- would read it to mean to lick off.

12 Well, that's just repeating what's in Sherman. That's not a
13 qualified opinion.

14 She's got no basis. She should've -- if she wanted to say, here's
15 how I -- first off, how a pediatrician would read anything.

16 Who cares. That's not pertinent. It's a POSITA, and that's what
17 Dr. Horowitz talks about is how a POSITA would understand these things.

18 But Raj says, this is how a pediatrician would understand the
19 English language translation in Sherman.

20 I can read English as well as anybody else. That's not a
21 qualified expert opinion.

22 We talked about the adherence limitation which petitioner admits
23 is not in the prior art.

24 And per the petitioner's assumptions regarding the adherence
25 characteristics of Vigantol doesn't satisfy the necessarily so standard
26 required for inherency.

1 We talked about there's no admissible evidence of the actual
2 composition of Vigantol.

3 I mean, in fact, they don't identify Vigantol oil as a piece of
4 prior art which I think they should.

5 If they wanted to rely on what's the composition of Vigantol,
6 and then they have to have some evidence for what its composition is but
7 they don't.

8 They just take something out of Harder, her referencing to
9 Vigantol and her speculation as to what it contains even though that isn't
10 accurate or it is ambiguous at worst.

11 Or at best, it's ambiguous because medium-chain triglycerides
12 or vegetable oil is not a medium-chain triglyceride. Vegetable oil is a long-
13 chain triglyceride.

14 JUDGE HARDMAN: Let me ask you that particular point, that
15 very specific point that vegetable oils are long-chain triglycerides, not
16 medium-chain. Is that in your patent owner response?

17 MR. ANDERSON: Yes, ma'am.

18 JUDGE HARDMAN: And where can I find that, please?

19 MR. ANDERSON: Well, again, if you look at page 17 of our
20 response, we say that there's no information regarding composition of the oil
21 she used.

22 And then if you look at our surreply, we point out there
23 specifically that -- and this is on pages 4 and 5 -- that there is no admissible
24 evidence as to what the composition is of Vigantol and that Harder's
25 statement that Vigantol contains medium-chain triglycerides, paren,
26 vegetable, close paren, is inaccurate because vegetable oil is long-chain

1 triglycerides.

2 JUDGE HARDMAN: So that specific point about the
3 vegetable is long-chain. That's only in the surreply, not the response.

4 MR. ANDERSON: Well, they raise that in their reply where
5 we pointed out there's nothing on the composition of Vigantol in Harder.

6 And then they say, well, what she says, it's MCT, paren,
7 vegetable oil. We then responded to that in our surreply.

8 JUDGE SNEDDEN: When you read Harder, though, Harder
9 actually discloses that the Vigantol oil contains only one excipient as a
10 vehicle for the fat soluble Vitamin D.

11 And it says, namely, medium-chain triglycerides. Another way
12 to read this reference is that they're explaining to us that Vigantol oil is
13 medium chain triglycerides. And they give the bad example of vegetable
14 oil.

15 MR. ANDERSON: Well, I think it's -- again ignoring whether
16 that's admissible evidence, the actual composition of it.

17 There's nothing that says that is, in fact, the only excipient in
18 Vigantol.

19 And there's nothing -- when she goes on to say that it's the
20 excipient of medium-chain triglycerides.

21 And then it says vegetable oil. I mean, I think if assuming a
22 person would be looking at this, they would go, wait a minute.

23 There's got to be something else because vegetable oil is not a
24 medium-chain triglyceride.

25 So her statement is at best ambiguous and at worse just wrong.

26 Thank you, sir.

1 JUDGE NEW: Mr. Anderson, while we have a few minutes
2 left, I'm not really very clear on the nature of nexus that you're saying exists
3 between the commercial success of the product and the claimed invention.
4 Can you elaborate on that for me?

5 MR. ANDERSON: Sure. I think there's -- actually, there really
6 is no question about the nexus because the evidence is undisputed that the
7 DDrops product is covered by the claims.

8 In evidence is the analytical testing of the composition of the
9 DDrops product.

10 And then we have the instructions which say, place one drop on
11 a mother's nipple or pacifier.

12 At the same time, there is no question that the petitioner's
13 copycat product is covered by the claims of the patent because we have in
14 evidence their manufacturer's chemical analysis showing that it's got the
15 right composition.

16 And their instructions say, place one drop on a mother's nipple
17 or a pacifier.

18 It's identical. There's no question of the nexus. And then when
19 you look at the commercial success, again, there's no question that when
20 DDrops introduced its product in the United States after its patent was issued
21 in 2015, it went from zero to a big number.

22 And there's no question that when petitioner completed the
23 second step of its copy and changed its composition to be identical, identical
24 to DDrops, its sales took off.

25 It became the biggest selling product on Amazon and the
26 biggest selling product in the brick-and-mortar segments.

1 JUDGE HARDMAN: The problem, though, Mr. Anderson, is
2 that the products -- the petitioner's product and also DDrops -- the
3 instructions are not co-extensive with the claim. Although they include the
4 claimed method, they also include prior art methods such as mixing it into
5 milk, juice, or other food.

6 So how can we attribute any commercial success, any praise, et
7 cetera, to the claimed method when the product has other means of use?

8 MR. ANDERSON: And we address that exact argument the
9 petitioner made in our surreply, Your Honor, because the law regarding
10 nexus does not require 100 percent the same.

11 And I just refer Your Honors in the interest of time to our
12 surreply where we present a number of cases about the nexus.

13 If you look at page 20, one of the cases says the Federal Circuit
14 has never held that the existence of one or more unclaimed features standing
15 alone means that nexus may not be presumed and we go from there.

16 So it's actually in there. Now I think while we've got other
17 evidence that we present on commercial -- excuse me, secondary indicia,
18 none of which they address other than commercial success and I'll get to that
19 in a minute.

20 The clearest secondary indicia and what they don't dispute in
21 their reply is copying.

22 This was a two-step process here. And if you look at Exhibit
23 246, when they were deciding we've got to come up with a product, in 2016,
24 this is after ours is on the market.

25 They look at four competing products, the D-Vi-Sol product,
26 which is the market leader, Wellbaby by UpSpring, different, Zarbee's,

1 different.

2 And if you look at 246, look what they highlight. That's their
3 arrow, DDrops, one drop per serving.

4 That was a feature that they wanted. And that's what they
5 decided to do.

6 They copied everything but the composition because they go to,
7 say, we're going to have one drop.

8 We're going to have 90 servings. Happens to be the same as
9 ours.

10 The only product that took that they have a copy of is the
11 DDrops product.

12 We're going to us -- they use the euro dropper style which we
13 have.

14 And this is what they're promoting. The only thing they didn't
15 do then was the composition.

16 They used a different composition, sunflower oil and another
17 ingredient.

18 And their product wasn't successful. It wasn't successful. They
19 introduce it.

20 Yeah, it's out there, but it's not an infringing product. It wasn't
21 until they changed the bottle.

22 And then they created a rancidity problem, a shelf-life problem.
23 And so, they had to fix that.

24 They told their manufacturer look at MCT. You're testing on
25 MCT.

26 It's the only composition they considered. They knew about the

1 DDrops product.

2 And that's the point where they just, oh, we're just going to
3 copy DDrops.

4 Because when I asked their CEO and their marketing person,
5 what did you do, it was conveniently, I don't recall.

6 I don't recall. You can read that in their deposition. It's I don't
7 recall, sort of like those of you who may remember the Hogan's Heroes
8 program, Sergeant Schultz.

9 I see nothing. I know nothing. I hear nothing. But you all
10 knew that he knew.

11 They say, well, we don't know. But they knew. They knew
12 exactly what they were doing.

13 They make it, the MCT product. They complete the copying.
14 They don't dispute their product that these steps resulted in a copycat
15 product.

16 And when they introduce it, success. And that's the only
17 change that they made in 2021 was to the composition.

18 That was the last step on what they needed to have a product
19 just like ours.

20 As I said, it then became the fastest growing brand in brick and
21 mortar omni-channels in 2021.

22 There's no question that the commercial success applied to the
23 patented features.

24 So I would respectfully request -- unless Your Honors have
25 additional questions.

26 And I skipped over a bunch of things because of your very

1 insightful questions which I appreciated.

2 Unless you have other questions, we don't think that the
3 petitioner has met their burden of proof which is always on them to prove
4 that claims 1 and 3 to 5 would have been obvious in light of any of the prior
5 art combinations that they offer in their hindsight reconstruction. Thank
6 you.

7 JUDGE HARDMAN: Thank you, counsel. Mr. Conrad, you'll
8 have 27 minutes. I'll start the clock when you're ready.

9 MR. CONRAD: Thank you, Your Honor. And Judge
10 Hardman, just to start off, I wanted to answer two questions that I said I
11 would.

12 The first, I believe, you're asking where in the record it's
13 supported that Tinworth doesn't matter.

14 And you can look at Dr. Raj's declaration, Exhibit 1040,
15 paragraph 14.

16 She says, regardless of the translation used -- she listed all of
17 them. Regardless of the translation used, it is my opinion that a practitioner
18 reading this instruction would understand each of these instructions to
19 amount to the same steps that the drop of Vigantol oil should be placed on
20 the top of a spoon, given to the baby so that the baby can lick it off from the
21 spoon.

22 The second question you had, Judge Hardman, was that where
23 is it in the record that there's -- Dr. Raj is testifying about a small spoon
24 rather than a plastic spoon.

25 And in our reply brief, page 14, we point out that petitioner's
26 pediatrician, Dr. Raj, confirms that a baby can suck and/or lick the drop off

1 from a small spoon.

2 Also in her deposition, Dr. Raj was pressed on this exact same
3 point that the Munchkin brand was not available before she -- she tried to
4 explain that she didn't know.

5 But then on paper 98, we point to some lines of testimony on
6 page 3 of that paper.

7 For example, pages 90 through 91 of Exhibit 2081, her
8 deposition, Dr. Raj says, can I add something to this line of questioning?
9 Sure, sure.

10 She says, I have throughout my career, including with my own
11 babies, used small metal spoons.

12 Metal spoons are available in a small size. And metal spoons
13 are used all of the world in many, many situations.

14 And then she continues onto the next page, page 91. Spoons is
15 something I'm very comfortable with.

16 This, referring to the Munchkin brand, was a spoon that I have
17 not used with my own babies.

18 As I said, I have used small metal spoons to feed them because
19 they were because they were both premature and often had to be given
20 supplemental feeds.

21 So this is a -- and again, on page 130 of Exhibit 2081, she
22 testifies about practicing in India and hundreds of mothers, she said, quote,
23 we used spoons.

24 She says, I think it's a logical thing just to use the spoon. Give
25 it to the baby in its mouth, not have it, wash it off, start all over again
26 because the drop is the drop. It's still there on the spoon.

1 So this is all testimony explaining why she came up with a
2 conclusion that it makes sense that Harder would work even though she
3 tested Munchkin spoons which were purchased from Amazon.

4 Her opinion is coming from a source of personal experience and
5 personal -- both of herself as a mother and also as a pediatrician here and in
6 India.

7 So there's no requirement in the law that we use the exact same
8 device.

9 But what Dr. Raj shows is that the property that the spoon she
10 tried had -- which is small is just as common sense would explain and
11 personal experience as well, that's going to fit into a baby's mouth. That's it.

12 I do want to -- I'll see if this works on the screen. It may not. I
13 want to address the copying argument, secondary considerations.

14 First, as the Board knows, secondary considerations is not
15 dispositive of an obviousness case.

16 It's just there to check to make sure that the gap between the
17 prior art and the claim that you are trying to cross is not too big that it's
18 blinded by hindsight or that it is, in fact, hindsight.

19 That's the purpose as the Board well understands a secondary
20 consideration.

21 So I will get into the actual strength of their arguments. But I
22 do want to point out that the obviousness case here is very strong.

23 Harder discloses the claimed method using the claimed
24 composition.

25 And the reason that we reach to Wolf and to European
26 Pharmacopoeia, the motivation to combine is simply to find out more

1 information about the product. That's it.

2 There's no necessary expert testimony that's required in order to
3 make that leap.

4 This is just -- the law does not require expert testimony in order
5 to make a case of obviousness.

6 We pointed that out in paper 98 that you can recourse to logic,
7 judgment, and common sense when looking for a motivation to combine.

8 As the Board knows, you can find that in the references
9 themselves.

10 And the Wyers v. Master Lock case, 616 F.3d 1231, it explains,
11 again, quote, no expert opinion was required to support the obviousness
12 determination because the technology was easily understandable.

13 So the motivation to combine is there. We didn't need to have
14 expert testimony to do that even though we did.

15 I do want to see if we can look at some secondary
16 considerations.

17 I don't believe it's going to show up. Anyways, I'm going to
18 refer to patent owner's demonstratives.

19 There's no page numbers, but I believe it is page 28 in -- sorry,
20 27 and 28 of the demonstratives which were shown earlier.

21 These refer to Exhibit 2046, pages 8 through 9. And these were
22 what patent owner wanted to show regarding copying.

23 What they showed was a company trying to introduce a product
24 by looking at what the competitors were on the marketplace.

25 This is the evidence that they're relying on to say that the
26 patented method is copying.

1 Nothing on these two slides say anything about the claimed
2 method.

3 What they're pointing to on here is the serving size. That's it.
4 In fact, if you look at these slides, it doesn't even mention anything about
5 medium-chain triglycerides.

6 For example, demonstrative page 27 which is Exhibit 2046,
7 page 8, what mattered in that comparison of the competition was that
8 DDrops had one drop per serving. That's it.

9 And when you're looking at whether there's a nexus to
10 secondary considerations of non-obviousness, it's critical to consider what
11 was already in the prior art.

12 And here their argument on secondary considerations assumes
13 that Vigantol doesn't exist, assumes that Harder wasn't published.

14 And therefore, if you start from scratch in a North American
15 marketplace which didn't have the product and you pretend that Harder was
16 not published, well, then we're going to have a different conversation about
17 secondary considerations.

18 I'm going to come up with a different argument. But here what
19 they needed to show was that their introduction into the American
20 marketplace which didn't already have a comparative product to looking,
21 their success was because of the patented method and not the product itself.

22 JUDGE HARDMAN: Let me ask you, counsel. In your
23 petition or reply, I didn't really see a response to copying.

24 I saw that you attacked nexus. But you didn't go through the
25 reasons why petitioner's product ended up the way it is.

26 And the case law tells us that access to the patented product

1 which I think probably isn't disputed that petitioner knew about DDrops
2 before it launched its own product, and substantial similarity, that is
3 circumstantial evidence of copying.

4 So we seem to have those two things in the record, access and
5 similarity.

6 Why wouldn't we then conclude copying because we have no
7 countervailing information on how the product ended up the way it is?

8 MR. CONRAD: So Your Honor, we do address the story and
9 we don't address the copying directly.

10 And the reason is this. It's pretty indisputable that the
11 petitioners knew about DDrops and knew about the product.

12 And then after that, introduced it. I'm not going to argue with
13 you about the details of whether we're looking at one drop surface size and
14 wanting to repeat that.

15 I think that's actually something that petitioner's employees
16 testified to.

17 But it was the one drug. What we do show in our reply is the
18 story of their copying because we're failing in order to ultimately completely
19 recreate their product with the MCT oil.

20 So as you saw when the product was considered during
21 development and launched, it was sunflower oil.

22 There wasn't anything in the record that showed that petitioner
23 actually tried to copy the product -- DDrops product because it had MCT oil.

24 In fact, there's also evidence in the record that they didn't copy
25 the instructions.

26 There's nothing in the record that says they did. Now patent

1 owner is making a circumstantial argument, of course.

2 But the record actually shows that there was a prior product, a
3 probiotic drop product.

4 And we point this out in our response to the motion to exclude.
5 A prior product that had an Italian manufacturer and it had a label in which
6 the drop was to be placed, I believe, on the breast, if I'm not mistaken, on a
7 nipple.

8 I don't remember the exact words. But that's where the
9 instructions came from.

10 The employees testified that it was just something they'd
11 already been successful with in a different product and they just simply
12 repeated that.

13 The patent owner's story, however, is that we failed with the
14 sunflower oil product and had to copy their product in order to succeed.

15 And I'm on slide 83 of petitioner's demonstratives. And the
16 evidence just does not support that.

17 We agreed not to talk hard numbers because the underlying
18 evidence is filed non-publicly.

19 But Exhibit 71 is what patent owners rely on to tell the financial
20 story that DDrops' product was declining -- or it was succeeding. I'm sorry.

21 And then we changed our product, their copying argument.
22 And then all of a sudden, they declined and we succeed.

23 But if you look at that exhibit, 2071, and we have a diagram or
24 a demonstrative up on page 83 that shows what happens here.

25 Petitioner launched their Vitamin D product with sunflower oil
26 in 2016.

1 Patent owner says they were successful and had rising market
2 share in 2018 and 2019.

3 But then they argue that after we switched to MCT oil, this two-
4 step process, then all of a sudden, their market share declined.

5 What the evidence actually shows is that in 2020 there was a
6 substantial decline in their market share.

7 What happened in 2020? Well, it's indisputable that we
8 changed our bottle format from a euro dropper which is a glass -- essentially
9 like a glass bottle that one drop will come out if you hold it upside down to a
10 squeeze bottle which if you're more familiar with -- or if you're familiar with
11 eyedrops or ear drops or something like that from personal experience, that's
12 what it's like.

13 It's a small bottle that you squeeze to get a drop out. That
14 change in the bottle format is what happened in 2020.

15 So for a massive drop in market share in 2020, that's the only
16 event that that could be pointed to in what we changed about our product
17 that has anything to do with the performance of the companies.

18 That's not the patent. The patent is not the bottle format. When
19 we reformulated to sunflower oil to MCT, the reason was not to copy
20 petitioner.

21 The reason was changing that bottle format created some head
22 space that wasn't there before, allowing for some potential rancidity of the
23 product.

24 And that wasn't -- that didn't make it to the marketplace. It was
25 potential.

26 The tests were showing. So they decided, let's reformulate.

1 And of course, MCT is known to be a stable product and that is what they
2 switched to.

3 Other competitors were using MCT as well. If you look at
4 Exhibit 26, page 9 that patent owner showed -- I'm sorry, page 8 that patent
5 owner showed earlier, Wellbaby by UpSpring listed other ingredients of
6 fractionated coconut oil as the only other ingredient.

7 That's the same as the DDrops product. So there's a natural
8 reason why they switched to MCT.

9 And it was to solve a problem that they had of their own
10 making in order to introduce a better product and not to copy petitioner.

11 But again, this is just arguing the finer points of the secondary
12 considerations.

13 None of this overcomes the obvious in this case because Harder
14 tells you almost everything you need to know.

15 And we are not using Harder to do something different, to solve
16 a new problem, or to answer questions that haven't already been asked.

17 On the adherence point, I think if I understand patent owner's
18 argument correctly, I think what they're trying to argue here is essentially
19 that claim 1 -- their claims are invalid under Section 112 because they've
20 claimed a spoon -- I'm sorry, they claimed an object.

21 And now they're sitting here trying to argue that, well, a
22 spoon -- it can't work on a spoon.

23 Some other object maybe, but not a spoon. I don't think that's
24 their intention.

25 Again, we're not litigating that here today. But I think it's just a
26 much more simple explanation in that the claimed requirement of adherence

1 is just addressed to what the patent owner describes in its comparison
2 between water-based emulsions, alcohol, some oils, and ultimately MCT oil.

3 And it's just simply saying that MCT oil is good enough for
4 whatever purpose they're serving, they need for adherence, and the method.

5 On the nutritional and therapeutic amount, I think Judge New,
6 you made the -- I believe it was Judge New, but perhaps not, made the point
7 that patent owner is not arguing that the preamble is limiting.

8 And I think they repeated that again today. So the preamble is
9 not limiting.

10 So a method of delivering nutritional therapeutic amount of
11 Vitamin D, that's just a stated statement of intended purpose.

12 Again, Harder discloses that, right? It discloses delivering
13 Vitamin D to a human being and that it has been successful in treating
14 rickets.

15 But again, the point for the remainder of the claim limitations is
16 that the nutritional therapeutic effective amount refers to what's in the drop,
17 not in what's being actually received by the person.

18 The point for obviousness that we needed to answer, that the
19 Board would need to answer is, does Harder give you a reasonable
20 expectation of success that that drop is going to be nutritional or
21 therapeutically effective? And it does. It says it's been successful for many
22 years.

23 One more point I did want to make on secondary considerations.

24 The nexus would have to be -- they would need to show that it's
25 not the bottle format.

26 It's not the one drop serving size. It's not even just the medium-

1 chain triglycerides itself.

2 But what it is, is the patented method of placing one drop on a
3 surface of something for a human being to suck or to lick off that that itself
4 is the reason their product has been so successful.

5 They haven't shown that. There just wasn't that product in
6 North America but even though there was a German one.

7 So they needed to take a step further to show that the reason
8 their success happened was not because of all the unpatented things about
9 their product or not even just a subset of it but about the specific methods.

10 It's not necessary to use that method in order to use their
11 product. And the evidence that they provided, for example, customer
12 reviews, we objected to it. It's hearsay.

13 But just in case the Board considers it to not be hearsay, that
14 doesn't support their case.

15 I put up on the screen Exhibit 2071, page 205. And this is what
16 appears to be an Instagram post.

17 And it says, I just love how easy the drops are to add to food,
18 drink, making for easy consumption.

19 It's all so natural with no preservatives or artificial colors,
20 flavoring, just coconut oil and pure Vitamin D3.

21 Nothing about the patented method. In fact, she's talking about
22 the non-patented method.

23 Again, page 210 of 2071 exhibit, another review points out, I
24 sometimes miss because my baby moves.

25 But it's rare to miss since the drop is slow and I can calculate
26 when it will drop. And that's when I open my baby's mouth.

1 Again, prior art method, a disparage method, in fact. That's
2 what the public is using their product for.

3 One more, page 213, the review points out, it's only one tiny,
4 clear, and tasteless drop I put in milk.

5 So the point I'm making with all this is not that this is the only
6 way the public is using it but that petitioner to meet their burden, to
7 overcome a very strong case of obviousness must tie their success to the
8 claimed method of one drop on the surface, not for any other reason.

9 And they just have not done that. So unless Your Honors have
10 any other questions, I believe that completes my argument.

11 The challenged claims are unpatentable. I respectfully request
12 that the Board find that they are obvious, the prior art.

13 And I think if you were to accept patent owner's argument,
14 what you are effectively allowing for is taking known home remedies,
15 known folk remedies, known non-scientifically tested remedies that is
16 already in the public domain that have been published, that have been maybe
17 known or used.

18 Here we're talking about published. And taking that from the
19 public simply because what you do is confirm scientifically that it is, in fact,
20 effective like everyone thought before.

21 So that's what's holding these claims patentable would mean.
22 And that is not the law.

23 The law does not say that you get an invention simply because
24 you did get good science.

25 You get an invention for something new and not obvious. And
26 in light of the prior art, the use of Vigantol is the claim method and was

1 obvious. Thank you.

2 JUDGE HARDMAN: Mr. Anderson, you have 10 minutes.
3 When you're ready, I'll start the clock.

4 MR. ANDERSON: Thank you, Your Honor. I am
5 immediately reminded of the late Chief Judge Mark, the Federal Circuit's
6 famous quote.

7 Only God works from new. Man must work with old elements.
8 And that's what you just heard they were claiming for their obviousness
9 argument.

10 All these elements are out there. Therefore, voila. But the fact
11 is you heard nothing in their rebuttal about motivation to combine because
12 they don't got nothing.

13 And they just pick and choose and they try to jump around and
14 ignore all the various deficiencies because they're hoping that Your Honors
15 will accept their argument about, well, if you take a little bit here and ignore
16 these problems with it and a little bit here and ignore these problems with it
17 and a little bit here and a little bit here.

18 And then you just throw it all together and there it is. That's not
19 a basis for finding obviousness.

20 Now I want to start kind of where they were spending a lot of
21 their time which is on secondary indicia because contrary to what they say, I
22 think the case law is very clear.

23 The secondary indicia alone can establish non-obviousness.
24 And here it is an incredibly strong case.

25 And I want to first talk about a little bit about copying. Now
26 just to be clear, what we put up on our demonstrative is Exhibit 2046.

1 That's not the only thing that we rely on. I would refer Your
2 Honors to our response, pages 50 to 53, where we have all sorts of
3 references to the deposition testimony of Ms. Kaderali and Ms. Medina that
4 talk about what they were doing.

5 I mean, they wanted -- in 2016, they even said we want an
6 innovative product.

7 And they were really focused on the one drop feature. Now
8 they said, well, look at Wellbaby by UpSpring.

9 It was using fractionated coconut oil. But look at what's on
10 Exhibit 2046.

11 Their serving size is four drops, four drops. It's not one drop.
12 None of the products were one drop except for DDrops.

13 That was the key thing. In 2016, for whatever reason because
14 nobody could remember why, they decided to use sunflower oil.

15 Fine. Sunflower oil it is. That's not an infringing -- that doesn't
16 infringe the patent.

17 They went along for five years. And then when they had a
18 problem, the only thing they looked at was MCT.

19 And they knew that DDrops had MCT. That completed the
20 two-step copy.

21 And if you look at their reply, this is literally what they say
22 about alleged copying.

23 Quote, it's on page 27, patent owner's reliance on copying by
24 others also fails.

25 Patent owner accuses a slew of alleged copyists. They provide
26 no details about whether the copied products meet the claims or whether

1 they can be used in non-infringing methods.

2 No nexus was established, and this evidence should be
3 disregarded.

4 They don't say one word, one word opposing our argument that
5 they copied.

6 And everything that you heard today is just their after the fact
7 lawyer attempt to rationalize what they did.

8 This is about as clear a case of copying as you can get because
9 as Your Honor, Judge Hardman, pointed out, you don't have to have direct
10 evidence of copying. But boy, this is pretty darn close.

11 It's certainly circumstantial because they had access. They did
12 everything and they end up with a product that's covered by the claims.

13 Now they talk a lot about nexus. Yeah. So we started to have a
14 decline in 2020.

15 But where we really had the decline and the evidence supports
16 this is 2021.

17 And petitioner's own documents which I showed which we
18 talked about show that in 2021 they become the biggest seller on Amazon.

19 And the number one brand in the brick and mortar and I forget
20 the other market segment -- markets.

21 They weren't there before. They didn't get there for five years
22 when they had their product that was sunflower oil.

23 And it didn't start when they went to a different kind of dropper
24 because that created the problem of the rancidity.

25 So then they had to fix that. And the way they fixed it was
26 we'll just take the last step.

1 Clear evidence of copying. Now nexus, as we were talking
2 about, they say that, oh, well, there's others using MCT.

3 We talked about how it has the one drop feature which in the
4 deposition testimony, they all said that was key.

5 We talk about how they wanted an innovative product. Well,
6 gee, they thought it was innovative, even in 2016.

7 They have a product that was as close to DDrops as they could,
8 as close to DDrops as they could, same kind of dropper, same serving size.

9 The only difference was, well, we don't have the chemical
10 composition that's required.

11 When they got to that, they had the success. They talk about
12 Raj.

13 Now as you know, we've got our motion to exclude Raj. If you
14 look at her declaration, she was asked to give an opinion as to how a
15 pediatrician would understand the various translations.

16 In fact, she didn't look at the various translations. She looked at
17 Sherman, the only translation, and said, anybody -- she's not qualified to say,
18 this is how a pediatrician would understand the Sherman translation.

19 She's not a linguist. She doesn't know German language. And
20 her opinion is this is how a pediatrician -- well, who cares about a
21 pediatrician. That's not a POSITA.

22 And she doesn't even know how they would understand it at the
23 time of the invention, 2006, because she didn't know the date of conception.

24 She then goes on to say small plastic spoons. Well, there's
25 nothing -- it's undisputed that there's no evidence if there were small plastic
26 spoons at the time of the invention.

1 You can't just guess or assume that. She didn't test metal
2 spoons, even though counsel provided her with a set of metal spoons.

3 She says, oh, you'd never use a metal spoon with an infant.
4 That's in her deposition, never use a metal spoon.

5 JUDGE HARDMAN: Counsel, why is a metal spoon
6 important?

7 Harder doesn't say anything about the characteristics of a
8 spoon.

9 MR. ANDERSON: Well, because Harder does say -- the fact is
10 Harder, because it uses a spoon, the only spoons that we know of that
11 everyone would think of would be metal.

12 And there's nothing that says you stick a spoon in an infant's
13 mouth.

14 That's contrary to all of the research evidence that we presented
15 that you don't stick a metal spoon into a small infant's mouth.

16 And Harder does not -- keep in mind the two paragraphs of
17 Harder is Option 3.

18 Option 1, the general case, is crush a tablet into a spoon and add
19 liquid.

20 And then it's just, like, pouring it in. It's a typical way. I even
21 remember my mom giving me aspirin where she crushed it in a spoon and
22 then added water.

23 God, did that -- I remember to this day how bad that tasted. But
24 that was the way it was done.

25 It's only if you have a special case where you've got an infant
26 who has an allergy or gastrointestinal problems that then she says, well, you

1 can try using this thing.

2 If you put two drops in, wash it out and start over because she
3 knows that this can be toxic.

4 Well, if it's toxic, how is it -- if it's the right composition, then
5 how is it two drops is too much?

6 Two drops creates this problem where she says, don't do it.
7 Wash it out. Start over.

8 If it's a therapeutic effective amount, two drops is going to
9 cause harm.

10 That alone suggests that it's not what she says it is. With regard
11 to adherence, in the claim, it's not talking about any object.

12 It says you've got to have an object that will work where adhere
13 requires that A adheres to B and they ignore the nature of the object B.

14 The patent claim does not encompass every spoon. It only
15 encompasses objects where there would be the proper level of adherence so
16 that one drop would permit the removal of a therapeutic and efficient and
17 effective -- a sufficient and therapeutic nutritional amount, whatever the
18 claim language says. Apologize.

19 JUDGE HARDMAN: But where does your patent teach the
20 properties of a spoon that meet the adherence quality if you're using MCT?

21 (CROSSTALK).

22 MR. ANDERSON: Sorry. It doesn't say spoon. It's an object
23 that has the -- well, the substance, the oil, the carrier with the Vitamin D has
24 the correct and proper characteristics so that it will adhere so that it doesn't
25 just drip off or run off.

26 And so as the examiner said in his statement of allowances so

1 that it will adhere to the surface.

2 And you can lick or suck it off and get a nutritional therapeutic
3 effective dose.

4 The examples in the patent uses nipples or pacifiers. Those are
5 the examples that were used in the patent.

6 It was a nipple or a pacifier. And they did all this testing, and
7 it's described in the patent in the examples of how -- to prove that you can
8 get a nutritional and therapeutic amount.

9 So for those -- unless Your Honors have other questions, I
10 appreciate the opportunity to be here today.

11 Thank you for your attention and all of your great questions.
12 And I would urge the panel to reject the petitioner's petition and not find the
13 claims 1 and 3 to 5 are invalid as obvious under the cited prior art. Thank
14 you so much.

15 JUDGE HARDMAN: Thank you, counsel. Thank you to both
16 sides for your presentations and time today.

17 Just a housekeeping matter. I had asked during our call last
18 week about Exhibits 1036 and 1037 and deposition transcripts of Drs. Reid
19 and Horowitz.

20 And the question was whether either side was wanting those
21 under seal because we don't have a pending motion.

22 Nobody has made an argument that those have actual
23 confidential information in it.

24 MR. ANDERSON: We do not, Your Honor, from the patent
25 owner's standpoint.

26 It was, I think their information. So it's up to the petitioner's.

1 MR. CONRAD: Your Honor, I think we went back and
2 checked.

3 And I don't believe that we have anything from petitioner's
4 information that we're concerned about in there.

5 JUDGE HARDMAN: Okay. So we will go ahead and get
6 those removed from under seal.

7 That's Exhibits 1036 and 1037. The other remaining issue was
8 patent owner's surreply at paper 91.

9 Patent owner's motion says that contains petitioner's
10 confidential information at pages 23 and 24.

11 And so my question for you, Mr. Conrad, is do you intend to
12 move to seal those pages.

13 MR. CONRAD: Your Honor, could you repeat that again?

14 JUDGE HARDMAN: Yes, it's pages 23 and 24 in patent
15 owner's surreply. And the surreply was filed at paper 91.

16 MR. CONRAD: Yes, Your Honor. I believe we are moving to
17 seal that one.

18 JUDGE HARDMAN: Can you -- so we have a pending motion
19 from patent owner.

20 So the easiest way, I think the most straightforward way is if
21 you put in a response to that motion. Could you get your response in within
22 a week?

23 MR. CONRAD: Yes, Your Honor. And if for some reason we
24 change our mind and don't want to seal that information, we'll let you know.

25 JUDGE HARDMAN: Thank you. And let us know within a
26 week then as well if you change your mind on that. Okay. With that, we are

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1 adjourned. We can go off the record.

2 (Whereupon, the above-entitled matter went off the record at

3 12:06 p.m.)

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