

RECORD OF ORAL HEARING
U.S. PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS, L.L.C.,

Petitioner,
v.

DNA GENOTEK INC.,

Patent Owner.

IPR2023-01424
Patent 11,536,632 B2

Held: January 24, 2025

Before LYNNE H. BROWNE, CHRISTOPHER M. KAISER,
and JAMIE T. WISZ, *Administrative Patent Judges*.

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 The above-entitled matter came on for hearing on Friday,
January 24, 2025, commencing at 10:02 a.m., at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, VA.

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PROCEEDINGS

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JUDGE BROWNE: You can be seated. Good morning. Can you hear me okay? I'm a bit congested. We're here for oral argument in *Spectrum Solutions, LLC v. DNA Genotek, Inc.* That is IPR2023-01424. I'm Judge Browne and with me is Judge Wysz. And also appearing remotely is Judge Kaiser.

Before I begin, I do have a few housekeeping items. Because one of our Judges is appearing remotely, we ask that you assist him, as well as our court reporter, by stating the number of any slides that you are referring to and also identifying yourself when you are speaking. We are familiar with the record and we have copies of your demonstratives. This hearing is scheduled to last 2 hours with each party having a total of 60 minutes, including any time reserved for rebuttal.

With that, we are on the record, and we will begin with appearances. Who is here for Petitioner?

MR. JENNINGS: Good morning, Your Honors. Joe Jennings of Knobbe Martens on behalf of the Petitioner. And with me is my partner, Ali Razai, also with Knobbe Martens.

JUDGE BROWNE: Okay. And, would you like to reserve any time for rebuttal?

MR. JENNINGS: I'd reserve 15 minutes for rebuttal, Your Honor.

JUDGE BROWNE: Okay. And then who is here for Patent Owner?

1 MR. ARJOMAND: Good morning, Your Honors. Mehran
2 Arjomand of Morrison & Foerster on behalf of Patent Owner. With
3 me is Steve Sundberg, also of Morrison & Foerster. Also on the
4 public line are Marley Macarewich of Morrison & Foerster and
5 representatives of Patent Owner DNA Genotek.

6 JUDGE BROWNE: Great. Thank you. I'll ask you about
7 rebuttal time when you begin. We can begin with Petitioner when
8 you're ready.

9 MR. JENNINGS: And Your Honors, I have hard copies of our
10 demonstratives.

11 JUDGE BROWNE: Oh, that's okay. We don't need those.

12 MR. JENNINGS: You don't need those.

13 JUDGE BROWNE: No. And I'm sitting here looking at this
14 timer, and I think it's -- I think I can start it. Hopefully I can figure
15 out how to use it because I usually do this at home. It doesn't seem to
16 be starting, so just go ahead and I will try to keep track. And
17 hopefully, you can keep track for yourselves.

18 MR. JENNINGS: Okay. Good morning, Your Honors. There
19 are four main points I'd like to address today. First, that the amended
20 claims in the revised motion to amend have broadened the scope of
21 the claimed invention, which is improper. Two, that even if the
22 amended claims were proper, it would have been obvious to combine
23 *Plante* and *Cho*. There would have been a motivation to make that
24 combination and a reasonable expectation of success. Third, it would
25 have been obvious to modify the size of the annular valve in *Cho*,
26 meeting the requirements of the revised claims of the motion to

1 amend. And then fourth, I'll address the three dependent claims that
2 Patent Owner argues separately.

3 Okay. Turning first to the broadened claims. "An
4 amendment made during an IPR may not enlarge the scope of the
5 claims of the patent or introduce new matter." It's the Patent Owner's
6 burden to show that the proposed amended claims comply with the
7 relevant statute, including the lack of broadening. They failed to do
8 that here and could not have done that if they had tried in their
9 motion.

10 Turning to claim 21 here, we see it's a biological sample
11 collection system and it claims a movable annular valve, initially in
12 the second aperture. That was in the second aperture refers to the
13 aperture of the cap. They deleted that requirement of the claims and
14 changed it to "a movable annular valve positioned in the interior
15 volume of the cap." And per the Federal Circuit's law, a claim
16 broadened in any respect is broadened and improper here. And we
17 can see they're removing a limitation. They're broadening it in that
18 respect, and it's pretty straightforward.

19 Turning to the next slide here. I'm catching myself, I didn't
20 use my slide numbers. We're on slide 5, and these are our illustrations
21 of the claim scope as it was affected by the revised claims of the
22 motion to amend. In figure A, depicted is a movable annular valve
23 that is in the aperture of the cap. Figures B, D, and C then show
24 movable annular valves that are in the interior volume of the cap, thus
25 within the scope of the amended claims, but not in the aperture of the
26 cap. So the claims are covered by the amended claims. These

1 devices, these illustrations, are covered by the amended claims, but
2 not the original claims.

3 JUDGE BROWNE: So Patent Owner would have us interpret
4 aperture to be essentially the same scope as a hole. Why shouldn't we
5 do that?

6 MR. JENNINGS: Why shouldn't you do that? I'm going to
7 turn to my next slide. Let's start with the claims. The claims refer to
8 "an outer wall defining an open end of the cap, an opposing closed
9 end of the cap, and an interior volume of the cap." And then they go
10 on, "said open end defining a second aperture." So the claims tell us
11 that it's the open end that defines the aperture and it distinguishes it
12 from the interior volume of the cap.

13 If we go to the specification, the specification is consistent in
14 distinguishing an aperture from the interior space or volume. On the
15 right-hand side, speaking of this reference from the specification first,
16 this is referring to the embodiment that we've been discussing in this
17 IPR quite a bit in figure 3. "The interior space 20 may be at least
18 partially defined by at least one of an interior wall 18. The inner wall
19 18 may further define an aperture 12." So again, the specification,
20 consistent with the claims, is distinguishing the aperture from the
21 interior volume that the aperture leads to. And the references on the
22 left are also from the specification. And the specification is consistent
23 in distinguishing an aperture from the space or the volume to which
24 the aperture leads.

25 And this is consistent with the plain meaning of the word
26 "aperture." The parties have discussed the plain meaning most often

1 used in the context of a camera. An aperture of a camera lets light
2 into the camera, but the aperture is not the space internal to the camera
3 where that light goes. And in fact, their expert acknowledged this
4 distinction, as we cited to in our papers, when he was asked about
5 aperture, and this is his testimony at Exhibit 1033, page 44, where he
6 acknowledged the aperture is the hole that lets light into a camera to
7 an imaging element within the camera. So even in that discussion
8 there, he's distinguishing from the hole, the aperture that lets the light
9 in, from what's contained within the space within the camera. The
10 light is allowed in through the aperture, and then to the imaging
11 element in the camera.

12 So I submit that it's straightforward when they've deleted a
13 limitation in the claim here in the aperture, replaced it with another
14 limitation such that the claims cover something that they didn't
15 previously cover, and it's straightforward. The *Sisvel* case is directly
16 on point. The Federal Circuit noted the helpful illustrations which
17 we've provided in this case with our figures B through D of examples
18 of embodiments that would fall within the scope of the new claims,
19 but not the old claims.

20 JUDGE BROWNE: Mr. Jennings, is it your opinion that this
21 issue, if we decide that the claims are broadened, would be dispositive
22 for this case?

23 MR. JENNINGS: Yes.

24 JUDGE BROWNE: Thank you.

25 MR. JENNINGS: And Your Honor, I was thinking about this
26 just last night, actually. Certainly in a District Court, if I was arguing

1 this in a District Court, the District Court would and could end the
2 case right there. Summary judgment, claims are broadened. I'm
3 going to acknowledge, I don't know under the Administrative
4 Procedures Act what the Board needs to do with respect to these other
5 points. So I'm going to address them here today. We did in our briefs
6 as well. But that is dispositive, it's straightforward, and it ends this
7 IPR.

8 Okay. So let's turn to the obviousness of combining *Plante*
9 and *Cho*, a familiar issue in this IPR with the related patent and now
10 here. So I show on slide 9, on the left is the *Plante* device, which is a
11 sample collection system. It has a cap with a reagent chamber in the
12 cap and a sample collection vessel with a sharp pointed knife that's
13 going to facilitate release of the reagent. The reagent chamber is a
14 cylindrical component holding reagents in a sealed manner in the cap
15 until it's applied to the vessel.

16 On the right-hand side, we're showing a figure of *Cho*. *Cho*
17 also has a cap with a sealed cylindrical reagent chamber, which is a
18 cylinder shown in I guess our color is orange there. And then that is
19 released through the use of a movable annular valve using the
20 terminology of the '632 patent. So two cylinders that move axially
21 with respect to each other when the cap is applied to the container to
22 release the reagent into the container.

23 Now, turning to our next slide, slide 10, we're now showing
24 the annular valve of *Cho* and the '632 patent, and they're startlingly
25 the same. *Cho* has the cap, the two cylinders. You screw the cap onto
26 the container. The cylinders move with respect to each other, causing

1 the outer cylinder to uncover a vent in the inner cylinder and releasing
2 the reagent. Similarly, in the '632 patent, a cap, an inner cylinder
3 containing a reagent having a vent that's initially covered by an outer
4 cylinder. The cap is screwed on to a container, uncovering the vent
5 and releasing the reagent into the container.

6 So let me turn to motivation to combine. We've addressed
7 this issue in the prior IPR and we've made four -- or presented four
8 different rationales for combining *Plante* and *Cho*. In slide 12, these
9 are summarized here. The first is the, "Safety design considerations
10 motivate replacement of *Plante*'s sharp knife." That was the
11 motivation that the Board relied upon in the IPR on the '646 patent,
12 and it holds true today. It's more than sufficient to justify the
13 rationale, but we also have the others. The Board at that time found it
14 to be sufficient and did not go on and address the others. But we also
15 addressed three other rationales. One, as Mr. Leinsing testified, one
16 of skill in the art would have recognized that the particularly long
17 sharp knife of *Plante* would have presented difficulties in molding,
18 motivating one to replace that knife.

19 Third, "Using *Cho*'s annular valve allows the cap to be sealed
20 prior to" release of the potentially toxic preservatives. Now, this is a
21 new rationale. It wasn't presented last time. This came to us when
22 Patent Owner was arguing many alleged problems with *Cho*, none
23 well-founded. But one problem they pointed to, they contended that
24 *Cho* didn't actually seal. And we argued against that. The Board
25 ultimately did not accept it. But it's something that we came to
26 appreciate when we were discussing that issue with our expert. And

1 the expert presented this because *Cho*, as Mr. Leinsing explains in his
2 declaration, doesn't release the material, the additive, until the cap has
3 been sealed onto the container, which is an advantage here when these
4 preservatives could be potentially toxic. It's one of the advantages
5 that the '632 patent relies upon. And so *Cho* has improved *Plante* in
6 that respect. And that motivation, never addressed by Patent Owner.

7 And then finally, "Replacing *Plante*'s cap with *Cho*'s cap,"
8 having an annular valve, "is a simple substitution of known elements."
9 On the one hand, a piercing member that's going to release a reagent
10 from a cap of a container and, on the other hand, a movable annular
11 valve that allows two cylinders to move, uncovering a vent to release
12 the reagents into the chamber.

13 Now, I'm going to go through a few of these, discuss this
14 safety which seems to be still on top of everyone's mind in terms of
15 Patent Owner's arguments, pointing out on our slide 13 how *Plante*
16 includes knife 19. And we've summarized Dr. Leinsing's testimony
17 regarding *Plante* and why it would motivate one to remove that knife
18 and find an alternative solution to releasing that reagent. As we
19 highlighted, "A POSA would have recognized that the knife in
20 *Plante*'s sample collection system created a risk of injuring a user and
21 others who handle the device. It has long been known in the field of
22 medical devices to avoid sharp objects if possible." And frankly, I'd
23 submit it's long been known in fields well beyond the medical devices
24 to avoid sharp objects.

25 But Mr. Leinsing pointed out, and as we relied, the '632
26 patent recognizes the detrimental feature of having sharp objects and

1 potential hazards, noting that the patent "improved safety for both the
2 sample donor and the end user, since, for example, sharp objects are
3 not included." And that's the second highlight there that we have on
4 the patent, column 5, lines 3 through 8. And on the first highlight talk
5 about avoiding the risk of exposure to any hazards as an advantage.
6 And remember, *Cho* avoids the risk of exposure to not only the knife,
7 but to the toxic solution before the container is concealed, a
8 motivation not even addressed by Patent Owner.

9 And Dr. -- or Mr. Leinsing, gave him a promotion there, I
10 guess, did cite to several sources of support for his conclusion that one
11 would have been motivated to remove the sharp from *Plante*. One is
12 the Needle Stick Prevention Act, which we've quoted on the left of
13 our slide 15, talks about the problems with needles and other sharps.
14 That's Exhibit 1012. And then on the right -- and that's a 2000
15 document -- or act. And then on the right is the CDC Workbook,
16 Exhibit 1013. And we're quoting there, "In the hierarchy for sharps
17 injury prevention, the first priority is to eliminate and reduce the use
18 of needles and other sharps where possible."

19 Now, I will note for the record that the Board excluded the
20 CDC Workbook in the last IPR. Patent Owner objected. We just
21 submitted that document itself and it was identified as on the -- its
22 URL as a 2008 document. And we've supplemented the record in
23 response to their renewed motion to exclude in this case. And I'm
24 going to address these issues on my next slide 16.

25 And so the workbook has a 2008 date on its URL. It's also
26 referred to on the OSHA website, which we submitted as Exhibit 1023

1 in this case, as a 2008 publication. And the workbook shows and the
2 OSHA website show that the workbook is intended for the public. It's
3 intended to inform the public on these serious issues in helping them
4 design products that avoid these concerns. And also in the workbook,
5 all references in the workbook predate 2008. And 2008, I mean, it's
6 not a closed case, 2008 is three years before their earliest critical date
7 of 2011.

8 So the only reasonable conclusion from the record of the
9 evidence in this IPR is that this CDC Workbook was, in fact, available
10 to the relevant public prior to the critical date and should not be
11 excluded here. Frankly, I think it's a little piling on. I think we have
12 more than enough to justify a rationale to remove the sharp from
13 *Plante*. But we had submitted this evidence and now we're supporting
14 it with additional support to confirm that it was available.

15 And so, as we all know, on this basic issue, the Board has
16 already found a motivation to combine *Plante* and *Cho*, and the record
17 here is even stronger to do so. And we've cited here on our slide 17 a
18 couple excerpts from the Board's conclusion on the motivation to
19 combine *Plante* and *Cho*. That's Exhibit 1044 at 40 and 1044 at 42. I
20 don't need to read them. I'm sure the Board is familiar with that.

21 So now let me turn to a reasonable expectation of success in
22 making that combination. First off, I want to say in their motion, they
23 argue there was no a priori guarantee of success when they argue
24 against this combination. Now, of course, that's not the law. The law
25 is reasonable expectation of success, as we point out and cite case law
26 in our opposition at page 20.

1 But Mr. Leinsing testified very clearly that there would have
2 been a motivation to combine these and one of skill would have had a
3 reasonable expectation of success. As he said, "A POSA would have
4 known that *Cho*'s threaded cap could be made to accommodate the
5 threaded sample collection vessel in the embodiment disclosed in
6 *Plante*. A POSA would have expected success in using *Cho*'s cap to
7 perform the same function when the cap was fastened to *Plante*'s
8 sample collection vessel." And, "It would have been clear to a POSA
9 that the combination of these references would have involved the
10 routine substitution of one cap with an annular valve for another with
11 a pierceable membrane."

12 And the large portion of Patent Owner's argument here
13 doesn't really go to the particular amendment that changed the size of
14 the movable annular valve, but it goes to the combination itself. They
15 attempt to refute the combination that the Board found in the '646
16 patent IPR and that we've explained, just went through all the reasons
17 to combine here.

18 So now I'd like to turn to the obviousness of modifying the
19 size of *Cho*'s annular valve and which leads to the conclusion that
20 claim 21 of the motion is unpatentable for obviousness. And in terms
21 of the motivation to modify the size of *Cho*, we presented three
22 different rationales. One, reducing the risk of sample contamination.
23 And Dr. Leinsing testified to this in his declaration on Exhibit 1027,
24 paragraphs 27 to 30. And second, that there are basically two options
25 of placement of the removable annular valve within *Cho*'s cap. And
26 he testified to that in his original declaration.

1 Let me back up for a second. So they first filed their first
2 motion to amend, and they described the size limitation in the context
3 of the first and second cylinders being within the cap, which they
4 meant from their arguments to mean entirely within the cap. And that
5 wasn't supported. We argued against it. They got preliminary
6 guidance and they filed a new motion to amend, the revised motion to
7 amend we're addressing here.

8 And in the revised motion to amend, they again addressed
9 size, but they did it with different language. And so in the revised
10 motion to amend, instead of the movable annular valve with the first
11 and second cylinders being within the cap or entirely within the cap,
12 as they thought they were saying, in the revised motion to amend they
13 said the first cylinder is positioned externally to the sample collection
14 vessel in both the closed configuration and the open configuration of
15 the movable annular valve. It still is addressing the size and it's
16 saying -- it's addressing that size by saying that outer cylinder stays
17 outside of the vessel both in the closed and open configuration.

18 So now getting back to the motivations to modify the size,
19 there are two options for placement of the movable annular valve in
20 *Cho's* cap. And that depends on the reference point that you're
21 looking at. Initially, Dr. -- or Mr. Leinsing said -- explained how you
22 could either have that movable annular valve with the two cylinders
23 entirely within the cap or extending out of the cap. Those two
24 options.

25 Now, when we're describing it in relation to whether the first
26 cylinder ever extends into the vessel or not, it's a matter of how much

1 you shorten, and I'm going to get to this, shorten the movable annular
2 valve depending upon the amount of additive. So then either the
3 aperture is going to be -- the aperture of the inner cylinder is either
4 going to be above where the outer cylinder abuts the container or
5 below where the outer cylinder abuts the container. But it all depends
6 upon adjusting the volume of the additive container based upon the
7 length of the cylinder in the movable annular valve of *Cho*.

8 And that's related to our third motivation being simple design
9 choices. One of skill in the art would recognize that simple design
10 choices would lead to adjusting the size of the movable annular valve
11 of *Cho* depending upon the particular application one was using it to
12 address.

13 Now, first going to our first motivation, adjusting the size to
14 reduce the risk of sample contamination. Patent Owner's expert Dr.
15 Wereley testified that there was a risk of contamination with *Cho*'s
16 design, focusing on the particular embodiment shown in *Cho* and the
17 fact that the amount of additive was such that in that embodiment that
18 the annular valve extended out of the cap. And he explained that one
19 might touch that before putting the sample in and that might
20 contaminate the sample if you're using it in a sample collection
21 container. And Mr. Leinsing explained, as we quote here on Exhibit
22 1027 at paragraph 30, that given that concern that would have
23 motivated one to modify the size of *Cho*'s valve such that it was not so
24 likely to be touched by a user.

25 Our next slide 23 illustrates the two options concept which I
26 discussed. And this is, as I mentioned, is related to the design

1 considerations, namely that one would know that different
2 applications are going to require potentially different amounts of
3 additive. And so you would adjust the size of the chamber, the inner
4 cylinder that holds that additive. On the left is figure 44 from *Cho*,
5 and on the right is what Mr. Leinsing explained was an obvious
6 modification for an application where you needed less additive, such
7 that the inner cylinder is essentially shortened to accommodate less
8 additive. And once it comes up to the point that it's above where the
9 outer cylinder abuts that outer cylinder or abuts the collection vessel,
10 the outer cylinder would not, as depicted on the right of our slide 23
11 and shown in page 7 of Mr. Leinsing's declaration of Exhibit 1041, the
12 outer cylinder would not extend into the sample collection vessel.

13 And so I explained how a POSA would be motivated to
14 change the size of *Cho*'s valve based upon the amount of the additive.
15 As Mr. Leinsing explained, "a POSA would be motivated to reduce
16 the vertical length of the reagent chamber in *Cho*'s cap and thereby
17 bring the first and second cylinders entirely within the boundaries of
18 the outer wall of the cap." That was addressing their first motion to
19 amend.

20 And then addressing their second motion to amend, where
21 they describe it slightly differently. "A POSA would have been
22 motivated to adjust the size of the movable annular valve and its
23 components depending upon the amount of the additive to be added.
24 A POSA would and could adjust the size of the cylinders that make up
25 the annular valve as he or she shall all fit for a given application."

1 So those are two sources of the evidence explaining this
2 motivation. I think it's pretty apparent just from looking at *Cho* and
3 recognizing that in every application you're not going to want to have
4 the same size of additive compartment. You're not going to use the
5 same amount of additive. And Mr. Leinsing also explained that in
6 applications, particularly using chemicals and things that could be
7 oxidized, a person would have been motivated to avoid empty space
8 in the additive compartment that would allow oxygen to potentially
9 oxidize the substance that you're storing there. And that's Exhibit
10 1027 at paragraph 33.

11 So in slide 24 here, this illustrates the modification where
12 we're going from figure 44 of *Cho* to a smaller additive compartment
13 such that the outer cylinder would not enter the sample collection
14 vessel because the additive compartment was shortened and the
15 aperture was above the point at which that outer cylinder abutted the
16 sample collection vessel. And this is explained in detail in Mr.
17 Leinsing's declaration, Exhibit 1041 at paragraph 15. So he goes
18 through the fact that one of skill in the art would know that different
19 applications call for different volumes of additive and would size the
20 inner cylinder accordingly, including such that it was sized short
21 enough that the outer cylinder would not enter into the sample
22 collection vessel.

23 And ultimately, the change, as Mr. Leinsing explains, the
24 change here does not in any way affect the functionality of *Cho*'s
25 valve. We still have two cylinders that move axially relative to each
26 other when the cap is screwed on to a collection vessel. It's just a

1 matter of sizing the additive compartment and how that adjusts the
2 relative relationship of the first and second cylinders: first cylinder
3 being on the outside, second cylinder being on the inside.

4 So let's go to some case law that we cited in our brief and like
5 to highlight here for the Board. So the case law recognizes that mere
6 changes in size are obvious. The Board has recognized in *Ex Parte*
7 *Martin Guram*, "It has generally been held that changes in sizes and
8 shapes of known elements are within the level of skill in the art,
9 especially in the absence of unexpected results or criticality." I want
10 to highlight there for a second on that term, "known elements."

11 Clearly here we have known elements. An annular valve in a cap with
12 two cylinders, the outer cylinder moving relative to the inner cylinder
13 to uncover a vent is a known element. And per this, generally it's
14 been held that sizes and shapes of known elements are within the level
15 of skill in the art, "especially in the absence of unexpected results or
16 criticality." There's no allegation in this case of unexpected results or
17 criticality.

18 And the Board here in the prior IPR, this is Exhibit 1044 at
19 page 43, already recognized that, "A person having ordinary skill in
20 the art would have understood how to size, scale, and otherwise form
21 the sample collection kit taught by *Plante* using *Cho's* cap." In that
22 IPR, they were arguing, well, you couldn't combine it with *Plante*
23 because, look, they're different sizes and it was like a physical
24 combination. They were trying to superimpose patent figures on top
25 of each other. Same principle applies here. One of skill in the art

1 would have known how to size that valve accordingly based upon a
2 particular application.

3 JUDGE BROWNE: Mr. Jennings, just so you know, you have
4 about 10 minutes before you get to your rebuttal time.

5 MR. JENNINGS: Thank you. I appreciate it. I keep looking
6 up, I see 45. Keep looking at my watch.

7 Okay. So let me turn on to a reasonable expectation of
8 success. And here on this slide, we're highlighting the testimony of
9 Patent Owner's expert in this case and we just include the answer here,
10 but I'm going to tell you the question I asked him, so one of skill in
11 the art would understand, however, that *Cho's* -- the volume of *Cho's*
12 additive space could be adjusted consistent with the invention
13 described in *Cho*, correct? And he answers, "So one of skill in the art
14 would recognize that the additive storage container, the size or the
15 volume of the additive storage container could be changed to
16 accommodate some operations, so holding some material. So he's
17 recognizing one of skill in the art could do that.

18 And he also recognized, and we cite it in our briefs, that one
19 of skill in the art would recognize that the axial length of the inner
20 cylinder could be adjusted and that that would adjust the volume and
21 that adjustments lead to a change in the amount of additive. And Mr.
22 Leinsing explained, you don't want empty space in with that additive,
23 avoid oxidation. So you're changing the amount of additive, you're
24 changing the size of that inner cylinder.

25 Okay. Now getting back to that issue of criticality, the '632
26 patent does not even discuss this new sizing limitation. And the

1 embodiments of the '632 patent show multiple instances where the
2 blocking member does extend into the sample collection vessel. Now,
3 they argue against this. Well, we don't have to show that the
4 particular limitation is inventive, but as the case law just showed, this
5 is a known element and we're talking about a size adjustment of a
6 known element. And they can't point to any criticality of this sizing
7 limitation that they attempt to rely upon.

8 And in response to our argument that the patent never
9 discloses any advantage or criticality for this size, they cite to some
10 advantages that the patent does discuss, one being safety. Well, when
11 they do that, they actually ignore the safety issue about the sharp
12 objects because that doesn't help their case. But they point to limited
13 risk of exposure to toxic substances in the '632 patent, but that does
14 not relate to the size. And *Cho* has the same advantage.

15 And they also refer to minimal parts. But if you look at the
16 '632 patent in context, the reference to minimal parts is in reference to
17 what they describe as a prior art device. And they talk about that prior
18 art device. It required two different caps: one that was put on first to
19 release the compartment, and then the '632 describes about how one
20 has to take that off and put another cap on. So that's the context of the
21 minimal parts.

22 There are two parts that a user needs to use in the
23 combination of *Plante* and *Cho*. You've got a collection vessel and
24 you've got a cap. User puts the cap on, screws it down, it becomes
25 sealed before there's any release of toxic substances, the substances
26 are released, and then that can be shipped off to someone to do some

1 testing. So that's the context of the minimal parts. It's not talking
2 about some attempt to minimize the number of parts in the particular
3 device. It's what the user is using.

4 And in large part to argue against obviousness, they are
5 arguing a host of molding difficulties, talking about an extensive and
6 costly redesign. But when they do that, one, it's not about the size.

7 And what they do point to when they get anywhere specific are
8 common features such as ratchet teeth, tolerances, holes, or apertures.

9 And these are all addressed by Mr. Leinsing in Exhibit 1041 at
10 paragraph 27.

11 Ultimately, the manufacturing of *Cho*'s annular valve is
12 within the level of skill in the art. And it's not even a detail that's
13 described in the '632 patent what they're challenging here, because,
14 after all, a patent specification, whether it be *Cho* or the '632 patent, is
15 intended to teach the invention. It's not a product manufacturing
16 specification. And that's the *In re Gay* case that we cite in our brief.

17 And Mr. Leinsing, talking about the ability to mold and make
18 these things, provided his opinion with two concrete examples
19 supporting it. And this is on our slide 29 where he refers to where he
20 states, "These documents support my conclusion that it was
21 conventional to mold, in high volumes, using two plastic cylinders
22 with an interference fit since well before the '632 patent." And that's
23 the *St. Gobain* product brochure from 2001 on the left, Exhibit 1045,
24 and a patent from 1996 on a stopcock valve, and both similarly using
25 cylinders that move relative to each other to function as a valve and
26 release a material.

1 So now I'd like to quickly turn to the issue of the three
2 amended claims, three amended dependent claims that they argue
3 separately. First is substitute claim 29 talks about "relatively movable
4 entirely within the interior volume of the cap" for the two cylinders of
5 the movable annular valve. This follows from claim 21. If you adjust
6 the size, it's obvious to adjust the size. Claim 29 is obvious for the
7 same reasons as claim 21, and that's explained by Mr. Leinsing on
8 paragraph 29 of his declaration at Exhibit 1041.

9 Claim 36, a separable -- I'm going to just highlight a few
10 words here in the interest of time. The key point was the "separable
11 two-piece sample collection system." And Mr. Leinsing explained
12 how in combining *Plante* with *Cho*, you're going to have a separable
13 two-piece collection system. Patent Owner wants to limit *Cho* to
14 beverages where it comes prepackaged with the cap on. Mr. Leinsing
15 went through and explained how if you're going to use the annular
16 valve of *Cho* in a sample collection container, you're going to have
17 them separated so that it facilitates providing a sample and putting the
18 cap on. And that's what's shown on the right side. This is *Plante*
19 figure 4 where *Plante* discloses packaging that allows the product to
20 be shipped with the cap separated from the container, and then the
21 same packaging, after the sample has been applied, the cap has been
22 put on, there's another place to put the fully assembled device to ship
23 it back. They seem to ignore that when they address claim 36.
24 They're just assuming *Cho* is a beverage container with things already
25 attached when it goes out to the consumer. In the combination, that's
26 not the case and it's obvious for that reason.

1 Finally, claim 33 -- dependent claim 33 has two issues. Well,
2 two issues and two-by-two, I guess. One is with respect to the flange
3 that whether it's on the first and second cylinder, whether they
4 disclose that, whether there's written description support, and also
5 whether there's written description support for whether the initial
6 contact between the flange and a portion of the sample collection
7 vessel upon engagement of the cap to the sample collection vessel
8 causes the annular valve to change from the closed to the open
9 configuration. As we pointed out, there's no flange on the inner
10 cylinder, the second cylinder in what's described in the '632 patent.

11 And initially in their motion, which was their burden, they
12 made the mistake. They referred to a continuation app, a claim and a
13 continuation app application filed years after the original filing, and
14 said, well, those "original claims" provided support for this flange.
15 We pointed that out in opposition. They obviously recognized the
16 error and backed away. And now they're badly reaching to try to find
17 a flange or any written description for a flange on the second cylinder.
18 And it's just not supported.

19 And their argument that it's somehow two species of a genus,
20 this is not anywhere near the two species of a genus in the *Hynix* case
21 where a bus could be multiplexed or not. This is a structure either on
22 one part of the device or somewhere else. And there's no explanation
23 of how the flange on the second cylinder that has the vent would
24 somehow function in these claims.

25 And also the specification doesn't explain how the initial
26 contact between the flange and a portion of the sample collection

1 vessel causes the annular valve to change from the open to the closed
2 position. Using the device of the '632 patent, the cap is put on and
3 screwed onto the sample collection vessel. The flange contacts that
4 sample collection vessel. That initial contact does nothing in the
5 embodiment of the figure 3, which is the subject of this claim that
6 supposedly provides support for it. One has to continue to screw the
7 cap on and it's only that process of screwing the cap on that causes
8 that outer cylinder to go up, open the vent, and allow the release. So
9 the initial contact in that process does not cause the opening of the
10 valve.

11 However, if there were written description support, *Cho* is the
12 same. *Cho*, if you combine it with *Plante*, you take the cap, you put it
13 onto the container, you screw it down, the outer cylinder comes up,
14 releases the valve, same as the '632 patent. Thus, if the claim were to
15 have written description support, it's invalid for obviousness for the
16 reasons we've explained.

17 If the Board has any questions, happy to answer them.
18 Otherwise, I'll reserve what time I may have for rebuttal.

19 JUDGE BROWNE: So it looks like you have about 11
20 minutes left in your rebuttal. And I don't see any questions, so we can
21 turn it over to Patent Owner.

22 MR. JENNINGS: Thank you, Your Honors.

23 JUDGE BROWNE: Before you begin, I wanted to make sure
24 your name is pronounced Mr. Arjomand?

25 MR. ARJOMAND: That's fine.

26 JUDGE BROWNE: Close enough?

1 MR. ARJOMAND: Yeah, close enough.

2 JUDGE BROWNE: Okay, thank you. And how much time
3 would you like to reserve for rebuttal?

4 MR. ARJOMAND: Let's reserve 15 minutes.

5 JUDGE BROWNE: Fifteen minutes. Okay. So by my clock,
6 that would give you until 11:43. When you're ready.

7 MR. ARJOMAND: Great. Good morning, Your Honors, and
8 may it please the Board. Turning to slide 1, this provides a roadmap
9 for Patent Owner's presentation today. First, we will show that claim
10 21 has not been impermissibly broadened. Second, we will contend
11 that the revised claims are patentable over *Plante* and show. And
12 third, we will establish that claim 33 is supported. Just to make it
13 clear for the Board, these are the only three issues that are currently in
14 dispute in this proceeding. There are no other issues in dispute with
15 regard to other claims not being supported, any claim being indefinite,
16 or any other grounds beyond *Plante* and *Cho*.

17 All right. Turning to slide 2. Slide 2 shows claim 21 in the
18 revised motion to amend. That's Paper 26. And claim 21 is directed
19 to a biological sample collection device. It recites three elements: a
20 cap -- sorry, a sample collection vessel, a cap, and a movable annular
21 valve. There are amendments here that are shown with respect to
22 issued claim 1 of the '632 patent. There were amendments directed to
23 the cap recitation, specifically that the cap was recitation was
24 amended to include an outer wall comprising an open end, a closed
25 end, and an interior volume of the cap. There were recitations added
26 with respect to the reagent chamber and the movable annular valve

1 being positioned in interior volume of the cap. And finally there was
2 a recitation added with respect to the cylinder being positioned
3 externally to the sample collection vessel in both the closed and open
4 configurations of the movable annular valve.

5 Now let me jump ahead here to slide 3 -- or slide 9, I should
6 say. There are three dependent claims at issue. You heard Petitioner's
7 counsel just address them. Claim 29. Claim 29 is directed to the first
8 cylinder and the second cylinder being "relatively movable entirely
9 within the interior volume of the cap." Substitute claim 33 is directed
10 to an annular valve comprising "a flange extending from at least one
11 of the first and second cylinders, and wherein initial contact between
12 the flange and a portion of the sample collection vessel upon
13 engagement of the cap to the sample collection vessel causes the
14 annular valve to change from the closed configuration to the open
15 configuration." That's substitute claim number 33. And then
16 substitute claim 36 is directed to "a separable two-piece sample
17 collection system," one piece being the sample collection vessel, the
18 other piece being the cap and the movable annular valve.

19 So with that overview, let me turn to the issue of broadening
20 with respect to claim 21. And I'm here on slide 21 -- actually on slide
21 11. And the slide 11 is the basis for Petitioner's argument with respect
22 to broadening. Specifically, they allege that claim 21 has been
23 impermissibly broadened because the "second aperture" has been
24 deleted and replaced with the "interior volume of the cap."

25 Now turning to slide 12, that argument is based on the
26 aperture being understood, from Petitioner's viewpoint, as an infinitely

1 thin plane. And so what you see here on slide 12 is page 4 from the
2 opposition to the revised motion to amend. That's Paper 32. And here
3 on page 4 they showed a figure A. And you can see that they've
4 defined aperture in figure A as an infinitely thin plane.

5 Now, we believe that Petitioners understanding of aperture as
6 an infinitely thin plane is inconsistent with the record. And turning to
7 slide 13 here, we believe that the proper understanding of aperture is a
8 volumetric open space. Specifically, we believe that understanding,
9 Patent Owner's understanding, is consistent with how a POSITA
10 would understand a term. It's consistent with the dictionary
11 definitions, it's consistent with the '632 specification and claims, and
12 it's consistent with the relevant case law.

13 So let me first turn to the POSITA's understanding and the
14 dictionary definitions in the record. I'm here on slide 14. And slide
15 14 sort of summarizes the evidence in the record from Dr. Wereley,
16 Patent Owner's expert, as well as dictionaries from both parties. So in
17 the first row on slide 14, there's testimony from paragraph 33 of
18 Exhibit 2025 of Dr. Wereley's declaration. And there he testified that
19 "an 'aperture' is not an infinitely thin, planar feature, but rather an
20 'opening' or an 'open space,' for example, a hole."

21 In his cross examination he testified similarly. This is at page
22 44, lines 16 through 18 of Exhibit 1033. He testified that aperture is a
23 "hole in a camera." And if you take a look at those two testimonies,
24 you'll see that they're consistent with the dictionary definitions in the
25 record. So Patent Owner's submitted the *American Heritage*
26 *Dictionary*, that's Exhibit 2028. And there the dictionary defined

1 aperture as "an opening, such as a hole." And in fact, if you take a
2 look at Petitioner's dictionaries, specifically Dictionary.com Exhibit
3 1031, it also defines aperture as "an opening, as a hole."

4 And so we believe that if you take a look at the testimony in
5 the record from Dr. Wereley about how a person of ordinary skill in
6 the art would understand aperture, and when you take a look at the
7 dictionaries that are in the record, it's very clear that aperture would be
8 understood as a volumetric open space. None of the testimonies that
9 are provided here on slide 14 nor provided in the dictionary
10 definitions by either party define aperture as an infinitely thin plane.
11 So that's just the evidence with regard to the POSITA's understanding
12 and dictionary definitions of aperture. But we also believe that the
13 Specification of the '632 patent is also consistent with aperture being a
14 volumetric open space.

15 So here I am on slide 15. And this shows on the left figure
16 3A of Exhibit 1001. It's annotated, it's highlighting inner wall 18 and
17 it's also highlighting aperture 22. And when Dr. Wereley was asked
18 about this figure and this disclosure, he said at page 42, lines 12
19 through 16 of Exhibit 1033, "the thickness of the aperture 22, which I
20 would refer to as the depth in this figure, In this view of 3A, the depth
21 goes from the outside of 18 to the inside of 18, inner wall 18." So he's
22 clearly indicating that there is a depth or a thickness to aperture 22,
23 and that depth or thickness would correspond to the depth or thickness
24 of inner wall 18 shown in blue in annotated figure 3A.

25 He further testified that you could think of aperture as the
26 absence or removal of material. So if you can take that testimony and

1 consider just a simple mathematical analysis, the volume that is
2 shown here in -- and pointed to as aperture 22 in figure 3A would be
3 the cross-sectional area shown in figure 3A of the aperture times the
4 thickness or depth that Dr. Wereley testified about. That's consistent
5 with our understanding of aperture as being volumetric open space.

6 It's also consistent with the specification of the '632 patent.
7 So here I am on slide 16. And so if you take a look at this, it refers to
8 at column 14, lines 24 to 27 of Exhibit 1001, it refers to an aperture
9 22. That's a singular reference and that conveys that the singular
10 aperture -- a single aperture, conveys what Petitioner would consider a
11 front and back opening of the aperture. If you're thinking of an
12 infinite thin plane, it would be the front plane of that aperture on the
13 outside wall of 18 and then the back plane, which would be on the
14 inner wall of 18, and it includes the volume in between those two
15 planes. So that's perfectly consistent with our view of aperture --
16 single aperture referring to a volumetric open space.

17 If you were to take their view of aperture as being an
18 infinitely thin plane, there would at least be two references to aperture
19 in figure 3A: one for that front plane associated with the front surface
20 of 18, and the second would be with the back plane associated with
21 the back surface of 18. So we think our understanding of aperture is
22 consistent with the specification, with the evidence in the record
23 associated with the POSITA's understanding, and also with the
24 dictionary definitions.

25 So I can move on to the patentability issue unless Your
26 Honors have any question with respect to broadening.

1 JUDGE KAISER: Yeah, I have a question on this issue. So
2 let's say we agree with you that an aperture that is defined by a wall,
3 as in the slide 16 that's on the screen right now, has some finite depth
4 that's defined by the thickness of the wall and, therefore, is a
5 volumetric space rather than just a two-dimensional opening, how do
6 we square that with what's in your proposed claim 21, where the
7 aperture is defined not by the size of the cap, but by the open end of
8 the cap? What's the thickness there?

9 MR. ARJOMAND: Okay. Yeah, let me address that question,
10 Judge Kaiser. Let me go back to slide 11. This shows claim 21, but it
11 includes a little bit more of the amendment and it specifically has, I
12 think, the recitation that you were pointing to, which is right before
13 the deletion of "second aperture" in place, where we replaced it with
14 "interior volume of the cap." The claim recites "an outer wall
15 defining an open end of the cap, an opposing closed end of the cap,
16 and an interior volume of the cap, said open end defining a second
17 aperture." Judge Kaiser, were you referring to that limitation?

18 JUDGE KAISER: Yes. Yeah. You've got sort of three things
19 that are being defined there, and then the aperture is being defined by
20 one of those three things and not by another (inaudible), which would
21 be the interior volume.

22 MR. ARJOMAND: Right. So I think the way that -- one way
23 to understand this claim language is that in the addition of those three
24 things, it introduces a volume, the interior volume of the cap. And
25 then what is then explained is that that said -- that volume is defined
26 by an open end, in other words, a hole or an aperture. So the interior

1 volume became -- is introduced as a volume, and then the next
2 recitation makes it clear that it's a volume that actually has an
3 opening, which makes it a hole or an aperture.

4 Does that address your question, Judge Kaiser?

5 JUDGE KAISER: I'm not sure, I guess. It seems to me, I
6 think the natural way to read that first -- the language that
7 immediately follows "a cap comprising" is to say the cap has an open
8 end, a closed end, and an interior volume. It's three separate things.
9 And then the open end defines something that we're going to call a
10 second aperture. And then in the original language, moving down to
11 the last clause of the claim that's shown on this slide, the annular valve
12 was positioned within that second aperture as opposed to within some
13 other portion of the cap, like, say, the interior volume of the cap. And
14 now it's being changed to position that valve within the interior
15 volume instead.

16 And I think that's Petitioner's argument and I see where
17 they're coming from. But I'm curious why it's wrong, given that, you
18 know, you've got a point that at least sometimes an aperture can have
19 some depth, but it's hard to see where that depth comes from when it's
20 being defined by an open end of some structure, here a cap, rather
21 than by the entire volume of that structure.

22 MR. ARJOMAND: Right. So I think it's very clear from the
23 record that an aperture always is a hole or an open space. It's a
24 volumetric open space. And so what the two terms, an interior
25 volume of the cap and the second aperture, are getting at the same
26 space. So the interior volume of the cap is being introduced as a

1 volume, and that volume at that point in the recitation, it could be any
2 kind of volumetric space obviously associated with the cap, but it's
3 just the volume. And what the second recitation, the follow-on
4 recitation says is when you have a volume with an open end, it's a
5 hole. So "second aperture" and "interior volume of the cap" are
6 getting at the same space, but in slightly different ways.

7 JUDGE BROWNE: So then why are they claimed separately?

8 MR. ARJOMAND: Well, the volume, the interior volume of
9 the cap doesn't convey the concept of a hole. But when you say "said
10 open end defining a second aperture," the introduction of the open end
11 makes it clear that you have it.

12 JUDGE BROWNE: So I guess one issue I'm really struggling
13 with is this equating a hole with an aperture and where that comes
14 from and where that's supported in the specification.

15 MR. ARJOMAND: Well, I think, you know, we can go back
16 to slide 15, for example, which shows figure 3A of Exhibit 1001, and
17 it's pointing to aperture 22. And what --

18 JUDGE BROWNE: Yes, but that's a different aperture than
19 the one we're discussing, correct?

20 MR. ARJOMAND: It's -- well, I think what it's showing is
21 how aperture is understood in general. That our view of aperture as
22 being a volumetric open space in the dictionary definitions defining
23 as, for example, hole is consistent with how aperture's also used in the
24 '632 patent.

25 JUDGE BROWNE: So let's say that we agree with you that,
26 an aperture does have a little bit of thickness. I don't think the

1 Petitioner is arguing that it is a flat, how did you say it, infinitely
2 extending plane. I think that we can all agree that there would be
3 some thickness there, but that is very different than the concept of an
4 interior volume.

5 MR. ARJOMAND: Well, Your Honor, I would respectfully
6 disagree about Petitioner's understanding of aperture. If you take a
7 look at here, slide 12, they draw aperture as a plane. It's a line, Your
8 Honor, that goes into the page, into figure A. It's drawn as an
9 infinitely thin plane. That's how they understand it. And there's no
10 definition that defines aperture as an infinitely thin plane. In fact,
11 what the definitions do provide is that aperture can be a hole. And
12 what the claim is trying to get at is there's an interior volume of the --
13 interior volume of the cap. And when you have open end, that makes
14 it a hole or an aperture.

15 So think of a sphere and then you cut a piece out of it, an
16 open end, it becomes a hole. The sphere, when it's just a sphere, when
17 it's just a volume, it's just a volume. But when you cut an open end in
18 it, it becomes a hole. And that's how the claim should be understood,
19 is that it introduces the volume, for example, a sphere, and then
20 because there's an open end, it makes it clear that volume is a hole.

21 JUDGE BROWNE: I understand your position.

22 MR. ARJOMAND: Okay, great. All right. Let me now turn
23 to the patentability issues. So let me turn to slide 18.

24 So we heard from Petitioner today the combination is based
25 on *Plante* and *Cho*. And here on slide 18 we see figure 1 of *Plante*.
26 And it's clear, and I think Petitioner wouldn't dispute this, that *Plante*

1 doesn't have an annular valve. It's also I think fairly clear here that
2 *Plante* is focused on having a minimum number of parts. And there's
3 also discussion in *Plante* in paragraph 6 of focusing on having a
4 minimum number of parts.

5 Now, turning to slide 19, this shows *Cho*. And *Cho* is a
6 beverage bottle that's designed to ship a beverage with a separately
7 stored additive to prevent deterioration and for enhancing mixing
8 upon later use. And so to that end the operation of *Cho* -- and I think
9 this is a really important concept to just make sure that we're all on the
10 same page because I sense in the way Petitioner presents its
11 arguments, they would like to skim over this concept or more
12 accurately how *Cho* operates. So the cap in *Cho*, the cap is attached
13 to the bottle during assembly to create a fluid tight seal with the valve
14 remaining in the closed configuration as shown here in slide 20, in
15 figure 44 on the left. So there's this first step in which the cap is
16 engaging with the bottle, specifically the bottle mouth 611, and the
17 valve remains closed in that engagement. Then later, only upon
18 further tightening does the slider 636 advance into the bottle and the
19 valve changes to the open configuration as shown in figure 45 on the
20 right of slide 20. So I think that is one really, really important point to
21 keep in mind as we go through the patentability analysis.

22 The other important point to keep in mind is that
23 fundamentally *Cho* is not directed to a biological sample collection
24 device. It's not. I mean the beverages, you know, Petitioner argued
25 that we keep saying that -- we keep arguing that *Cho* is limited to a
26 beverage bottle. It's the additives and the beverage material can be

1 different. But at the end of the day, the structure of *Cho* is a structure
2 of a sort of two-step operation that's really opposite or orthogonal to a
3 biological sample collection system.

4 So in the '632 patent, the way it works is you have a two-
5 piece collection system. You have an open sample collection vessel
6 and a cap and you deposit the biological sample in the vessel. And
7 then after you do that, then you engage the cap to the sample
8 collection vessel, and that operation is what opens the valve and
9 releases the additive so that the biological sample that's been
10 deposited can be preserved.

11 So those two concepts, kind of the two-step operation of *Cho*
12 compared to the one-step operation of the '632 patent, and that *Cho* is
13 not directed to a biological sample collection system and the claims
14 are, I think our just like big picture points that are very important here
15 in the patentability analysis.

16 So let me turn to slide 21 and this provides some passages in
17 the '632 specification that talks about the '632 patent focusing on a
18 minimum amount of parts. As you can see from this passage, I don't
19 agree with Petitioner's counsel saying that a minimum amount of parts
20 is limited or is only focused on having a minimum amount of parts for
21 the user to use. It simply says here "a minimum amount of parts and
22 does not require the removal of or exchange of piece -- or exchange of
23 a piece or an object thereof." The "and" might -- after "and" might
24 relate to user use. But the first part of that passage, which is
25 highlighted here on slide 21, is clearly directed to a minimum amount

1 of parts. And also, unlike *Cho*, the '632 patent is also directed to
2 limiting or eliminating the risk of exposure to toxic solutions.

3 So the '632 patent and the claimed invention achieved these
4 objectives through a very simple design. And here I am on slide 22.
5 And the simple design is that there's only three elements in claim 1: a
6 sample collection vessel, a cap, and an annular valve. And the
7 annular valve itself has only three elements: a first cylinder, a second
8 cylinder, and a vent. And this arrangement has a number of
9 advantages, as shown here on slide 23: a minimal number of parts,
10 that's important in this field; limited or no risk of contamination; and
11 also limited or no risk of exposure to toxic chemicals. So these are
12 advantages that are important and are achieved by the claimed
13 invention.

14 So with that overview, let me just turn now to the claim
15 language. And we're here on slide 24. And as we've discussed, there
16 are a number of amendments that are made with respect to issue claim
17 1 that are shown here on slide 24. And I think that the key point is
18 that we've clarified that the reagent chamber and the movable annular
19 valve are positioned in the interior volume of the cap. And we've also
20 recited an additional feature relating to the first cylinder being
21 external to the sample collection vessel in the open and closed
22 configurations.

23 And turning to slide 25, we think there's plenty of support and
24 there hasn't been any challenge from Petitioner regarding those
25 limitations. But I think it's important to make clear, like how, you
26 know, how those limitations map to the disclosure in the '632 patent.

1 And what slide 25 shows, it shows figure 3A on the left that shows the
2 valve in the closed position and it shows figure 3B in the middle that
3 shows the movable annular valve in the open position. And so what
4 you see in figure 3A is that the reagent chamber 20 and the annular
5 valve, which is inner wall 18 and annular blocking member 62, are in
6 the interior volume of the cap 24 in the closed position.

7 And then once the biological sample is deposited into tube
8 14, and I'm now moving to figure 3B, the user attaches the separately
9 shipped cap to the tube. So upon attachment, what happens is that the
10 flange 48 on inner wall 18 connects or contacts with coupling feature
11 50 on the rim of the sample collection vessel. And that causes the
12 annular blocking member to recess into the cap as the user is
13 tightening the cap. And in this way the valve opens and the additive
14 is deposited into the tube 14 to preserve the biological sample.

15 But what is important from a claim perspective with regard to
16 the first cylinder, which maps to the annular blocking member 62, is
17 that in any configuration, whether it's the closed or the open
18 configuration, the annular blocking member is never in the sample
19 collection vessel 14 or the tube 14. It's always external to that. And
20 that's clearly shown in figures 3A and 3B.

21 Now, turning to slide 26, this claimed invention clearly
22 distinguishes from *Plante* and *Cho*. As I mentioned, *Plante* does not
23 have an annular valve at all. And if you take a look at *Cho*, it doesn't
24 meet the recitations that we've added. So this is showing, on slide 26,
25 it's showing figure 44, which is the closed configuration of *Cho*. And
26 you can see that *Cho*'s annular valve has additive storage container

1 620 that's comprised by 624 and end plate 622, and a slider 636,
2 which is the inner cylinder there. And as you can see there, both of
3 them are deep into the bottle mouth 611. In fact, they go into the
4 bottle body 610. And this is already in the closed configuration.
5 Once the cap is tightened in *Cho*, in that second step operation where
6 the valve opens, the slider 636 further enters into the bottle body for
7 enhanced communication with the additive and the material in the
8 bottle body.

9 So there's really no dispute that claim 21 distinguishes over
10 *Plante* and *Cho*. I don't think Petitioner has made that argument.
11 They have relied instead on obviousness. And the foundation for their
12 obviousness argument is based on a number of kind of contentions
13 that they make. And they've made this repeatedly in their briefing.

14 So here on slide 27 we've collected those contentions. I think
15 you've heard today from Petitioner's counsel that "*Cho*'s valve is
16 essentially identical and functions identically to the claimed
17 invention." You've heard from Petitioner's counsel that "*Cho*'s valve
18 includes the same basic parts as the claimed valve and functions in the
19 same way." And you've also heard from Petitioner's counsel that this
20 is a matter of a "simple substitution" of putting in *Cho*'s cap and
21 annular valve with *Plante*. In our view, respectfully, we think that
22 these contentions are factually wrong and, frankly, nonsensical.

23 So turning to slide 28, this is showing *Cho*'s complex valve
24 design. And I just want to pause right here. This is figures 43, 44,
25 and 45A. This is the 21st embodiment of *Cho*, the only embodiment
26 that Petitioner is replying -- relying on. And you don't have to spend a

1 lot of time looking at this figure to realize that this looks nothing like
2 what I just went through with regard to the '632 patent, figures 3A and
3 3B. This is an incredibly complex design.

4 And turning to slide 29, this provides kind of a list for Your
5 Honors of the features or parts that are associated with *Cho's* valve.
6 So, as you recall, when I explained sort of the simplicity of the '632
7 invention, I indicated that the annular valve -- or the annular valve
8 only has three parts. It has a first cylinder, a second cylinder, and a
9 vent. *Cho's* valve here has 17 features parts. There's the upper cap
10 634 and all the features that is associated with that. There's the inner
11 cap 624 that's associated with the additive storage container 620
12 together with these additional features There's a bursting film 640 and
13 then there's the bottle body and the external threads. It's not correct.
14 It's simply not correct for Petitioner to say that *Cho's* valve has the
15 same basic parts as the claimed invention or as the '632 patent's
16 annular valve. It's just factually incorrect.

17 So turning to slide 30, this is showing figure 3A of the '632
18 patent in comparison to *Cho's* valve design. And I put in this slide to
19 make it easier for you all -- for Your Honors to sort of see the
20 differences clearly. So let me just kind of drill down on what those
21 differences are.

22 So we first talked about *Cho's* cylindrical valve components
23 636 and 624 going -- let me just make sure. Yeah, it's inner cap 624
24 and going into the bottle mouth. Unlike the '632 patent, which is
25 shown here on the right, the first cylinder never enters into the sample
26 collection vessel and, frankly, neither does the second cylinder or the

1 inner wall 18. The outer cylinder in *Cho* includes external thread
2 622b and it engages directly with bottle 610 and internal threads 634a
3 of the upper cap. In the '632 patent, as you can see on the left, the
4 outer cylinder does not engage directly with the interior threads of the
5 cap and only contacts the rim of the sample collection vessel upon
6 attachment of the cap.

7 *Cho* includes a number of ratchet features, four ratchet
8 features. It includes ratchet plates 632b and 622a, and it also includes
9 ratchet 622c and 613. And then there are other differences. There are
10 ring-type seal protrusions in *Cho* 636b and c that prevents leakage
11 between the inner cap 624 and the slider 626. There's the
12 incorporation of a wedge feature 636d and there's a bursting film 640.
13 There's just a lot of structural differences between figure 3A and
14 figures 44 and 45A. And what these structural differences point to
15 really are differences in operation.

16 And I touched upon this earlier in my presentation today, but
17 here in slide 31, I kind of provide again, just for Your Honors' benefit,
18 that the '632 patent is directed to a one-step operation. Specifically,
19 the cap of the '632 patent is shipped separately from the empty
20 biological sample collection device or vessel. And then when the cap
21 is attached to the biological sample collection vessel, it brings the
22 flange, that coupling feature 48 on the inner cylinder, into contact
23 with the rim of the sample collection vessel, that's coupling member
24 50, which causes the outer cylinder to move and basically open the
25 valve from closed to open to release the additive.

1 In contrast, here on slide 32, *Cho* has a completely different
2 mode of operation. It's a two-step operation. And I don't think there's
3 any dispute regarding this as well from Petitioner. In the first step, the
4 cap is attached to the bottle during assembly at the factory and it's
5 filled to create a fluid tight seal with the valve remaining in the closed
6 configuration during distribution. That occurs when the ratchets that I
7 discussed, specifically 622c and 613, engage. That creates the fluid
8 tight seal and creates the connection. And in that situation the valve is
9 still closed. Only later the user, and this is step two, upon further
10 tightening of the upper cap 624 does it then open the valve from the
11 closed position to the open position. So that's in slide 32.

12 JUDGE BROWNE: Mr. Arjomand, I did want to warn you,
13 you have about 10 minutes left before you'll be getting into your
14 rebuttal time.

15 MR. ARJOMAND: Okay. Thank you, Your Honors.

16 So let me then point to -- Let me then direct us to slide 34,
17 Your Honors. And so given these structural and operational
18 differences, what Petitioner has had to do is that they've had to really
19 change *Cho*. And they keep trying to emphasize that it's just a sizing
20 issue. All it is is just a sizing issue. But it's a complete structural
21 redesign of *Cho*. And I'll go through that. It's not an accurate
22 characterization to say that it's a sizing issue. And frankly, I think if
23 you take a look at what they've created, it's really based on hindsight,
24 using our technology claim 21 as a blueprint for creating what they
25 have created.

1 And this structural redesign presents a number of issues.
2 There are issues associated with molding and manufacturing
3 complexities that go well beyond a POSITA's skill level. There's
4 issues associated with clinical diagnostic product requirements that a
5 person of ordinary skill in the art would consider not -- would direct a
6 person of ordinary skill in the art away from the combination. And it
7 would negate the advantages of *Plante*. And so their -- Petitioner's
8 counsel wants to sort of kind of stay at a very high level on these
9 issues. But when you actually dig down into the details, you really do
10 see that there are a lot of reasons why the combination would never be
11 made by a person of ordinary skill in the art.

12 So let me quickly turn to slide 35. And let me go quickly
13 through the structural redesign of *Cho*'s valve. So here this is showing
14 the first two changes. They've modified the length of slider 636;
15 we've talked about that.

16 They have eliminated the inner cap 624. You didn't hear
17 Petitioner's counsel mention that. But they've eliminated a part.
18 They've eliminated 624. And you can take a look at their surreply on
19 this issue. It does not respond to this point. They point to a paragraph
20 in Mr. Leinsing's declaration that doesn't indicate -- that doesn't
21 support their point that 624 has not been eliminated. Clearly, when
22 you look at this modified *Cho* figure, 624 has been eliminated. The
23 inner cap has been eliminated.

24 Turning to slide 36, the Petitioner has modified the vertical
25 dimension of the upper cap 634 by extending the outer walls. And it's

1 also increased the number of internal thread 634a available to engage
2 with the external thread 612 of the bottle.

3 And then turning to slide 37, Petitioner has significantly
4 enlarged circular end plate 622 of the additive storage container 620,
5 and it's modified the bursting film. So for them to say it's simply a
6 resizing, I don't think again, is consistent with the record. This is a
7 complete redesign of *Cho*.

8 Now, I did mention that I think when you take a look at these
9 changes that are made, a person of ordinary skill in the art would
10 never make those changes and would never make the combination
11 because of all the complexities that are associated with their
12 combination.

13 So given the limited amount of time, this is all on the record,
14 there's lot of testimony and evidence in the record about injection
15 molding difficulties, and those are actually based on the Injection
16 Molding Handbook, Exhibit 2029, that Mr. Leinsing relied upon.

17 And just to give you a quick sense of what those complexities
18 would be, we talked about *Cho*'s valve, and this is slide 39, having
19 multiple ratchets. It has actually four ratchets: two ratchet plates,
20 632b and 622a, and then 622c and 613 are also ratchets. So that adds
21 complexity that I think a person of ordinary skill in the art would not -
22 - would give them reason not to make the combination.

23 There's also complexity associated with the ring-type seal
24 protrusions that are provided in the *Cho* valve. And so here I'm on
25 slide 41. This is testimony from Dr. Wereley, paragraph 46, Exhibit
26 2030. He talks about these features, such as the ring-type seal

1 protrusions, "require precise molding to tight tolerances." And you
2 know, there's -- when you start shrinking these products -- or these
3 elements, the way Petitioner is doing it, the tolerances get smaller and
4 smaller, and so the molding issues become greater and greater.

5 And the reference that they cite to, I think Petitioner's counsel
6 pointed to slide 29 to say that this is all easy manufacturing. But if
7 you take a look at the *St. Gobain* reference that they rely upon, it
8 doesn't recite tolerances required for manufacturing, nor the amount of
9 development time required to bring those products to market. So the
10 evidence that they've submitted doesn't really address or respond to
11 the point that Dr. Wereley is making regarding precise molding to
12 tight tolerances.

13 Let me also quickly get to some of the -- just very briefly, Mr.
14 Leinsing also provided some mold designs. Dr. Wereley in his
15 Exhibit 2030 addressed all the issues with Mr. Leinsing's mold design,
16 that they really do not accurately convey all the features that are in
17 *Cho's* valve, that it wouldn't work. And that testimony, Your Honors,
18 is un rebutted because Petitioner never deposed Dr. Wereley after he
19 submitted Exhibit 2030. So we believe that the record makes very
20 clear that whatever Mr. Leinsing has conjured up in terms of mold
21 designs, they've been thoroughly rebutted by Dr. Wereley and have
22 not been -- and that testimony has not been rebutted by Petitioner.

23 So turning here to slide 49, Your Honors, this is showing a
24 passage from our -- I think our reply. And what we're trying to say,
25 it's the top portion of slide 49, we say that, "Modification and
26 incorporation of *Cho's* complex multi-component valve design would

1 have led to a long development time and increased fabrication and
2 assembly costs." And I think one thing you heard from Petitioner is
3 that that's all directed to manufacturing. That's not really important
4 for obviousness. That's not the case, Your Honor.

5 So we had cited *Ethicon* case here where a District Court
6 criticized Mr. Leinsing exactly for what he's done here, which is he's
7 made a complete redesign of a valve, here in this case he's made a
8 complete redesign of, in this case, the Gallo device. And he didn't
9 consider the time and amount of resources necessary in making that
10 redesign.

11 And turning to slide 50, we cited the *Hulu* case, which is a
12 PTAB case out of 2019, that, you know, indicated that, you know,
13 these issues associated with manufacturing, in this case, for example,
14 cost because of the clinical diagnostic product requirements, cost
15 issues are very important, those go to non-obviousness. It's not
16 correct legally and factually for them to try to sweep this under the
17 rug to say, oh, this is just manufacturing. This doesn't really go to the
18 combination, what's taught in the references. You know, let's not
19 think about the real world issues that are involved here. But if you
20 take a look at what a person of ordinary skill in the art would do,
21 when you're looking at the complexity of *Cho*'s valve and the
22 modifications that they're trying to make, I don't think a person of
23 ordinary skill would be motivated to do that.

24 They criticize or they quote -- it's not criticize, they quote Dr.
25 Wereley as indicating that he testified that these changes could have

1 been made. But I think if you take a close look at his testimony, it
2 really doesn't really go to what they're trying to say.

3 First of all, here on slide 51, we've provided some testimony
4 at page 69, line 13, to page 70, line 9, from Exhibit 1034. His
5 testimony wasn't unbounded. He said, yeah, the additive storage
6 compartment or, you know, the additive storage compartment could
7 be changed to some extent, but not to any extent. And he also, you
8 know, he also indicated that, you know, this testimony was from --
9 well, this testimony I should say is from the '646 IPR. They never
10 deposed Mr. Wereley with regard to his testimony relating to the
11 revised motion to amend. As I mentioned, Exhibit 2030, once it was
12 submitted, they didn't depose him. So this testimony is relating to a
13 whole other proceeding.

14 And then if you look at the remainder of his testimony, it's
15 always in reference to what a person of ordinary skill in the art could
16 do. It's not what a person of ordinary skill in the art would do. And
17 we think that there is plenty of evidence in the record that a person of
18 ordinary skill in the art would not make this combination. And the
19 reason we say that is I think you need to take into account what the
20 person of what the level of skill in the art here is.

21 This is slide 52. This is paragraph 23 from Exhibit 2014.
22 Here Dr. Wereley says that a person of ordinary skill in the art has a
23 degree "in a scientific field relevant to mechanical aspects," so a
24 bachelor's degree, "and some experience of disposable medical
25 devices." But what is required to make this combination requires
26 really a highly trained, highly specialized engineer. And this is in

1 paragraph on slide 53, citing paragraph 61 of Exhibit 2030 of Dr.
2 Wereley. He says that I don't think a person of ordinary skill in the art
3 as defined by either party, but as defined, would be able to do what
4 the Petitioner is challenging. And again, this testimony was not
5 challenged, was not -- Mr. Wereley was not cross examined on this
6 testimony. So I think it's unrebutted.

7 With the few minutes that I have I would like to just quickly
8 mention that the combination between *Plante* and *Cho* also doesn't
9 make sense. So if you go back, I'm on slide 59, if you think about
10 how their combination works with *Cho*, remember it's a two-step
11 operation. The cap is engaged to the bottle body. So if that's received
12 by the user for depositing of a biological sample collection device, it
13 will need to remove that cap. And given the ratchet systems that are
14 associated with *Cho*, that would actually be very difficult to do
15 because those ratchets are one way. And then there's no guarantee
16 that once you deposit that sample that you'll have a fluid tight seal
17 again because you've just gone against the ratchets to yank open the
18 cap.

19 If you do what I think Petitioner's counsel was suggesting
20 today, which I hadn't heard of before, which is to say that you have
21 the cap separate, *Cho*'s cap separate from its vessel, and you deposit
22 the vessel, you still are not going to achieve what is the purpose of
23 this whole proceeding, which is to preserve the biological sample.
24 Because what happens is the user deposits the biological sample in the
25 vessel and closes the *Cho* cap, but because it's a two-step operation,
26 it's going to close at the first step because the ratchets are going to

1 connect and engage. And so it will not be clear to the user that the
2 valve has still not opened in that arrangement. It will take additional
3 cranking of the cap in *Cho* for the valve to open. So I don't think the
4 *Plante-Cho* combination makes any sense in combination when you
5 consider how *Plante* works.

6 Finally, let me just briefly address --

7 JUDGE BROWNE: I just wanted to let you know you've only
8 got about 10 minutes of your rebuttal left.

9 MR. ARJOMAND: Okay. Okay. Thank you, Your Honor.
10 I'll be really quick and I'll reserve the remainder of my time for the
11 rebuttal.

12 I do want -- I want to quickly address claim 33. And I think
13 the arguments regarding support, I think, are not correct. And we've
14 briefed this I think fairly well in the reply, and I'm not going to repeat
15 those arguments. But I think the most important thing to realize, and
16 I'm here on slide 64, is that it's not that the initial contact of the flange
17 and the portion of the sample collection vessel causes the annular
18 valve to change from the closed configuration to the open
19 configuration. Rather, it's that initial contact upon engagement of the
20 cap to the sample collection vessel, that captures the concept that I
21 was telling you about with regard to the '632 patent's one-step
22 operation. As you make that connection, as you engage the cap to the
23 sample connection vessel, the valve starts opening up. And I think
24 that's what claim 33 is getting at and it's supported in the record.

25 And we think that the *Hynix* case is actually on point because
26 just like this case, there are only two species. It's a very small genus,

1 only two species. And the testimony, again, from Dr. Wereley on this
2 issue was unrebutted. He testified that he thought there was support
3 for the genus.

4 I would also like to briefly, briefly add that I don't think
5 they've established that the claim 33 is obvious in view of *Cho*. And I
6 think the key thing to realize here is that in *Cho* the end plate 622
7 that's attached to inner cap 624 is already going to be in their modified
8 version, is already going to be in contact with the portion of the mouth
9 of the bottle body prior to changing the annular valve from the closed
10 configuration to the open configuration. So there is a contact, but the
11 valve doesn't open. That's *Cho*.

12 In our invention, as reflected in claim 33, the contact opens
13 the valve and that's not a timing issue, Your Honors. That's actually a
14 structural -- that's a structural difference because of the flange and the
15 coupling member 50 that's on the sample collection vessel that engage
16 together. That's different from *Cho* structurally. And they have, if
17 you take a look at the record on this, they have not addressed that
18 structural difference. So we believe claim 33 provides an additional
19 basis for patentability.

20 Unless Your Honors have any further questions, I'll reserve
21 the remainder of my time for everybody.

22 JUDGE BROWNE: Looks like you have about nine minutes.

23 MR. ARJOMAND: Thank you.

24 MR. JENNINGS: First, I'd like to address a few points on the
25 broadening issue. I'm not going to pull up their slides, but in their
26 slide 14, where they had dictionaries, et cetera, this concept of an

1 open space, it comes out of thin air from their expert, extraneous.
2 He's citing to a dictionary that says an aperture means a hole. He adds
3 this concept of an open space. And so it's all extrinsic to the patent
4 and not consistent with the plain meaning that the aperture is the hole
5 and not the space.

6 And this concept of a infinitely thin plane or something really
7 doesn't advance the issue. If you look at our slide 5, and let's look at
8 the illustration of figure D. Now, figure D has an aperture which
9 we've identified. Now, if we talk about that having some thickness
10 and it's not infinitely thin, clearly that movable annular valve in that
11 illustration is not in the aperture, but it is in the interior volume of the
12 cap. And --

13 JUDGE KAISER: I'm sorry, before you --

14 MR. JENNINGS: Yes.

15 JUDGE KAISER: Before you move on from that slide, can I
16 just ask you one quick question about one of your figures there?

17 MR. JENNINGS: Sure thing.

18 JUDGE KAISER: So I take your point that figures B, C, and
19 D show valves that are in the interior volume, but not in the aperture.
20 Figure A shows a valve that I think you've said is in the aperture. Is it
21 also in the interior volume? In other words, do the new claims cover
22 figure A as well as figures B, C, and D?

23 MR. JENNINGS: Yes, that's in the interior volume. All four
24 of those are in the interior volume. Only figure A is in the aperture
25 per the original claims' requirement. Right? So the embodiments of

1 B through D are not covered by the original claims, but would be
2 covered by the new claims.

3 JUDGE KAISER: Okay. All right. Thank you.

4 MR. JENNINGS: And the claim language makes clear the
5 distinction between the volume and the aperture, the "outer wall
6 defining an open end of the cap, an opposing closed end of the cap,
7 and an interior volume of the cap, said open end defining a second
8 aperture." The specification, similarly, I focused on the column 14 in
9 my original presentation. But the reference to column 5, lines 24 and
10 25, "The chamber may comprise inner walls which define an interior
11 space and an aperture," again distinguishing the difference between an
12 interior space and an aperture.

13 So that that ends the case in our view. But I'm going to go on
14 to some of the points that Counsel addressed on obviousness. So
15 Counsel argues that Petitioner completely modified *Cho*. I submit
16 that these are unsupported exaggerations. If you look at their slides
17 and what they're pointing to, they're talking about enlarging this,
18 modifying this dimension. No, Mr. Leinsing explained that changing
19 these dimensions had no change on the function of the device. It's the
20 length of that inner cylinder that is adjusted to accommodate less
21 additive. It doesn't change how the device functions.

22 Now, they even go so far as to argue in their papers that this
23 complete modification by pointing to the number of threads on Mr.
24 Leinsing's drawing and contending that was part of this complete
25 modification. Now, the threads in whether it be *Cho* or the '632 patent
26 are relatively crude schematics to show the person of ordinary skill in

1 the art that one part is screwed onto the other. These are not
2 manufacturing drawings. Granted, *Cho* does show more detail. *Cho*
3 explains his device in greater detail. So *Cho* explains some details
4 about how the seals occur. The '632 patent in the embodiment there
5 shows crude schematics of threads and leaves it to one of skill in the
6 art to determine the actual sealing. *Cho* shows some detail. And now
7 they're going to criticize *Cho* because it shows more detail. But the
8 fundamental basics are *Cho* has a cap with an inner cylinder and an
9 outer cylinder which move relative to each other when the cap is
10 screwed onto the container to release a material from the inner
11 cylinder through a vent that was covered by the outer cylinder.

12 JUDGE BROWNE: Mr. Jennings, Patent Owner argued that
13 in the modified *Cho* figure, the inner cap 624 is eliminated. When I
14 look at that figure, I can't really tell, but would you like to respond to
15 that argument?

16 MR. JENNINGS: It wasn't eliminated. The inner cap -- so
17 *Cho* has more reference numerals referring to his parts. Right? The
18 inner cap 622, 624 is simply part of the outer cylinder that when it
19 was shrunk up, it becomes -- it's much higher up. So it was the
20 bottommost part in figure 44. You shrink it up, it's the bottom most
21 part once it's shrunk up, but it's not been eliminated. The outer
22 cylinder is still there. *Cho* does have more reference numerals
23 because *Cho* is describing particular features of the outer cylinder in
24 greater detail than the '632 patent. But they're both speaking to a
25 person of ordinary skill in the art.

1 And Mr. Leinsing -- I mean to call -- when we presented the
2 side by side, and I can't see how they could call our comparison that
3 those are essentially equivalent, identical, nonsensical. They have the
4 basic same features as these claims.

5 Now, they point to this *Ethicon* case with Mr. Leinsing to
6 give him a knock. Right? The District Court found against him. This
7 case is completely different. We're talking about a change in a
8 movable annular valve that doesn't affect the function. It's a change
9 related to size. And in fact, in this case, the Board has already found,
10 consistent with Mr. Leinsing's testimony, that that would have been an
11 obvious combination with *Plante*.

12 Now, I could have knocked Dr. Wereley. Dr. Wereley, you
13 were wrong last time. You told us it wouldn't work for this reason,
14 wouldn't work for that reason. Where does that advance? Let's focus
15 on the substance of our case and the changes. We didn't hear any
16 much from them about the details regarding the modification of size
17 or any change in functionality of the valve.

18 Now, they argue about supposed cost, but they provided no
19 details about the cost of *Cho*'s annular valve as shown in figure 44, if
20 they want to treat that as a manufacturing drawing versus making it
21 smaller. And also they never made any comparison to that cost versus
22 the benefits. We have undisputed benefits of avoiding sharps. That's
23 a significant issue. I mean, you have a device when you have *Cho*
24 where you take from whatever one in how many thousand or whatever
25 with *Plante* and you go to *Cho* with this movable annular valve and
26 you've got zero sharp injuries because you're not using sharps to

1 puncture a reagent chamber. And you also have no exposure to the
2 toxic substances.

3 Their argument seems to be focused on this concept that *Cho*
4 is pre-attached and is limited to beverages. And I was really surprised
5 when Counsel said about providing a cap separate from a container
6 and combining the two after the sample was put in the container
7 because it was right in our petition. And it's clearly the way you
8 would combine *Cho*'s cap with *Plante* for that application. So their
9 two-step operation concept with *Cho* just misses the point.

10 And they appear to agree that they are limiting *Cho* to
11 beverage applications where it's prepackaged with two different types
12 of beverages. That ignores *Cho*'s teaching that it's used in medicines
13 and chemicals as was found by the Board in the last IPR. It ignores
14 the manner in which it would be combined with *Plante*.

15 And how am I doing on time?

16 JUDGE BROWNE: I think I can give you a couple more
17 minutes, then I can give Patent Owner a few minutes as well.

18 MR. JENNINGS: And just one final point on the mold
19 designs. You know, whether it's six molds as Dr. Wereley said or
20 three molds as Mr. Leinsing said, ultimately those are manufacturing
21 details and patents are not intended to be product manufacturing
22 specifications. And granted, we only showed with Mr. Leinsing one
23 view of a mold. If someone was actually making the full details of a
24 mold, they would have multiple drawings, the top view, the side view,
25 et cetera. And they criticize us for the details, but the general concept
26 is that these are basic, simple parts consistent with the documents that

1 Mr. Leinsing relied upon and manufactured in large volumes every
2 day. Thank you.

3 MR. ARJOMAND: Sorry, Your Honors, that was a little
4 faster than I expected.

5 JUDGE BROWNE: And I'll give you a little bit as well.

6 MR. ARJOMAND: So let me first begin on the issue of
7 whether inner cap 624 has been eliminated or not. So I'm back on
8 slide 35 of Patent Owner's demonstratives. And Your Honor, when I
9 look at this slide which shows modified *Cho* figure 44, you see that
10 the inner cap 624 reference number is pointing to the same structure
11 as 622, which is the end plate. So I think that it's pretty clear that the
12 inner cap 624 has been eliminated.

13 We made this argument in the reply, Your Honors, and if you
14 take a look at their sur-reply, they have on page 7 a footnote that says,
15 "Patent Owner incorrectly asserts the modification eliminates inner
16 cap 624, which remains in both the unmodified and modified valves."
17 And they cite to Exhibit 1041 and paragraphs 11 to 12, which are Mr.
18 Leinsing's third declaration, I believe. And if you go to paragraphs 11
19 and 12 of Exhibit 1041, I don't see anything relating to 624,
20 specifically the inner cap not being eliminated. I think it's pretty clear
21 that the inner cap has been eliminated. And I think it belies again
22 their view that the changes here to the *Cho*, specifically its valve, are
23 simply resizing. It's a redesign, structural redesign of the *Cho* valve.

24 And it's -- you know, Counsel for Petitioner pointed to the
25 increase in threads, which is on the next slide, Your Honors, which
26 pointed to the next slide, which is slide 36. And yeah, that is a

1 modification, but there's -- there are like six other modifications,
2 including the elimination of the inner cap 624. So again, they are not
3 fully addressing our point regarding the structural redesign of *Cho's*
4 valve.

5 With respect to *Ethicon*, I think that the point of *Ethicon* and
6 why we cited that case, Your Honor, and I would direct you to -- I
7 direct you to slide 49, I think what it goes to is, again, kind of the
8 issue of obviousness from the perspective of a person of ordinary skill
9 in the art and what that person would or would not do. And I think
10 with mechanical inventions, it's very common to fall into the trap of
11 hindsight.

12 And one of the things that you look at are, are the
13 modifications that they're proposing realistic? And when you
14 consider the long development time and the increased fabrication and
15 assembly cost, it's not realistic to make those modifications to *Cho's*
16 valve as they've done. And again, we've provided that testimony. It's
17 Exhibit 2030, paragraphs 34 and 59 of Dr. Wereley's final declaration,
18 which they never cross examined him on. And I didn't hear
19 Petitioner's Counsel rebut our point that they have not addressed or
20 questioned Dr. Wereley on these issues. And at the end of the day,
21 the burden of persuasion rests on their shoulders.

22 The *Ethicon* case highlights kind of that trap of hindsight
23 that's typical in mechanical cases. And it shows that Mr. Leinsing has
24 fallen into that trap before. He's tried to redesign devices, in this case
25 the Gallo device, and he didn't consider the amount of time or
26 resources.

1 And I think pointing to slide 50, the *Hulu* case, I think is an
2 important case as well. Because in the *Hulu* case, what happened
3 there was that the combination involved replacing one type of
4 memory with another type of memory. That other type of memory
5 that the Petitioner was focusing on was incredibly costly. There was
6 evidence in the record that it was a very costly switch. And the Board
7 credited that testimony, credited the fact that cost was an issue.

8 So, again, I think it's really easy to sort of point to the figures
9 or to, again, continue to disparage the invention as being simple, as
10 the figures not being clear. But the reality is that when you take a
11 look at what their combination is to achieve the claimed invention,
12 which has been amended to overcome *Plante* and *Cho*, I don't think
13 they've provided enough of a showing to establish that the
14 combination would have been performed by a person of ordinary skill
15 in the art with reasonable expectation of success.

16 I think they want to constantly go back to the previous
17 proceeding. This is a refrain through all their briefings, Your Honors:
18 look at what you did in the '646 IPR. Well, this is a different case.
19 Not only is it a different case, it's a different claim. We have provided
20 a revised set of claims that are distinguishable over *Plante* and *Cho*.
21 And I think we think that they are also patentable over *Plante* and
22 *Cho*, even though, as I mentioned, the burden of persuasion rests
23 squarely on Petitioner's shoulders.

24 Unless Your Honors have any further questions, we'll rest.

25 JUDGE BROWNE: No, no further questions.

26 MR. ARJOMAND: Thank you.

1 JUDGE BROWNE: I would like to thank both parties for your
2 presentations. They've been very helpful. The case is submitted.
3 (Whereupon, the proceedings at 12:16 p.m. were concluded.)

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