

MORRISON FOERSTER

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Clerk (00:01):

The United States Court of Appeals for the Federal Circuit is now open and in session. God save the United States and this honorable court.

Judge Lourie (00:11):

Good morning, ladies and gentlemen. We have five cases on the calendar this morning. Three consolidated cases from a PTAB patent case from the ITC and the case from the court of federal claims that has been submitted in the briefs and not argued. The consolidated cases are *C.R. Bard v Medline Industries*, 2020-1900, 1908, 1910. Mr. Matsui, please proceed.

Brian Matsui (00:45):

Thank you, your honor. And may it please the court. Brian Mitsui for C.R. Bard. I would like to primarily address two issues. First, the board's error with respect to the requirement that two syringes be stored in one compartment and a medical assembly in another compartment. While that error runs through all three patents, it is enough to reverse or vacate the board's decision for all the claims from claim 45 and higher that are addressed in the '088 patent appeal. Second, I would like to address the requirement in claim seven of the '596 patent that the drainage bag be positioned between the tray bottom and the catheter. This error adds claim seven, eight, and 13 that should be reversed or at least vacated in the '596 patent appeal. With any time remaining, I'll address the other issues. The board's errors there largely flow from or are related to the kinds of errors the board made in the two issues that I want to focus on.

Brian Matsui (01:44):

So starting with the two syringes in one compartment requirement, the board committed a simple legal error and how it applied obviousness. This is a simple requirement. It just requires two syringes in one compartment and the medical assembly in another compartment. The board found that the prior art disclosed all the elements in the claim: tray, syringes, a Foley catheter, sterile materials, multi-compartment, single-layer trays. But the board imposed anticipation-like requirements and the obviousness analysis. It required that a single reference expressly disclosed two syringes in one compartment and it dismissed each reference one by one while ignoring combinations and the creativity of a person of ordinary skill in the art. If we look at the '088 appendix pages 44 to 47, in four pages there, the board individually dismisses Solazzo, Serany, and Disston for not expressly describing or describing two syringes in a compartment. And it does so about 10 times in those four pages. Now, setting aside that another reference—

Judge Lourie (02:53):

Mr. Matsui, you're saying that it's—it's fairly obvious within the skill of a person of ordinary skill to add a second item of the same nature as the first item in a kit of this sort.

Brian Matsui (03:10):

Certainly your honor. I mean, for over 60 years, there have been single-layer trays with these types of items. And we have the EMI reference that shows multiple syringes in a single compartment. We have Serany, which shows in single layer trays of cleaning balls stored together. And it was well within the capabilities of a person of ordinary skill in the art to move syringes from one tray to another. I think an important fact here is that Solazzo itself discloses two syringes. It specifies that one of those syringes, an inflation syringe, is in compartment 27, and the medical assembly is in compartment three. But for that second syringe, which is an irrigation syringe, it doesn't specify what compartment that that syringe is in. And there just aren't very many places that you could put that second syringe. As our expert explained, it was really compartment three or compartment 27. So you're really dealing with a finite number of predictable choices of where you could put that second syringe. It was really only going to be in one of those—those two compartments, but as I mentioned—

Judge Lourie (04:21):

What kind of deference do we owe the PTAB? They did a fairly thorough job, didn't they?

Brian Matsui (04:29):

Well this is a legal error, your honor. So there—this is review de novo because the board—when you look at those—those pages from appendix 44 to 47, it was just analyzing each reference one by one and faulting them for Solazzo not expressly describing two syringes in one compartment or Serany only describing a single syringe. That's a legal error, what the board did there with respect to the obviousness analysis. But even if the court were to sort of look at this as a factual issue, which I don't think it should because of the requirement of express disclosures, there certainly isn't any substantial evidence to support the board's decision that a person of ordinary skill in the art could not put two syringes in one compartment, particularly because really the question here is just where do you put Solazzo's second syringe because Solazzo describes there are two syringes in it. You have both an irrigation syringe and an inflation syringe, and that irrigation syringe has to go somewhere in the tray. So really there are only a couple options where you could put it in.

Judge Lourie (05:39):

Do you think the board—do you think the board was essentially examining for anticipation, not obviousness?

Brian Matsui (05:45):

It really seems that way, that it was looking for—at least with respect to these core claim requirements, it was looking for anticipation-like references because it just examined each reference one by one. And then the only fault it really gave at all was that the reference itself did not describe or expressly describe two syringes in one compartment. And that's why this—that really makes this case, you know, like—almost like a KSR where you didn't have prior art that, you know, separately disclosed electronic sensors, pedals with six pivot points, no single prior art reference disclosed that, but the claimed arrangement was obvious. And that's what the Supreme Court has said. That's what this court has said on numerous occasions.

Judge Chen (06:34):

Mr. Matui, this is Judge Chen. For this category of claims dealing with two syringes in one compartment, medical assembly, and the second compartment, I believe there is at least one of the claims in this category that talks about specifically an inflation syringe and a lubrication syringe. Is that right?

Brian Matsui (06:57):

Well there's—with respect to like claim 45 and higher, it's really talking about just two syringes in one compartment, but there's—

Judge Chen (07:07):

Right. That's true for the '088 patent. I'm talking about one of the other two patents in this consolidated set of appeals or this combined set of appeals.

Brian Matsui (07:15):

Yes, your honor.

Judge Bryson (07:16):

Claim seven of the '596 patent I think is the inflation and lubrication syringe, correct?

Brian Matsui (07:22):

That's correct. And there's no dispute, though, that—

Judge Chen (07:25):

So, Mr. Matsui—so I understand your—your theory of obviousness for claim seven of the '596 patent would be that it would—it would be obvious or a skilled artisan would be motivated to have three syringes in compartment 27 of Solazzo?

Brian Matsui (07:40):

I mean, certainly that—that is—I mean, just to—to take this—your question in steps. I mean, it would have been obvious to replace a lubrication syringe for the lubrication tube. That's—that's basically undisputed and the board and the 400 IPR agreed that it would have been obvious to place lubricant in a syringe and to substitute the lubricant syringe for lubricant tube. But yes, I mean, EMI teaches that you can put three syringes in a single compartment, so it would have been obvious and certainly within the skill of a person of ordinary skill in the art to put all three syringes in compartment 27. There's—there's nothing that would—that would dissuade a person of ordinary skill in the art from doing that. And it certainly was within their level of skill. And you had references like EMI, which had the multiple syringes three syringes, in fact, in one compartment.

Brian Matsui (08:35):

You have Serany, which shows storing like materials together. Persons of ordinary skill in the art, as both Disston and Serany show, would want to put things in an order that would be useful. So they could easily move the syringes around to find a good way for them to be used. But then looking at claim seven, the other requirement in claim seven in the '596 patent that I'd like to talk about, which is the drainage bag positioned between the Foley catheter in the tray and the tray bottom, which affects the claim seven, eight, and 13 of the '596 patents. The board made two errors there. And the first is that it

repeated its expressed disclosure requirement. It effectively required a picture specifically showing the drainage bag between the tray bottom and the catheter. And we're in the '596 patent, which is the 1910 appeal. And if we look at appendix 20 of the of the board's decision, they say Serany simply fails to expressly describe or illustrate a fluid receptacle that is wholly located between the bottom of the container and the catheter. And appendix 19, it says without such an express description, we agree with Dr. Singh that Serany illustrates at least a portion of a fluid receptacle being located above the catheter, not between the catheter and the bottom—and the bottom of the container. And then the—

Judge Lourie (10:10):

Mr. Matsui. Let me ask you, is it your view that arranging known items used for the known usual purpose differently is within the skill of the art?

Brian Matsui (10:25):

Yeah. Yes, your honor. And I don't think there's any dispute that you could move these items in different containers—different portions—different containers within the single-layer tray. I mean, the board found that in the 400 IPR appeal—the 400 IPR, which Medline didn't appeal, that you could move various items and there would be motivation to combine references like Serany and Solazzo together. So I don't think that there can be any dispute here that it was within the level of ordinary skill in the art, in this very simple field, to be able to arrange items in different ways. And then you have prior art references like Serany and Disston, which basically provide motivation for persons of ordinary skill in the art to do so in ways that would be convenient for—for the user.

Judge Bryson (11:24):

Mr. Matsui, this is Judge Bryson. I wonder if I could turn your attention if you were done with—with that discussion, but either complete your thought on that or—or turn to claim one of the '088 and in particular, if you would address the limitation requiring the first compartment based member defining a mnemonic device, indicating which of the devices is to be used first.

Brian Matsui (11:53):

Yes, your honor. So with respect to the, you know, the syringes at different height requirements, the mnemonic device requirements, all that's required with respect to that claim requirement is some sort of base structure that would basically, you know, indicate a different height requirement. So that would indicate to the user which syringe basically to use first and—

Judge Bryson (12:24):

So do you think—let me ask you a follow-up question then with respect to that assertion: do you think that if one syringe is slightly higher than the other, but they are at opposite ends of a large chamber, that that is enough by virtue of their slight difference in height to establish the mnemonic device limitation?

Brian Matsui (12:41):

I think so because these are very broadly written claims, but I don't think that the court has to go so far where you say it's a very slight level of height. You have Solazzo, which has a terraced—a terraced bottom. The board—the board found that it has a terraced bottom with a higher area in a low area and has the lubricant at a higher level than it has the inflation syringe. And given that terraced bottom, a

person of ordinary skill in the art would understand that—that you have the different height requirement here that’s required by—by these claims. Now some of the plans required—

Judge Bryson (13:17):

So the different height—different height requirement is required by a number of claims, but the mnemonic device requirement is, as far as I can tell, only in two of the independent claims, including claim one of the ’088. And so what I’m trying to see here is whether the—your argument is that as long as there is a difference in height that satisfies the mnemonic device requirement, and in particular, the requirement that the compartment-based member defines such a mnemonic device. In your view, is height difference enough?

Brian Matsui (13:57):

So I think to sort of take apart that question, your honor, the—the base member in—in Solazzo is terraced. And so, in that sense, it is having a mnemonic device, and—and the height requirement comes from the fact that the patent itself says that having things at different heights is a mnemonic device. It has a like—example, a stair step-based member.

Judge Chen (14:22):

Mr. Matsui, I realized that Solazzo itself describes the—the floor of the tray is a terraced arrangement. But in reality, I think we can all agree, it’s a sloped floor to the tray, right? And the board then made a—a fact finding that any syringe that’s placed on the sloped portion of the floor would roll down to the bottom, to the flat bottom section of the tray. Is that right?

Brian Matsui (14:54):

I mean, yes. If you took all the items out, the board was saying that the items might fall down to the bottom, but that—but that’s part of the problem because the board there imposed additional claim requirements in its analysis, because it basically required that the syringes be held in place without any—anything else helping with them to stay in place. It required a specific contour and shape for the syringes to be held, but nothing on the claims require that. All it requires is a base member that has the mnemonic device, which we have as the terraced bottom, or in the claims that just require—some claims don’t require the mnemonic device in the claims that just require different heights. It just requires them to be at different support at different heights, and nothing in that claim language would require that it’s the—the base alone that has to support the syringes at different heights or the base alone has to provide that—that—that height requirement. And so it was only by the board’s decision—

Judge Chen (16:00):

I guess if you’re looking at claim 25, it recites that the first compartment itself is supporting the first and second syringes at different heights according to the predetermined steps of the catheterization procedure. So I guess when I’m looking at there is why was it wrong-headed of the board to understand that this limitation is calling for something about the design of the compartment itself that supports these syringes at different height levels.

Brian Matsui (16:36):

Well, your honor, the base of the tray is still supporting the syringe, even if it is resting on other items. It’s just like I’m sitting on a chair right now, but the floor is still supporting me, even though I’m sitting on the chair. That—the issue here is just whether or not what this broad claim language, whether the

syringe is being supported by the tray. And it is, even if there are other items that are helping it maintain that different height. And we have in here, as I mentioned, a terraced bottom, so we have a tray bottom shape that—that would basically lead to those syringes to be stored at different heights. And there's just nothing in the claims that require that it be supported by the tray bottom alone or that have that specific shape or contour, which the board required. And just, you know, an additional point I'll make, your honor, is that we were never given any notice that the board was going to impose these requirements upon us until the final written decision. So at the very least, we should get a remand—

Judge Chen (17:38):

In the patent owner's response, that JA542, didn't the patent owner make this very argument that Solazzo's sloping floor can't possibly support the syringe located there because it'll just roll down to the bottom?

Brian Matsui (18:00):

Your honor, but they never asked for any sort of specific claim construction with respect to this—this—this requirement. It was only in the final decision that you start to get language like the contour and shape that the—

Judge Chen (18:13):

The point is, is that wasn't that enough notice to you that clearly the patent owner was arguing inside of that argument against Solazzo was the patent owner was contemplating a specific conception of this different height limitation and what's required of the design and the trade to—to create and establish different height arrangements to support the syringes.

Brian Matsui (18:43):

I think that that just was not specific enough to give us the notice that would be required. When particularly it—had we known that the board was going to impose these requirements, we could have shown that you could have different height requirements like Serany, where it shows the forceps are stored above the cleaning balls. And so I—I don't think that that's a situation that's fair to the petitioner to have, or to a party, to have a claim construction effectively imposed on us in the final written decision. And it makes it like those—the other cases where this court has remanded.

Judge Bryson (19:20):

Mr. Matsui, if—since we're beginning to run out of time, I would like for you to address if you would claims 10 and 15 of the '761 patent. And in particular, the limitations requiring that the first compartment, lubricating jelly chamber lubricate as the catheter passes from one chamber to the next. I don't see that limitation being suggested by anything in the prior art references. Other than that little notch in Solazzo's divider. Do you rely entirely on that little notch?

Brian Matsui (20:06):

I mean, yes, the—the notch is what—what shows that you can have the pass-through limitation made as you go from one compartment to the other. And Medline itself really doesn't make any arguments with respect to this limitation, other than to say that you couldn't, or wouldn't, put lubricant into the compartment 27 of Solazzo. So, so that's basically the—

Judge Bryson (20:34):

Yeah. The idea—since the limitation requires that it be lubricated, as the catheter passes from one to the other, is the idea that you would put lubrication on the edge of the notch? Is that—is that the concept that you have in mind?

Brian Matsui (20:53):

No, it's—as you would pass the catheter through, then it would basically have the lubrication that would go from the compartment—one compartment to the other.

Judge Bryson (21:05):

Mr. Matsui, would you regard that as—as a use limitation and this—this is an article of manufacture. It's not a method claim. Would you regard that lubrication as not lending patentable significance to this—to this claim?

Brian Matsui (21:31):

Yes, your honor. All—all that is required here are the structures, and we have the—the necessary structures disclosed in the prior art. If there are no other questions, then I'd like to reserve my time for rebuttal.

Judge Bryson (21:45):

We will do that. Mr. Hoover?

Allen Hoover (21:54):

Yes, your honor. My primary question is—am I audible enough?

Judge Bryson (22:06):

Enough.

Allen Hoover (22:09):

Okay, your honors. Well, thank you very much. Good morning. And may it please the court. Allen Hoover for Medline, the challenger in this case barred in its briefing, and half of PTAB has ignored a number of fundamental issues with their patent challenge. One question that must be asking an obvious in this analysis is, was there a need in the art and did the patent owner, or the patentees, solve that need or attempt to solve that need with—

Judge Bryson (22:45):

Mr. Hoover, I don't know that that's the first question in an obviousness analysis. Isn't this a KSR case where we—we've got an article of manufacture consisting of all known materials used for their well-known purposes arranged in various ways. And the only distinguishing features seem to be the shape of the container and perhaps a use aspect to some of the claims.

Allen Hoover (23:21):

I think the claims here are directed towards a product or method where the components are known in the arts, but are arranged and provided in a new way.

Judge Lourie (23:37):

Do you say a product or method? I thought they were all apparatus claims.

Allen Hoover (23:41):

I believe they're all apparatus claims in the challenge claims for this appeal. Yes, your Honor.

Allen Hoover (23:49):

So looking at the Solazzo reference, the problem to be addressed is the CAUTI problem, catheter-associated urinary tract infection. And we asked the experts for Bard and the expert for Medline. Both testified that the Solazzo problem or the Solazzo reference would not be useful in solving the CAUTI problem. Bard has not rebutted that in his briefing before the court, but both party's experts that agreed that that was the case. That the Solazzo reference would not be useful in solving the CAUTI problem. I'm not sure how the—the obviousness challenge that Bard raises gets off the ground with that unrebutted—

Judge Chen (24:38):

Mr. Hoover. Mr. Hoover, I mean—I understand you have this broad-based position, but it would really help me if we got down to something more nitty gritty as to the different issues with specific claim limitations, like, for example, why wouldn't it be obvious to put two syringes into Salozzo's compartment 27? We know there's a second syringe; Solazzo doesn't identify where it stores that second syringe, but it would seem to be plenty obvious to a skilled artisan that you would put it where the other syringe is already illustrated as being disclosed. That is compartment 27.

Allen Hoover (25:27):

Solazzo has multiple compartments, your honor. It has two lubrication compartments. It has a lubricant packet. And, for example, one skilled in the art might consider placing the lubricant packet in the lubrication channel or lubrication well of Solazzo, and if there were a syringe, it could be placed in there.

Judge Chen (25:48):

You're saying the syringe could be put in the lubrication well 31 or 33?

Allen Hoover (25:53):

Yes. The board found that it was not obvious to do that with respect to claim 45 of the '088 patent. The board considered the expert testimony and considered their references in detail and made a factual finding—

Judge Chen (26:14):

Okay. The question is, why wouldn't it be obvious to place Solazzo's second syringe in any existing compartment of Solazzo?

Allen Hoover (26:28):

I think that the claim requires more than just two syringes in a compartment.

Judge Chen (26:34):

I'm just talking about that particular limitation though.

Allen Hoover (26:38):

Pardon me, your Honor?

Judge Chen (26:39):

I'm talking about just that limitation, the second syringe of Solazzo. You have to put it somewhere, and any of the illustrated compartments in which a second syringe could fit would seem to me to be a very obvious place to locate Solazzo's second syringe. Am I missing something?

Allen Hoover (27:03):

Well, I guess the board found otherwise. I think the exercise today is on the standard of review. Was there evidence to support the board's finding that it was not obvious to do that? We have expert testimony to that effect and given the expert testimony, which is substantial from really all the experts, but particularly Medline's experts, the worst decisions should be sustained on that ground. That would point out further that—

Judge Chen (27:32):

Can you tell me what experts said? Any of the experts said in the record that explains why it would be not obvious to put the second syringe in compartment 27? A field artisan would not be motivated to locate it there.

Allen Hoover (27:52):

On that point, I would refer it to the testimony of Mr. [inaudible] and Dr. Yoon, who are Bard's experts, who referred to the general nature of the kit of Solazzo. And both of them said this is a patent of— Mr. [inaudible], for example, this is a patent illustration that teaches certain concepts. It's not a design drawing, showing how something would be made if it was to be put into production. So we know that there's a syringe. The second syringes slot was somewhere in the kit. It doesn't have to be in the tray. The kits have been made in the past with separate boxes, with separate components. And is it possible that it could be placed somewhere else? Could it be placed, for instance, on top of the wrapping of the kit? Could it be placed in separate boxes in the Serany reference? Separate box from the catheter assembly, which is also a requirement of the claim 45. So there are other places where it can go besides in the compartment. And so the board found that it was not obvious based on the references to put them—one of the skill in the art would not be motivated to—to put it in a second compartment or the same compartment as the other syringe or syringes in Salozzo's case and with a catheter assembly in a separate compartment.

Judge Lourie (29:17):

Mr. Hoover, could you address claim one and in particular, Mr. Matsui's arguments with respect to the first compartment support the base members support defining a mnemonic device.

Allen Hoover (29:34):

Yes, your honor. Bard did not ask for any special construction of that term. As the patent challenger, it was incumbent upon them to do so. We did point out, as you noted in our panel, the response that

the—that is how we were construing the reference that the—it was basically that the tray itself is supporting the syringes and defining the mnemonic device, and at that point—

Judge Lourie (30:10):

In other words, you're saying that a device is simply the shape of the container.

Allen Hoover (30:17):

I think it's the tray, your Honor.

Judge Lourie (30:20)

And that's a device?

Allen Hoover (30:26)

I don't think that the other components [inaudible] is making is correct.

Judge Lourie (30:27):

The word "mnemonic," in my understanding, means memory, and that—that sort of calls for the mental step of thinking that something at a higher level is to be used before an item of a lower level. That's a very strange claim.

Allen Hoover (30:46):

Well, the claim does call for the tray to have the mnemonic device. There's nothing in the patent that suggests that if it was, you know, stuff on top of other stuff, for example, that it would be somehow a mnemonic device. In the evidence here is that Solazzo does not in fact teach the syringes at any particular heights. The testimony of Dr. [inaudible] And Dr. Yoon is on—very much on point on the syringe height of the illustration in Solazzo. Mr. [inaudible] said he—we asked him, "Well, what are the two lines?" And the one drawing was Solazzo. And he says, "To tell the truth, I'm not a hundred percent sure." We asked Dr. Yoon where the lubricant was positioned in Solazzo. In Bard's brief, they refer to this as the doctor was testifying about the syringe. He was actually testifying about the lubricant height. And he says, "I don't know if that represents some type of [inaudible] or not."

Judge Lourie (31:55):

Mr. Hoover, you—you weren't, obviously, in the patent office, but then you start off your brief by saying the courts should affirm for other reasons that the references are incompatible with each other, and that there were secondary considerations that the board didn't consider. That's—can you explain why you didn't start out defending what the board did and you had to look for other reasons to affirm?

Allen Hoover (32:26):

Well, I guess I think the—the—there was such strong reasons for affirmance on multiple fronts, your honor. It was hard to choose, frankly. I feel that the Salozzo reference describes the tray and the reference teaches that urine and clots are to be dispensed into the tray and the Salozzo tray. Therefore, you would not add a bag to it. And to me that is very, you know, very compelling. I also find the secondary evidence here to be very strong. It's undisputed that Bard copied the Medline device. They praise it. They called it innovative. And so we thought that that was evidence. The court should hear. Nonetheless, on the factual findings, they are also very strong on this issue of the height of the syringes.

All four experts agree that—all of four technical experts agree that the Salozzo reference doesn't show that feature. And so on just the basis that the board did decide that that particular feature is not found in Salozzo, and it's not finding the other references either. I'd like to discuss, if I might, the lubricating jelly application chamber. We have evidence from our expert, Ms. Ciabetta, that the Solazzo tray was not useful for lubrication, the recess 27. The compartment that Solazzo shows is too deep. And she says If you put lubricant there, the purpose of the Solazzo tray, again, is to dispense urine and clots—

Judge Chen (34:19):

Mr. Hoover. Mr. Hoover, this is Judge Chen. When I look at compartment 27, I—you know, there's this question of whether it's too deep so that you could lubricate the tip of a catheter. And I guess what I'm wondering is why is it too deep? I mean, why can't you just, you know, dip the catheter down into that compartment until the tip reaches where the jelly is, and like a French fry you've—with ketchup, you've—you've dipped the tip of the catheter into the jelly.

Allen Hoover (35:01):

Well this is a medical procedure and this is done in a fairly high volume and in hospitals and the emergency room setting for example, where things are very stressful. And Ms. Ciabetta did opine that it was not really sized for that. Could somebody make it work? I—I guess probably so in your French fry analogy, but the use of the device is in the hospital-type setting—caregiver setting, and the compartment was deemed to be too deep. That's the evidence—among the evidence that Ms. Ciabetta presented.

Judge Chen (35:47):

I understand you have an expert that said that. I'm—I'm really trying to understand why is it too deep? Why is it unusable? Is it something about the claim language itself that requires structurally a—I don't know—a shallow well or compartment as opposed to something a little deeper, like compartment 27?

Allen Hoover (36:12):

I don't think that Solazzo compartment 27 with the well that's shown would allow user to reach one's hand in there to lubricate the catheter. And could you sort of shove the catheter down in there? That's not really conducive to how a medical procedures should be performed.

Judge Chen (36:31):

Well how do we understand then, your claim? I mean—I mean, to me, you know, if I could use compartment 27 to—as a ketchup well for my French fry, what—what—what is it about your claim term about a compartment configured to receive lubrication jelly to—to lubricate the catheter tip as somehow forcing me to understand that we're talking about a very shallow well? Is that your [inaudible] I guess, is what I'm trying to understand. What is your conception of what that claim term means?

Allen Hoover (37:12):

I think it means a place where lubricant is dispensed in the use of the kits. Ms. Ciabetta and Dr. Singh testified, additionally, that in the Solazzo tray—Ms. Ciabetta said that in the Solazzo tray—

Judge Chen (37:30):

Mr. Hoover, Mr. Hoover, you—you keep referring to Solazzo. Right now I'm asking you a different question, which is what is your understanding of what the claim actually requires? Don't talk about Solazzo. Put Solazzo away. Let's just talk about what your claim means and how I feel the artists understand it as a structural matter. What is the structure of the compartment for receiving the lubrication jelly that requires it to be something that's not too deep?

Allen Hoover (38:06):

I think it must be suitable for receiving lubricants when using the catheterization procedure.

Judge Chen (38:16):

And what does suitable mean?

Allen Hoover (38:19):

I think it the—the user must be able to lubricate the catheter effectively in that compartment.

Judge Chen (38:32):

Okay. And can you just explain to me, one person to another, what is it about compartment 27 that makes a person unable to use that well as a place to lubricate a catheter tip?

Allen Hoover (38:54):

As Ms. Ciabetta explained, that well is where urine and clots go in the Solazzo device. When you catheterize the patient, you often need to measure the urine output. You need to evaluate the urine. You need to, sometimes—

Judge Chen (39:15):

Putting that to the side—putting that to the side, I'm—I'm talking more about the structure of compartment 27 and how it is configured as a structural matter. You're telling me it's not configured to receive jelly and to lubricate the catheter tip.

Allen Hoover (39:38):

I did—I refer your honor to, I believe it's the Giannelli case, where there were handles in the exercise machine, and they're configured for pushing, and the prior art had handles. And they were configured for pulling in that—in that particular machine in that embodiment. So they're just handles. So you can say, "Well, any handles, you could push or pull them," but the court said, "No. In the prior art, they were not configured for pushing," I think it was, because his machine was expressly designed for pulling. And it couldn't be used for pushing. I think this is the case on that—on that front. Is it a plastic surface of a tray? Yes, it could—could lubricant be placed on the plastic surface of the tray as a general matter? Of course. In Solazzo, is in a lubrication jelly application chamber—absolutely not, for the reasons given by the experts. And in the same order as this Giannelli case, with the—with the handles. I think it has—you have to look at the context of the reference and what the reference is teaching you to do. Not simply at is there a plastic surface that lubricant would rest on. And that is how I would distinguish the Solazzo compartment 27.

Allen Hoover (41:03):

Is it okay, your honor, if I moved to the '596 and the drainage bag and the orientation there of?

Judge Chen (41:14):

Sure, please.

Allen Hoover (41:18):

Yes. Again, we hear from Bard in its briefing and an argument today that there was a surprise claim construction. Again, that is also not correct. Bard was incumbent on Bard as the patent challenger under the board rules to present at any particular claim construction that it thought deviated from, I guess, the plain meaning of the terms. The evidence shows that the Serany reference doesn't meet that claim limitation. It shows the catheter going around the bag and not on top of the bag, and it's not really positioned for the immediate use as it is in the Medline patent. And so I don't believe Bard is correct either as a legal matter or on the facts. The Bard or the board found facts that the Serany reference doesn't show that feature. And given that, they—that was the only reference that Bard relied on for that feature, those claims are sustainable on that basis as well, independently of the two syringes. I'd like to talk if I might, your honor, about the lami reference as well.

Allen Hoover (42:37):

We've heard a lot from Bard about the lami reference, I guess one point is that they didn't put the lami reference in the challenge grounds, but I understand it's in the record, so the court can consider it. But we do have evidence from our expert, Dr. Singh, that the lami reference is not relevant and in the 109 IPR, the board expressly credited that—that declaration and discounted the opinion of Bard's experts. That stepping point a lot of these proceedings, but why is lami relevant? The board found that lami was not relevant because it talks about a completely different procedure. In another one of the proceedings, the board found that the lami reference was schematic in nature. It wasn't really showing you a specific structure. Now, one of the points that Bard makes is that in the 36 IPR, I believe, that the board didn't discuss lami, so therefore there must be an error. Well, in the other 35 IPR decided the same day and the other IPR is decided on the same references. The board did discuss lami and did distinguish it and differentiate it. So the fact that they did not mention it in one of two IPR decisions decided on the same day is not a basis to reverse.

Judge Chen (44:00):

Could you talk about the various potential issue preclusion issues here? Let's assume for the moment we have to send some of these claims back to the board. And the other side has made an argument that there's no need to consider any of the secondary consideration evidence. Moreover, there's no need to consider your arguments about motivation to combine Solazzo with a drainage bag because that's been—there's issue preclusion there given an already final board proceeding, as well as replacing the lubrication tube with a lubrication syringe.

Allen Hoover (44:49):

Certainly. I'll tackle them in that order. On the secondary considerations, as we indicated in our brief, the board didn't make the nexus findings on essentially all of the secondary considerations that we presented. There are hundreds and hundreds of millions of dollars of sales of these products. We put in evidence tying that to the claim people buy the product because they really like it. Not because of other reasons. We put in evidence of copying. We put in evidence of praise. Bard called the Medline product

innovative. The board didn't reach that. The board didn't reach that in the other IPR for the '400 patent. And they didn't explain why they didn't reach it. I think there is one issue that the board did decide against Medline and only one on the secondary considerations, which was that Medline had not proved that the kit itself was the sole cause of the decline of CAUTY rates in the ER. And I would say that that's an issue that we'd be precluded on. On the issue of the motivation to combine, we did, as the court has noted, lead with that. Eleven days after we filed our brief, this court decided the [inaudible] court case, which Bard hopefully sights in its brief. That case goes against us. And so we're going to drop that issue for this appeal. On the motivation to substitute a lubricant package for a syringe in the Salozzo reference, we didn't contest that below.

Judge Lourie (46:37):

Mr. Hoover, I—I missed what the issue was, again, that you said you were dropping for this appeal.

Allen Hoover (46:45):

I think that we have argued that there—in the sole—the sole issue that we will drop for this appeal is the adding a bag to the Salozzo reference. Bard has said that we are precluded because we didn't appeal the '400 patent. And so could somebody use the Salozzo reference? We don't feel that that's a correct position for the reasons we stated, but the board held against us on that issue. And that issue was not a factor in any of the four IPRs that we are here on today. The board does not agree with us in any of those proceedings that it was, you know, adding a bag to Salozzo was somehow a factor. What the board did do was find that other features of our claims were absent from all of the references. The board weighed evidence, decided credibility issues, agreed with Dr. Singh, agreed with Ms. Ciabetta, disagreed with Bard's experts on a number of occasions, discounted their testimony, and Bard's appeal today is predicated on asking the court to reweigh that evidence in large part. But with that, your honor, I think I'm out of time. Unless the court has further questions, I would like to pass back to Bard's counsel.

Judge Lourie (48:14):

I don't have any further questions. Thank you, Mr. Hoover. Mr. Matsui, we have some rebuttal time.

Brian Matsui (48:21):

Thank you, your honor. So I—I'd like to start with the—briefly, if the two syringes in one compartment limitation. There's—our experts explained at appendix 1395 that the two possibilities basically were compartment three or compartment 27. There was never any discussion, that I'm aware of, of storing the syringe outside of the—the tray itself. And so you're dealing with a finite number of predictable places in which you could put that second syringe for Solazzo. With respect to the drainage bag, it's very similar. You have a drainage bag positioned between the Foley catheter and the tray bottom. There really only are a couple places that you could put the catheter. You could either put it basically underneath the—the—the drainage bag. You could put it on top of the drainage bag. I suppose you could put it around the drainage bag, but in those last situations, you're going to have a situation where the drainage bag is positioned between the Foley catheter and the tray bottom.

Brian Matsui (49:24):

There's, again, just a finite number of predictable solutions in which a person of ordinary skill in the art could figure out where to position these various items within a tray. And then when you look at a prior art reference like Disston at appendix 33 of the '596 appeal, where you have the bag that's flat on the

tray bottom itself, it—given the fact that you basically want to have these trays so they're ready to use so you can use them in the order in which the items are going to be used, the only logical place in which you would put the catheter is on top of the fluid receptacle bag. With respect to the lubricant compartments, the claim language here is just the first compartment is configured to receive lubricating jelly. There's nothing that would indicate any sort of shallow structure or any sort of any additional types of requirements.

Brian Matsui (50:22):

Again, these are apparatus claims. They're not method claims. So all that matters is that you have the structure and with respect to Solazzo's compartment 27, nurse Ciapetta basically said at appendix 10.9.3.6, and this is in the '596 appeal that she criticized Solazzo's central compartment is relatively deep, but then her conclusion at the bottom was that clinicians are more likely to use an open flat space. So it's not that they're not going to be used. It's not configured to receive—to receive lubricating jelly. It's just that they're more likely to use a shallow container. So again, you have Solazzo that meets the requirement, the broad requirement here that it's just configured to receive lubricating jelly.

Judge Chen (51:15):

Mr. Matsui, if I—go ahead.

Judge Lourie (51:15):

Mr. Matsui, if in your view, what would you consider to be a chamber that would not be configured to accept lubrication for purposes of lubricating the tip of the catheter?

Brian Matsui (51:35):

I'm not entirely certain what type of chamber wouldn't be configured to receive.

Judge Lourie (51:40):

That's my problem. You seem to be saying basically anything would qualify to satisfy this limitation. If you can give me an example of something that you would agree would not qualify, I would be interested in hearing what it is.

Brian Matsui (51:53):

I mean, one could imagine that there could be a container that could be shaped a certain way that would prevent the actual catheter to get into it. You were thinking about these trays for—in the context of them being dipped down with basically compartments that go straight down, but one can imagine a tray that would have situations where the compartment goes off to a side in which you could not put the catheter actually to fit inside that—that compartment. But here we have a situation. I don't think the court needs to address that type of hypothetical because here we have a tray that clearly is configured to receive.

Judge Chen (52:34):

Mr. Matsui, what if compartment 27 in Solazzo was 12 inches deep? Would that be too deep?

Brian Matsui (52:42):

I don't think it would, your honor, because catheters themselves are very—are very long. And so I think that certainly at some point you could get to a situation where a catheter just would not be able to reach the bottom of a tray, but I don't think 12 inches might accomplish that.

Judge Chen (53:01):

And then, finally, what do you have to say about what the board said, which was, well, the way Solazzo is designed, Compartment 27 has nothing to do with receiving jelly. That's where wells 31 and 33, that's where Solazzo describes and discloses the place to squeeze out the lubrication jelly, and compartment 27 is all about the urine overflow and things like that. So that would probably be one of the very last places where you would squeeze out some lubrication jelly. Can you describe—can you respond to that?

Brian Matsui (53:48):

Yeah. I mean, our expert explained that clinicians would put lubricating jelly in lots of different compartments. And again, we're talking sort of more the board's conclusion. There is talking more about how the tray would actually be used by actual clinicians, not what the structures of the tray themselves are. And since these are apparatus claims, the mere fact that they have these structures is enough for the claims to—the claims would have been obvious. And I understand my time has expired. If there are no further questions, we would ask that the court reverse the board.

Judge Lourie (54:26):

Thank you, counsel. We appreciate the arguments of both counsel and the cases submitted.