

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TRI-VASCULAR, INC.,
Petitioner,

v.

SHAUN L. W. SAMUELS,
Patent Owner.

Case IPR2013-00493
Patent 6,007,575

Held: September 3, 2014

Before TONI R. SCHEINER, RICHARD E. RICE, and
SCOTT E. KAMHOLZ, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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9 The above-entitled matter came on for hearing on Wednesday,
10 September 3, 2014, commencing at 1:00 p.m., at the U.S. Patent and
11 Trademark Office, 600 Dulany Street, Alexandria, Virginia.
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15 P R O C E E D I N G S

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17 JUDGE KAMHOLZ: Good afternoon. We will hear
18 argument now in case number IPR2013-00493, Tri-Vascular,
19 Incorporated versus Shaun L. W. Samuels. Counsel for the parties,
20 would you please introduce yourselves, starting with Petitioner.

21 MR. CHAKANSKY: For Petitioner, Michael Chakansky
22 from Hoffmann & Baron.

23 MR. SCOLA: Dan Scola, also from Hoffmann & Baron.

24 MR. DIEDERIKS: For Patent Owner, Everett Diederiks,
25 Diederiks & Whitelaw.

26 MR. WHITELAW: Nicholas Whitelaw, Diederiks &
27 Whitelaw.

28 JUDGE KAMHOLZ: Thank you. Per our order dated
29 July 31st, 2014, each side will have one hour to argue. The Petitioner
30 will argue first and may present all of its arguments concerning

1 unpatentability of the claims for which trial was instituted. The
2 Petitioner may reserve rebuttal time and should begin argument by
3 indicating how much time will be reserved for rebuttal. The Patent
4 Owner may also reserve rebuttal time, but rebuttal is limited to
5 responding to arguments made by the Petitioner in opposition to the
6 motion to amend.

7 I will remind the parties that the Petitioner bears the
8 burden of proving any proposition of unpatentability by a
9 preponderance of the evidence, and the Patent Owner bears the burden
10 of proving the patentability of any proposed claim.

11 I will also remind the parties that this hearing is open to
12 the public and a full transcript of it will become part of the record.
13 Please also remember to mention any slide that you are presenting or
14 to provide a pinpoint citation into the record for any material
15 displayed.

16 Are there any questions?

17 MR. CHAKANSKY: No, Your Honor.

18 JUDGE KAMHOLZ: Mr. Chakansky, please proceed.

19 MR. CHAKANSKY: Your Honor, may I approach and
20 hand out hard copies of the demonstratives?

21 JUDGE KAMHOLZ: Yes, please.

22 MR. CHAKANSKY: I'm afraid I have one of those new
23 computers that don't hook up to the audio/visual, so we will be using
24 the ELMO.

1 On behalf of Petitioner, I would like to reserve a half
2 hour for rebuttal, and we will proceed by beginning with the Samuels
3 '575, which we believe a preponderance of the evidence shows is
4 obvious in light of the prior art of record, and the obvious
5 combinations and/or additions or substitutions of the prior art, mainly
6 the Todd '745, the Samuels '851 and the Lazarus '838.

7 To begin, the Samuels '575 patent discloses a device for
8 affixing a stent graft to the inside of a blood vessel or, for that matter,
9 any tubular structure of the human body. It seeks to accomplish that
10 without damaging -- without the damage that's associated to the blood
11 vessel with the barb means of affixing a stent graft to a blood vessel.
12 It accomplishes that by using an inflatable cuff with a
13 friction-enhancing surface, including inflatable protrusions with a
14 circumferential bridge.

15 The beginning of the analysis for the obviousness should
16 really start with the Samuels '851 patent. That patent, by the same
17 inventor, sought, in part, the same object, which was to affix a stent
18 graft to the inside of a blood vessel, or other tubular structure of the
19 human body. It accomplished that function with two features, one of
20 which was inflating an inflatable cuff with inflatable protrusions to
21 affix the stent graft to the vessel, as well as the further affixing of the
22 stent graft by use of a barb.

23 The first affixation means for the '851 for Samuels was to
24 permit the device to be positioned and repositioned in a non-harmful
25 manner to the blood vessel. We believe that starting with that, the

1 inventor in Samuels '575, now using a concept of not harming the
2 blood vessel for use of objects like barbs, would have, in an obvious
3 manner, looked at the prior art, including Todd. Todd consists of an
4 inflatable balloon catheter whose outer surface has protuberances that
5 enable the catheter, when inflated -- balloon catheter, when inflated,
6 to grip the wall of a blood vessel, or other tubular structure in the
7 human body, in a non-damaging fashion, for keeping it in place.

8 Todd utilizes several different forms of protuberances. It
9 discloses knobs, it discloses spiral ridges, it discloses annular rings.
10 And at this point, I think it's important to look at an exhibit proffered
11 by Patent Owner, namely Exhibit 204, which purports to be a
12 representative cross-section --

13 JUDGE RICE: It's actually 2004, Mr. Chakansky.

14 MR. CHAKANSKY: 2004, yes, thank you, Your Honor.
15 And I think it should be up here, and this purports to be a
16 representative cross-section of figure 8 from Todd '745. We disagree.
17 First, there is no cross-section in the patent itself of figure 8. The only
18 cross-sections that are given are figures 2 and 4, which respectively
19 relate to figures 1 and 2.

20 And perhaps we can get the Todd Exhibit 1008 up, and,
21 for example, this is figure 4, which is a cross-section of figure 3
22 across the 4-4 line. And that's the way it's described in the
23 specification. It's kind of hard to make out whether those knobs -- and
24 those are knobs, 40 are described as knobs in Todd -- are inflatable or
25 not, but irrespective, that looks an awful lot like Exhibit 2004, and

1 there is no support for 2004, Exhibit 2004 in the specification of
2 Todd, in the claims of Todd, in any testimony that was given --

3 JUDGE RICE: Could I interrupt you there?

4 MR. CHAKANSKY: Sure.

5 JUDGE RICE: Why did you say that it's hard to tell
6 whether the knobs 40 are inflatable or not? Could you explain that,
7 please?

8 MR. CHAKANSKY: Oh, I'm sorry, I would retract that,
9 if I could. It's just a hard thing to see whether or not -- I think the
10 overall -- in Todd we're talking about the overall inflatable portion
11 includes the 40, the inflatable knobs on top. The whole thing is
12 inflatable. And to be engaged in work, it has to inflate.

13 And if one looks at -- maybe we can do it -- the
14 description of figure 7, of Todd, and we're now looking at Exhibit
15 1008, column 7, about the lines of 34 to 40, make that 47. It says,
16 figure 7. Figure 7 is the annular ridges -- is the spiral ridges, is wound
17 about the exterior surface of the balloon, when inflated, the spiral
18 ridge contacts and tightly grips the walls of a body passageway in
19 which it is inserted.

20 That would suggest at the very least that figure 7, with its
21 spiral ridges, is inflatable, and if one looks at figure 7, it, with 48,
22 spiral ridges, looks much closer to figure 8's annular rings 52. But
23 basically there's no basis for a cross-section showing that either figure
24 8 or figure 7, for that matter, is not inflatable.

1 JUDGE RICE: Is there any basis for saying they are
2 inflatable?

3 MR. CHAKANSKY: Besides the reference on column
4 7, with respect to the spiral ridge, there is no explicit statement that
5 they are inflatable.

6 JUDGE KAMHOLZ: The issue is whether they are
7 hollow.

8 MR. CHAKANSKY: Excuse me?

9 JUDGE KAMHOLZ: The issue is really whether they
10 are hollow, right?

11 MR. CHAKANSKY: The issue insofar as the figures in
12 the '575 patent shows their circumferential ridges are hollow at some
13 point, yes. Hollow is a question. And inflatable, I would suggest --

14 JUDGE KAMHOLZ: Well, if they're not hollow, are
15 they inflatable? Could they be inflatable?

16 MR. CHAKANSKY: I think if you're looking at the
17 cuff, for example, and it has a surface that is a friction-enhancing
18 surface, the whole thing is inflatable. The friction-enhancing surface
19 does not work, does not grip, unless the object is inflated. If you're
20 saying whether or not the actual ridges, and in this case the annular
21 ring is hollow, prior to, I don't think it makes a difference.

22 But on the other hand, I would suggest that when
23 inflated, and it talks about a spiral ridge being inflated, that it suggests
24 that at least with respect to 7, figure 7, the spiral ridges are hollow.

1 JUDGE KAMHOLZ: So, the claim recites an inflatable
2 cuff.

3 MR. CHAKANSKY: Yes.

4 JUDGE KAMHOLZ: And then among the various
5 components of that inflatable cuff is an inflatable protrusion.

6 MR. CHAKANSKY: Correct.

7 JUDGE KAMHOLZ: But you're saying the fact that the
8 cuff is inflatable means the protrusion is inflatable, regardless of
9 whether it's hollow?

10 MR. CHAKANSKY: I said that in both instances,
11 they're inflatable.

12 JUDGE KAMHOLZ: So, what does that second
13 "inflatable" mean?

14 MR. CHAKANSKY: The second inflatable means that
15 they're not hollow to begin with. They're not -- they're not something
16 that needs on its own to be inflated, as opposed to being part of an
17 inflatable object, which is the inflatable cuff. The purpose is the
18 same, at the end, even -- even the same with the '575 patent discusses
19 that fixation is not permanent until hardening agents are -- as inflation
20 materials are incorporated and hardened. And, in fact, it has a
21 dependent claim that points out that a hardening agent is used.

22 So, whether they start off hollow as part of the inflation
23 cuff or wind up -- they wind up in the same state, which is filled with
24 a substance.

1 JUDGE KAMHOLZ: Patent Owner has taken the
2 position that the circumferential ridge in Todd is solid material;
3 rubber, plastic, I'm not sure.

4 MR. CHAKANSKY: There's no basis for that in the
5 specification.

6 JUDGE KAMHOLZ: Let's just assume for the sake of
7 argument that their Exhibit 2004 is an accurate representation.

8 MR. CHAKANSKY: Okay.

9 JUDGE KAMHOLZ: I understand that's a hypothetical.
10 Is that protrusion inflated or inflatable?

11 MR. CHAKANSKY: If it's on top of an inflatable
12 object, like a balloon or a cuff, I would say it is.

13 JUDGE KAMHOLZ: Would you say a car is inflatable
14 because it rides on tires?

15 MR. CHAKANSKY: I would say that the ridges of the
16 tire are part of the inflatable part of the tire.

17 JUDGE KAMHOLZ: So, solid --

18 MR. CHAKANSKY: But I would --

19 JUDGE KAMHOLZ: So, a solid rubber tread is
20 inflatable because it's on the outside --

21 MR. CHAKANSKY: It's part of an inflatable object, it's
22 part of the tire that's inflatable. Well, a tire is a bad example because
23 it doesn't really expand very much. But let me address it in a slightly
24 different way. There's really no difference whether it's solid or not, it
25 serves the same function. And if you want to go and look at Todd, the

1 function of Todd, its protuberances, its ridges, its annular rings, are to
2 provide gripping means for an object placed in the blood vessel.

3 Now, if we would take that and we put it, for example, on
4 the '851, which already has inflatable protrusions, it would be obvious
5 in bringing it over and combining them to make those inflatable, as
6 well, so that the device is inflatable.

7 JUDGE RICE: I think we're interested in the claim
8 construction, not necessarily in how the device functions. Let me just
9 ask Mr. Kamholz's or Judge Kamholz's question in a different way.
10 What's the difference between a protrusion on an inflatable cuff and
11 inflatable protrusion on an inflatable cuff, under Petitioner's claim
12 construction?

13 MR. CHAKANSKY: The initial claim construction is
14 there is no difference. They're one and the same. The inflatable --

15 JUDGE RICE: So, that claim construction gives no
16 meaning at all to inflatable in the term "inflatable cuff?" Or excuse
17 me, inflatable in the term --

18 MR. CHAKANSKY: Well, we have a problem
19 understanding --

20 JUDGE RICE: Excuse me, excuse me, please, let me
21 start over. So, Petitioner's claim construction, I think, as you just
22 indicated, gives no meaning to inflatable as used in the term
23 "inflatable protrusion?"

1 MR. CHAKANSKY: We've had a problem
2 understanding inflatable protrusion. It only appeared in the patent as
3 part of the original claims.

4 JUDGE RICE: But the patent discloses inflatable ridges,
5 how can you say it does not disclose inflatable protrusions?

6 MR. CHAKANSKY: If we are inflating the two, from
7 ridges to inflatable protrusions, then we would say that it would have
8 to be the inflatable protrusion would have to be inflatable.

9 JUDGE RICE: Well, you don't have to equate it. Isn't an
10 inflatable ridge a type of inflatable protrusion?

11 MR. CHAKANSKY: Well, see, we're trying to look at
12 the claims together. We have claim 2.

13 JUDGE RICE: Could you answer my question before
14 you move on?

15 MR. CHAKANSKY: I'm sorry, Your Honor.

16 JUDGE RICE: Yeah, I just asked isn't an inflatable ridge
17 a type of inflatable protrusion?

18 MR. CHAKANSKY: Yes.

19 JUDGE RICE: All right. Now, please, proceed.

20 MR. CHAKANSKY: Okay. What I wanted to just add
21 and inform you a little is there's a little confusion for us because we
22 have claim 2 depending from, for example, claim 1, and that talks
23 about coarse surfaces, which are not inflatable in the description in the
24 patent -- in the specification, and how it depends from an inflatable
25 protrusion, I don't understand and can't reconcile.

1 But I will agree that inflatable ridge is a ridge that can be
2 inflated. Inflatable protrusion, if you want to equate an inflatable
3 protrusion to an inflatable ridge is something that is inflatable. And
4 by that I mean hollow. At some point. Maybe not hollow, excuse me,
5 because there could be a recess.

6 JUDGE RICE: Please proceed.

7 MR. CHAKANSKY: Okay, thank you.

8 So, whether or not Todd teaches an inflatable ridge,
9 certainly the language there suggests that the ridge of figure 7 would
10 be inflated -- inflatable. I don't think it's a stretch to say that in a like
11 manner the similar pairing of annular rings are also inflatable.

12 To combine in an obviousness determination the
13 functions of an element of annular rings of Todd, which provide
14 gripping to the Samuels '851, is obvious if one takes a look at the '851
15 and recognizes that in the construction of the '851 apparatus, one starts
16 with inflatable recesses, okay, and then one bonds the barbs to it.

17 So, if one simply did not have to remove it, simply did
18 not add the barbs to the '851, one would have an inflatable cuff with a
19 friction-enhancing inflatable protrusions on its surface used to
20 position and affix the stent in position in the blood vessel.

21 JUDGE KAMHOLZ: Are you relying on Samuels '851
22 for disclosure of an inflatable protrusion?

23 MR. CHAKANSKY: We have testimony of Dr. Clark
24 identifying figure 3, and can we get -- let's put figure 3 up. We're
25 talking about figure 3. I'm sorry. All right, of the '851, and

1 Dr. Clark's testimony at 130, that is Exhibit 1021, and basically it
2 becomes in figures 3 and 4, in fact, we have to read two pages,
3 "Question: You just said in figure 4 that really would not fit your
4 definition of an inflatable protrusion. So I'm trying to understand
5 what it is.

6 "Answer: The barbs are the inflatable protrusion. What I
7 took your question to mean was does the material occupying the
8 recess -- so the forges of the wall of the cuff that serves as the recess
9 as seen in figure 3 -- that attains a slight convexity to its contour in
10 figure 4, and are those convexities the protrusions that you are
11 referring to. The protrusions that I'm referring to are numbered 18 in
12 figure 4. It's the barbs that are the inflatable protrusion.

13 "Are the barbs inflatable?

14 "The barbs are not. The barbs are -- the recess is the
15 inflatable protrusion that delivers the barb to the wall of the blood
16 vessel."

17 When we inflate, partially inflate the '851, and it pushes
18 out the recess a little, that is an inflatable protrusion. And, indeed, in
19 discussing the type of protrusions, dips were also included in the '851
20 patent, below the surface.

21 So, we would argue that --

22 JUDGE KAMHOLZ: Where is this addressed in the
23 petition?

24 MR. CHAKANSKY: Excuse me?

1 JUDGE KAMHOLZ: Where is this argument that the
2 inflatable -- that the barbs are the inflatable protrusion?

3 MR. CHAKANSKY: No, no, the argument -- that's the
4 statement of Dr. Clark. He also went on to say that the recesses
5 become inflatable protrusions. It's the --

6 JUDGE KAMHOLZ: My question is where did you lay
7 this argument out in the petition?

8 MR. CHAKANSKY: I believe when we said it was a
9 102, in Samuels '851 was a 102, we said that the -- when partially
10 inflated --

11 JUDGE KAMHOLZ: We didn't institute on the 102.

12 MR. CHAKANSKY: Excuse me?

13 JUDGE KAMHOLZ: We didn't institute on the 102.

14 MR. CHAKANSKY: It's in the petition, but I guess it's
15 not part of this review?

16 JUDGE KAMHOLZ: That's correct.

17 MR. CHAKANSKY: Okay. Okay. Then if the Board
18 believes that it is not part of the review, then I would also add that
19 '851 has -- discloses an inflatable cuff for affixing -- I'm pretty sure
20 we did it with one of the -- would you bear with me a second and let
21 me check with the claims chart?

22 In -- actually as part of our description of that element, in
23 Samuels '851, we say, on page 27 of paper 1, but it's one of the
24 grounds that was not instituted. Let me see if the ground that was
25 instituted has -- should have that as well.

1 Protrusions. Yes, if one looks at page 40 of paper 1, one
2 sees element 1a-3, and I apologize, but it then says, in Samuels '851,
3 "see disclosure in claims chart 1 above," and in claims chart 1 above,
4 it has Samuels '851, the cuff 10 which includes a plurality of
5 reinforced recesses. So, I would retract my statement, it is part -- I
6 believe part of the review.

7 JUDGE KAMHOLZ: Thank you.

8 MR. CHAKANSKY: So, to look at Samuels '851, with a
9 concept now of not using barbs, or not damaging the blood vessel or
10 other tubular structure by the use of barbs, and barb-like materials, it
11 was obvious to take the inflatable cuff, which was also capable of
12 maintaining the stent graft in position, all right, and further providing
13 it with -- further gripping means to keep it in position. The gripping
14 means being Todd '745, and whether Todd '745 is hollow, inflatable,
15 or solid, it's -- when you brought it over to the inflatable cuff of
16 Samuels '851, it would have been obvious to incorporate it in either
17 solid or inflatable form.

18 JUDGE KAMHOLZ: Just in place of the barbs?

19 MR. CHAKANSKY: In place of -- well, there are -- in
20 place of the inflatable protrusions, which we had argued were
21 themselves formed -- let me drop that, that was not part of this thing.

22 In place of the inflatable protrusions which offer the
23 friction-enhancing surface in the '851.

24 JUDGE KAMHOLZ: So, in the '851 patent, the surface
25 is covered with recesses, individual recesses, in which rests a barb --

1 in which is affixed a barb at the bottom of each recess. The
2 combination that you are proposing is to replace the recesses and the
3 barbs entirely by the circumferential ridges of Todd?

4 MR. CHAKANSKY: Yes. Keeping in mind that --
5 keeping in -- I'm sorry, keeping in mind that the recesses were only
6 temporary recesses, that as implemented, the recesses were to be
7 pushed out by the inflation material, partially initially, in a
8 repositional manner, such that the barb would not be deployed, and
9 then finally all the way out when it deployed the barb, as shown in
10 figure 4.

11 So, if, for example, we just didn't bond the barbs to the
12 '851 device and we fully inflated it, we would have inflatable
13 protrusions that protrude above the surface of the inflatable cuff,
14 engaging the vessel. And instead of -- and if circumferential ridges is
15 a requirement and it be a continuous circumferential ridge, then we
16 would substitute the circumferential ridge, the annular ring of Todd
17 for those protrusions, and thereby provide gripping means.

18 So, we would just substitute Todd for the barbs.

19 JUDGE KAMHOLZ: So, the circumferential ridge is
20 running through recesses?

21 MR. CHAKANSKY: I would substitute. I would not --

22 JUDGE KAMHOLZ: So, recesses -- you would
23 eliminate the recesses, eliminate the barbs, and just have a
24 circumferential ridge around the surface 14?

1 MR. CHAKANSKY: I would -- I would take those
2 recesses and join them to each other, in a form of a circumferential
3 ridge that was continuous around the inflatable cuff.

4 JUDGE KAMHOLZ: A circumferential recess?

5 MR. CHAKANSKY: I'm sorry, maybe that's a problem.
6 The recess is only --

7 JUDGE KAMHOLZ: The problem, Mr. Chakansky, is
8 that none of this is laid out in the petition, so we don't know what your
9 argument is.

10 MR. CHAKANSKY: Instead of -- I would just say the
11 simplest way of looking at it and what was done is instead of
12 incorporating recesses and inflatable recesses that became inflatable
13 protrusions, one would substitute around, circumferentially around the
14 cuff, the inflatable cuff, a circumferential ridge, similar to the one that
15 is in Todd.

16 JUDGE KAMHOLZ: And that's inflatable because it is
17 riding on an inflatable cuff?

18 MR. CHAKANSKY: It is both inflatable because it's
19 riding on an inflatable cuff as well as there's no reason -- there is
20 nothing in Todd that says that it's not inflatable. There is nothing
21 there. To go ahead and say that because -- to say that Todd requires
22 there to be a solid ridge, or I guess a solid ridge, as opposed to an
23 inflatable ridge, there's nothing there. We are dealing in '851 with
24 inflatable items, and inflatable items, I believe, inflatable cuffs and

1 stuff, because when deflated, they take up less volume and are easier
2 to insert in blood vessels.

3 So, it would be obvious, one would think, that when one
4 brought over inflatable ridges -- when one brought over ridges,
5 inflatable or not, from Todd, one could make them -- one would make
6 them inflatable. It would dovetail in with the purpose which was to
7 get them into small blood vessels, it would serve the same function
8 because at the end, Samuels says, to permanently affix, we've got to
9 inflate it with a hard -- with a hardening agent anyway, so the ridges,
10 as well as the cuff, will become hard. It just would appear to be
11 obvious to one of ordinary skill in the art, why not, if the purpose is to
12 get rid of the barbs, if the purpose is to perform -- to still provide the
13 problem of gripping means, and if there is a goal that it should be as
14 small as possible to get into the blood vessel, let it be inflatable.

15 JUDGE KAMHOLZ: You have a minute remaining in
16 your initial time.

17 MR. CHAKANSKY: Can I take another five minutes off
18 of the rebuttal time?

19 JUDGE KAMHOLZ: Please.

20 MR. CHAKANSKY: Lazarus. Lazarus, in a similar
21 fashion, Lazarus is a graft that has toroidal collars to help attach and
22 affix the device to the blood vessel or tubular structure. It also has a
23 porous surface to encourage in-growth of tissue. It's held in place at
24 least initially by the inflation of the toroidal collar. In fact, it has to be
25 held in position for at least several days to several weeks because for

1 completion of in-growth takes several days to several weeks, which is
2 another -- the in-growth is another way of affixing it, further affixing
3 it, and --

4 JUDGE KAMHOLZ: I will apologize in advance, I do
5 not know how to make the device stop beeping. I am going to give
6 you an additional five minutes starting now.

7 MR. CHAKANSKY: Thank you very much.

8 In Lazarus, it talks about not wanting to damage the
9 blood vessel by the use of barb-like materials and fasteners. It would
10 have been obvious in addition to or in combination with Lazarus to
11 add the annular rings of Todd to further enhance the affixation or
12 attachment of the graft of Lazarus to the blood vessel.

13 Once again, we have an inflatable -- we have an
14 inflatable collar in Lazarus, the purpose, Lazarus talks about the
15 material as being compressible, at least, so as to form and get into the
16 blood vessels more easily. It would have been obvious to take the
17 ridge -- the annular rings/circumferential ridges of Todd and add
18 them -- add them to Lazarus to further ensure that the device did not
19 move.

20 And I think I'll save the rest for the rebuttal. I'm told I
21 have to add that old elements performing, these are old elements, the
22 ridges of Todd, and they're known functions, which is to grip and affix
23 devices within the blood vessels, and putting them together yield a
24 predictable result, and therefore makes the '575, the Samuels patent,
25 obvious. Thank you.

1 JUDGE KAMHOLZ: Thank you, Mr. Chakansky. You
2 have 33 minutes remaining.

3 Mr. Diederiks?

4 MR. DIEDERIKS: Excuse me just one second, because
5 I'm going to use the PowerPoint and I will take just a few moments to
6 reconfigure this. I was told by the gentleman outside how to do it.
7 Hopefully that will stay there because it doesn't screw in.

8 So, it is my intention today here to, first of all, discuss the
9 invention in general, because I want to discuss some of these figures,
10 the structure, then when we talk about the claim, we see exactly what
11 we're talking about.

12 JUDGE KAMHOLZ: Would you like to reserve any
13 time?

14 MR. DIEDERIKS: Oh, I'm sorry, I apologize, yes, we
15 would like to reserve -- the plan at this time is that I would discuss up
16 to the point of the amended claims, and I was going to let
17 Mr. Whitelaw discuss the amended claims, and we would reserve 15
18 minutes.

19 So, we will discuss general aspects of the invention and
20 the structure, and then particular aspects, and we're going to use those
21 particular aspects to what I consider show glaring distinctions with the
22 applied prior art.

23 So, this figure here, which is figure 1 reproduced from
24 the Samuels patent, and I'll refer to that as the subject patent, we have
25 shown here stent 5, okay, which includes a lumen 15. It has an

1 inflatable cuff 17, that general one with the arrow. It has an inner
2 surface 19 of the cuff, and that cuff also has an outer surface 23. And
3 that outer surface of cuff 17 is formed with the number of spaced
4 inflatable circumferential ridges 25.

5 Now, I'm hesitant to just continue with my presentation
6 here, which I'm going to do, but I do want to mention at this point that
7 there are various embodiments in this application, okay, and there was
8 some reference made to the core surface and we're worried about
9 claim 2 and how it works in, that type of thing. When this was before
10 the examiner, the examiner did not allow other embodiments except
11 for the one with circumferential ridges.

12 Now, claim 2 says that that outer surface can be -- and I'll
13 actually read it, if you can get claim 2 for me, that it can be coarse.
14 Well, there's no reason that you can't roughen, and that's what that
15 means, it roughens that outer surface. It doesn't mean it's an inflatable
16 ridge anymore, it just says where the friction-enhancing outer surface,
17 which is that outer surface that I just indicated at 23, is coarse, is a
18 coarse surface. And we know that this is going to become in friction
19 engagement and to make it coarse just adds to that frictional
20 engagement.

21 Very briefly, what we are trying to attempt here in this
22 invention is you are taking a -- you have a blood vessel wall, 85, and
23 these are figures directly out of the Samuels subject patent, and
24 figures 5a and 6a, and we'll go through with 5b and 6b, they go
25 together, one is just a cross-section looking in the other direction.

1 So, you have a blood vessel such as a human artery, 85,
2 and there is a constriction on it, 83. So, obviously the blood flowing
3 through there has a change of pressure, it has a different blood flow
4 and you want to correct that. So, what we do is we insert stent 5 into
5 this location of the constriction, we inflate it, you determine that it's in
6 the correct position, and if it's not, you deflate it, reposition it, inflate
7 it, and I'll go on this in a little more detail in a second. And then once
8 you fully inflate it in the right position, it will allow the blood flow as
9 it was before.

10 Now, to describe this figure here, I'm really only
11 referencing one of the first stage where you basically are inserting a
12 guide wire, 81, that guide wire 81 is used to guide a catheter, 87, and
13 on that catheter is the stent of the invention. So, it's in a collapsed
14 state, right out of the patent, it's on a collapsed state on that catheter,
15 and in here it's indicated at 89, and you can see the rings, which are
16 not separately labeled. Once you get in the position at the
17 constriction, the next figure shows it inflated.

18 Now, at this inflated position, it can be fluoroscoped to
19 determine if it's at the right location. Obviously with the inflation,
20 you see the enlargement of the circumferential ridges, which are
21 indicated there, at 91, and if you're in the proper position after
22 fluoroscopy, well, then you can move to the next step, which is to
23 remove the guide wire and the catheter, 81 and 87. If not, as
24 discussed in the patent, you deflate, you reposition, you re-inflate.

1 Now, that being the general, this is figure 2, which is of
2 an essence of this invention here. This is a vertical cross-section of a
3 portion of that stent, and here we can see, as we discussed before, that
4 cuff, that inner surface 19, we can also see that outer surface 23, and
5 we also see the circumferential ridges 25. As clearly shown in this
6 figure, and described in the written description, ridges 25 provide
7 along and form part of that outer surface 23.

8 Reference numeral 27 in this figure denotes an inflatable
9 chamber, which is in fluid communication, and it's located -- it's in
10 fluid communication between that inner surface 19 and that outer
11 surface 23, and also, in fluid communication with the circumferential
12 ridges.

13 So, Petitioner specifically mentioned that one of the
14 aspects or obvious advantage, I believe he used, was that you want to
15 get these as small as possible. You're going through that constriction,
16 and you want to get these as small as possible.

17 So, if you could imagine 25 as being solid, and we'll talk
18 about that later, but that's what we propose Todd is doing in any of the
19 rejections, the best a deflation can do for repositioning or initial
20 positioning is move surface 23 against 19. You're still going to have
21 that extra dimension associated with those ridges 25. However, that's
22 unlike this invention, where 25 itself inflates and deflates, and
23 therefore when you have a deflation, 25 also goes down to 19, and
24 you have a much, much smaller diameter and you can get into a much
25 smaller constriction.

1 This, we wanted to point out, because we're making
2 arguments of what's disclosed here and I wanted to point out some of
3 the actual quotes from the patent itself with respect to this. And I'm
4 not going to read them all, but if you look at the very top, as shown in
5 figure 1, and I pointed out figure 1, outer surface 23 features a number
6 of inflatable ridges 25 disposed about its circumference. Inflatable
7 ridges 25.

8 The next one says in the next paragraph, "As illustrated
9 in figure 2," that we had up, "circumferential ridges 25 are in fluid
10 communication with the inflatable chamber 27 of cuff 17."

11 And I will drop down to the fourth one, "By doing so,
12 constricted portion 83 is compressed between blood vessel wall 85
13 and stent 89, the latter of which is fixed in place by way of protruding
14 ridges 91."

15 Now, I do believe that there were various -- I was
16 confused as to what the rejection was being applied here, but I know
17 what the one is in the case. We have two rejections, both of which are
18 103. In each of those rejections, we've taken the position that first it
19 would not be obvious to combine, and second, even if you did
20 combine them, they would not meet the claim limitations.

21 As for the first type of argument, this, we believe, is
22 covered in the briefs, and based on my time, I'm not going to go over
23 it much. Other than to say that I would highlight Clark's deposition
24 on this fact, where they specifically asked whether that would be
25 obvious to combine, and he did not believe it would be obvious to

1 combine aspects of a catheter with a stent. We have both a catheter
2 and a stent. The catheter delivers the stent, but we're going to take
3 aspects of the catheter and modify the stent. That, I think, was his
4 position on it.

5 What I want to do with the time I have is say, even if we
6 did make the combinations, even if we did take structure from Todd,
7 and move it over to either the earlier Samuels patent arrangement or
8 the Lazarus one, we still would not meet the claim limitations.

9 Now, this is figure 8 taken from Todd, and I don't need to
10 go over all this because it was already up for you, but the catheter is
11 indicated at 26, and the ridges are at 52.

12 Now, before I go too much further, I do want to point out
13 one thing, because I want to address some of the arguments made
14 here. I do think that -- I don't want you to be misled by some of the
15 discussion with reference to some portion in the Todd patent by the
16 Petitioner in referring to when inflated, the spiral ridge 48 contacts
17 and tightly grips. The fact of the matter is, that "when inflated" does
18 not refer to the spiral ridge. As a matter of fact, you can look in the
19 paragraph right after it, and it talks about -- here we go, inflated
20 balloon. These ridges are on the balloon. They're on the exterior
21 surface of the balloon.

22 And I will get to it in a minute, we're going to talk more
23 about -- well, we can switch right now to it, why don't we go to this
24 cross-section, which was the question of some comment. Without
25 having the ELMO here, I can't present the other figures, I could take

1 the time to switch it over again, but it was stated that figure 4 looks
2 much like figure 8, okay? Figure 8, figure 4. And we have in the
3 Todd patent, we had, just like the Petitioner said, we have a first
4 figure, and then figure 2 shows a cross-section of that. This
5 cross-section is completely clear to me that it is a cross-section
6 standard in the patent of how you do a cross-section when it's solid.

7 We have another embodiment in figure 3, which has a
8 cross-section in figure 4. The other embodiments, all they do is
9 change the outer surface structure, which are adjacent 40, those nubs
10 in this one, in the original figure 4, and we made it -- there's other nub
11 embodiments, there's diamond embodiments, there's a spiral
12 embodiment, which should not be used here. We go down to figure 8,
13 which is the ring embodiment.

14 We introduced this into the record early in these
15 proceedings, and there's no objection to this being an accurate
16 depiction. It is absolutely consistent with the cross-sections given in
17 the other figures. And it is correct that there is absolutely no
18 disclosure with respect to what is adjacent, those nubs that are -- or
19 rings adjacent number 40 to be inflatable.

20 And I will bring back the tire example, which, Judge, you
21 mentioned, but we also put in our earlier filings, and I do believe that
22 if you -- the tread on a tire is not inflatable. The tread on the tire is
23 solid. If I have a low tire, I have 25 PSI and I go to the gas station to
24 fill it up to 33, does the pressure in that tread change? No. There's no
25 change. If I asked you my PSI in my tires is 33, what's the pressure in

1 the tread? I don't know, because it doesn't matter. You don't inflate
2 the tread when you inflate the inside of the tire; you do not inflate
3 those solid rings when you inflate 32.

4 JUDGE KAMHOLZ: But the tread sticks out more.

5 MR. DIEDERIKS: Yes, the tread would stick out more,
6 but if I took -- and I'm just -- let me go back here. If I went to ours,
7 and if I made 25 solid, and I inflated between 19 and 23, 25 would
8 stick out more. But if I make 25 in the deflated position, 23 would go
9 against 19 and 25 would still stick out more. Something you don't
10 want. Something that was even mentioned by the Petitioner that it's
11 known that you want to put it in a constricted area, you want to get as
12 constricted or low profile, low profile is in the patent, as low profile as
13 possible.

14 Another way to look at this, and it will be the last one, I
15 can move on, is I could take a knife and shave those ridges right off.
16 That would not deflate the area 32. If I tried that with this, I tried to
17 shave off any part of 25, I deflate the whole cuff. That shows the
18 difference between inflation, to me, and noninflation.

19 I want to next move to the claims because I just want to
20 bring out that I'm not speaking or I went through this whole
21 discussion of what some of the subject matter was, what some of the
22 limitations, that it is here, that we're not -- I'm not just talking about
23 the abstract, I'm an ex-examiner, I don't like to see people argue things
24 that aren't even in the claims.

1 So, here it is in the claims. We have an inflatable and
2 deflatable cuff. Now, first take a look at claim 1, it has the cuff and
3 an inner surface and it has a friction-enhancing outer surface and it
4 has the inflatable protrusion. This is all part of the cuff. This is all
5 under (a). We don't have a cuff and then a separate protrusion, and
6 then a separate circumferential ridge, this is all part of the cuff.

7 A cuff inflates and deflates the structure associated with
8 that cuff in the inflatable protrusion, which is the circumferential
9 ridge, which I already quoted was a protruding ridge and which was in
10 fluid communication with that same chamber 27, which inflates the
11 cuff.

12 The next claim 14 has the same thing. We have -- we
13 have a cuff, it has that inner surface, it has that friction-enhancing
14 outer surface, it has an inflatable/deflatable chamber disposed
15 between them, that's that chamber 27. That friction-enhancing outer
16 surface is defined as having the inflatable protrusion, and that includes
17 at least one circumferential ridge.

18 Claim 23, as I said before, there's various embodiments,
19 this actually has an embodiment where there's a plurality of cuffs that
20 may be spaced, and then it says each of the cuffs, including that same
21 structure, it has that inner surface, it has that outer surface, it has the
22 inflatable chamber disposed there between. That outer surface has the
23 inflatable protrusion, that is the circumferential ridge.

24 Now, I'm not exactly sure of my time, but there is --

25 JUDGE KAMHOLZ: You have 28 and a half minutes.

1 MR. DIEDERIKS: Twenty-eight before I reach my?

2 JUDGE KAMHOLZ: Forty-five.

3 MR. DIEDERIKS: Well, I will let Mr. Whitelaw go in
4 just a minute, he will take some of my time. I just have a couple of
5 more slides here. First of all, I just in general, in this whole process,
6 attorney argument is great, we can sit here and argue until we're blue
7 in the face, both opposite ways, but we were the only ones to present
8 expert testimony, expert declarations in this case.

9 So, there's a *prima facie* case of obviousness, assuming
10 that was the position taken by the Board, we submit that we rebutted
11 that with the experts. There's no experts coming back on the other
12 side. What we have is experts and attorney argument,
13 noncontroverted, against any other experts from the other side.

14 And these are statements. One of the things when you
15 gave us instructions concerning getting any testimony or expert
16 declarations, is we want to know what else they know. Don't just
17 limit their input to what's in the few patents that we have before us,
18 three patents at the time. What other evidence do they know about?

19 So, these are quotes from declarations, Mr. Samuels'
20 declaration, later on Mr. Clark's declarations, and one of the things
21 that was pulled out of these declarations, or that came up, is where do
22 they get this other information that they look at? Where do they do
23 their searches? Where do they know where their technology is from?

24 Well, where do doctors? They don't normally subscribe
25 to the OG and thumb through patents. No, what they do is they get

1 medical journals, they get medical magazines, publications of every
2 kind in the medical field. And this actually lists quite a few journals.
3 We have PubMed common articles, we have Endovascular Today, I
4 could go through a few more, but there's specifically listed where they
5 got some information from.

6 And in particular, with the Clark deposition, he said, you
7 know, there has been a product like this disclosed and emphasized in
8 our field. Endovascular Today talks about an Ovation abdominal
9 stent graft, includes a network of inflatable channels and sealing rings
10 that provide a unique customized fit. This word "unique" is up there
11 on the top, obviously this has emphasis added, that is bolded there. I
12 want to also indicate that -- I'll put it in here, innovative is used, low
13 profile is used, conformable is used, these are all things associated
14 with these inflatable channels or rings, and rings is the exact word that
15 the Petitioner used when referring to these ridges, when these rings
16 are inflated, and this -- this is new. This is new as of 2012, 2013.

17 Forget the fact that calling it new, calling it innovative,
18 calling it unique, all of the things that I'm quoting, was made by the
19 president of the company of the Petitioner, forget that, if you do look
20 past that for a second and say, well, what does this suggest to one of
21 ordinary skill? Because that's who we're talking about. This is what
22 they think is new. This is the technology at this time.

23 So, it's new here, but when you go to keep a valid patent,
24 all of the sudden it's extremely obvious and it was claimed to be
25 anticipated.

1 So, to summarize my part, or just to finish up on my part
2 and to move on to Mr. Whitelaw, I submit that the Patent Owner has
3 rebutted any *prima facie* case of obviousness before the Trial Board
4 and has done so not just with attorney arguments, but with the only
5 expert testimony in this case.

6 Thank you very much.

7 MR. WHITE LAW: May it please the Trial and Appeal
8 Board, my name is Nicholas Whitelaw, and I represent Dr. Samuels.
9 I'm here to discuss the motion to amend the claims in this patent.

10 Lead counsel, Mr. Diederiks, has already presented
11 arguments as to why the present claims are patentable, and those
12 arguments also apply to the amended claims. However, it appears that
13 the circumferential ridges are not necessarily being interpreted
14 separately patentable, and the amendments are designed to address
15 these issues.

16 As specifically set forth in the motion to amend, the
17 proposed amendments to the claims are supported by the specification
18 as filed, specifically figures 2 and 3 -- excuse me, 1 and 2, and the
19 corresponding discussion on pages 5 to 8. There's already been a
20 discussion showing how most of the limitations are shown in figures 1
21 and 2, so I'm not going to hit that again.

22 The Petitioner's position on the papers is that the
23 amendments enlarge the scope of claims and that is a mistaken
24 position. The position alleges there's no longer a requirement to inject
25 inflation material into the cuff; however, originally amended claims

1 specify that the circumferential ridge is part of the cuff, and therefore
2 inflation of the ridge is inflation of the cuff.

3 And we can go through the slides and see that the
4 inflatable cuff, for example in paragraph (a) here, includes the
5 circumferential ridge. Also, while I'm on the claim, I note that the
6 language of this claim emphasizes inflatable in front of the
7 circumferential ridge and that the inflation material passes into the
8 ridge to inflate the cuff.

9 Claim 14 also has the cuff having a ridge. In this case,
10 the ridges are disposed about the inflatable cuff and in fluid
11 communication with the inflatable chamber. So, once again,
12 emphasizing the inflatable nature of the circumferential ridges. And
13 the same can be found in claim 45, in this case the protrusions are
14 formed as inflatable ridges.

15 The Petitioner has also taken the position that the
16 amendment to claim 25 is not -- excuse me, covers -- is not supported
17 by the specification, because claim 25, according to the Petitioner,
18 covers sequential inflation of the ridge first, and then the cuff second.
19 That claim 25 up here, and the inflation material is being injected into
20 at least one inflatable circumferential ridge. There's no first inflating
21 the ridge and second inflating the cuff.

22 JUDGE KAMHOLZ: You're relying on syringe 71 and
23 tubing 61 as the structure correspondent to the means in part C -- I'm
24 sorry, part B.

1 MR. WHITELAW: Part B, the means for injecting
2 inflation material into at least one circumferential ridge of the cuff --
3 wait one second here. So, syringe -- which syringe, I'm sorry?

4 JUDGE KAMHOLZ: Syringe 71.

5 MR. WHITELAW: Syringe 71, yes, and it would also
6 include some of the tubing as well.

7 JUDGE KAMHOLZ: Yes, so the way that you have
8 amended the claim requires -- does it, I should say, does it require that
9 the fluid be injected directly into the circumferential ridge? I notice
10 that you added that language specifically into limitation (b). Your
11 position now seems to be that by introducing the fluid anywhere in the
12 cuff, it will necessarily infiltrate and inflate the ridges. And on that
13 basis, the claim is supported. Is that correct?

14 MR. WHITELAW: Yes. It is correct. It's all one open
15 chamber, so wherever you put the inflatable material in there, it's
16 going to go and permeate throughout the entire chamber. That's
17 shown in figure 2.

18 JUDGE KAMHOLZ: So, what does that language
19 mean? I mean, you add the words "the at least one inflatable
20 circumferential ridge of," what meaning does that add to the claim?
21 Isn't that equivalent under your argument to means for inflating the
22 cuff? Or means -- I should say means for inflating -- means for
23 injecting an inflation material into said cuff.

24 MR. DIEDERIKS: Could I question what claim you're
25 referring to?

1 JUDGE KAMHOLZ: Claim 25.

2 MR. DIEDERIKS: Ah, that makes sense, okay.

3 MR. WHITELAW: The difference would be in the
4 function. The means for injecting an inflation material into the at
5 least one inflatable circumferential ridge may structurally be similar to
6 what it was before the amendment, but this requires that the inflation
7 material go into the ridge.

8 JUDGE KAMHOLZ: Well, this is simply a recitation of
9 the function that is performed.

10 MR. WHITELAW: The -- I understood the question to
11 be what is the difference, and the difference is mainly in the function.

12 JUDGE KAMHOLZ: But the structure that corresponds
13 to the function remains the same, it's a syringe and tubing?

14 MR. WHITELAW: Yes.

15 JUDGE KAMHOLZ: Does the function that a means
16 plus function limitation perform form part of the limitation?

17 MR. WHITELAW: Yes, the function does.

18 JUDGE KAMHOLZ: Or is it only the structure?

19 MR. WHITELAW: It is not only the structure. The
20 function must also be considered.

21 JUDGE KAMHOLZ: So, the prior art must perform the
22 function?

23 MR. WHITELAW: Yes.

24 JUDGE KAMHOLZ: As well as provide the structure?

1 MR. WHITELOW: Yes. Moving on, also as set forth in
2 the motion to amend, the claims 25 to 45 are patentable. There are
3 several points on this. Since the amended claims add further
4 limitations to already examined claims to specify the ridges
5 themselves are inflatable, the amended claims would still be allowable
6 for the same reasons as the original claims were allowable, as argued
7 by co-counsel.

8 But furthermore, the Patent Owner has met the burden of
9 the Board's standard of showing that the amended claims are
10 allowable over the prior art in general, and I will refer to the expert
11 testimony of Dr. Clark. In his declaration, he discusses the inflatable
12 circumferential ridge as not being in the medical field prior to the
13 invention, and that's in paragraph 8 of his declaration, and the
14 Samuels declaration also supports that in paragraph 5c.

15 In the opposition to the motion to amend, the Petitioner
16 argued that the proposed claims are not patentable based on six new
17 grounds of unpatentability. All the grounds rely on Todd to disclose
18 inflatable ridges, and as we've discussed at length in this hearing,
19 Todd shows only solid ridges, so all the grounds should fail.

20 JUDGE KAMHOLZ: Do you have any evidence in the
21 record, for example, expert testimony as to whether the ridges in Todd
22 are solid?

23 MR. WHITELOW: Well, any evidence, yes. Todd itself
24 shows several cross-sections which are analogous to the one in figure
25 8.

1 JUDGE KAMHOLZ: Well, I understand that argument,
2 you're inferring from figures 2 and 4 --

3 MR. WHITE LAW: Yes.

4 JUDGE KAMHOLZ: -- that figure 8 is showing a solid
5 ridge?

6 MR. WHITE LAW: And also that nowhere does it say
7 anything other than solid.

8 JUDGE KAMHOLZ: But it does say "when inflated."

9 MR. WHITE LAW: I believe that modifies balloon, if
10 I'm not mistaken.

11 JUDGE KAMHOLZ: Do you have any expert testimony
12 interpreting that passage in Todd to explain why it means what you
13 say it means?

14 MR. WHITE LAW: I could not answer that one way or
15 the other right now, I would have to review again.

16 JUDGE KAMHOLZ: You may bring that up in rebuttal
17 if you wish.

18 MR. WHITE LAW: Thank you.

19 The next section I wanted to talk about was the file
20 history. In opposition of the motion to amend, the Petitioner had
21 discussed some amendments made during prosecution. The general
22 idea was that when the Patent Owner made these amendments, which
23 were directed to protrusions without rigid components and a
24 circumferential ridge continuously disposed, that the Patent Owner
25 did not argue the prior art failed to show inflatable protrusions.

1 The inference was, I guess, that since that argument
2 wasn't made, the Patent Owner acquiesced to it, which we firmly
3 disagree with. The actual file history shows that the -- it clarifies that
4 the examiner identified allowable subject matter in connection with
5 the inflatable protrusions being circumferential ridges of the cuff. The
6 Patent Owner actually withdrew and did not make the amendments
7 with the -- without rigid components or continuously disposed, but
8 rather took the dependent claims 3 and 4 and the material therein,
9 directed to inflatable protrusions, at which point the examiner allowed
10 those claims.

11 Furthermore, one of the claims was actually amended in
12 the examiner's amendment to obtain allowance and the limitations
13 were also directed to the inflatable protrusions.

14 Finally, the newly cited reference, Holman '537, and I
15 don't know if I can pronounce this, Menasche '412, do not meet the
16 amended limitations. Holman does not include a circumferential
17 ridges since the tubular 40 do not correspond to inflatable ridges and
18 inflatable cuff, and the ridges 36, sort of like Todd, are solid. At least
19 from the cross-section and the hashmarks in it.

20 It seems that somewhat through the argument Petitioner
21 may be acknowledging that the claims do require inflatable ridges,
22 and the question remaining is do solid ridges mean claimed inflatable
23 ridges, we say the answer is no, and the claims are patentable both
24 before and after amendment.

1 That's all I have, unless there are questions. To answer
2 your question from earlier, whether there's other evidence from
3 experts regarding solid protrusions.

4 JUDGE KAMHOLZ: Yes.

5 MR. WHITELAW: That can be found in Samuels
6 Exhibit 2003, page 2, and it's paragraph 5b. Todd discloses a balloon
7 catheter and it says in there, "various protuberance configurations are
8 disclosed, each of which represents a solid structure added to the outer
9 balloon wall."

10 JUDGE KAMHOLZ: What exhibit is that?

11 MR. WHITELAW: 2003, Samuels Exhibit 2003, page 2.

12 JUDGE SCHEINER: What we have is 2002.

13 MR. WHITELAW: This is the declaration of Clark.

14 JUDGE SCHEINER: Oh, I'm sorry.

15 JUDGE KAMHOLZ: It's Exhibit 2003, declaration of
16 Clark.

17 JUDGE SCHEINER: Yes, Clark.

18 MR. WHITELAW: I apologize if I miscited. Were there
19 any other questions or can I clarify anything?

20 JUDGE KAMHOLZ: No, thank you.

21 MR. WHITELAW: Thank you very much.

22 JUDGE KAMHOLZ: Mr. Diederiks, are you going to
23 speak or just remove that?

24 MR. DIEDERIKS: I'm sorry, I was going to remove this
25 and let them have their ELMO back.

1 JUDGE KAMHOLZ: Mr. Chakansky? You have 25
2 minutes.

3 MR. CHAKANSKY: I want to start off addressing some
4 of the items brought up by Patent Owner's counsel, as was held by the
5 Federal Circuit in Perfect Web 587 F.3d 1324, at 1329, and I'm
6 quoting this, "We therefore hold that while an analysis of obviousness
7 always depends on evidence that supports the required Graham factual
8 findings, it may also include recourse to logic, judgment and common
9 sense available to the person of ordinary skill that do not necessarily
10 require explication in any reference or expert opinion."

11 Further, from that page, "Nor are expert opinions always
12 a prerequisite, for in many patent cases expert testimony will not be
13 necessary because the technology will be easily understandable
14 without the need for expert explanatory testimony."

15 We believe this is such a case. Additionally, the citation
16 or reference to Samuels' declaration at page 2, the reference to Todd,
17 merely states, without saying the basis --

18 JUDGE KAMHOLZ: Are you referring to the Clark
19 declaration?

20 MR. CHAKANSKY: Excuse me, I should identify, yes,
21 reference to the Clark declaration, Samuels Exhibit 2003, at page 2,
22 paragraph (b) simply states that various protuberance configurations
23 are disclosed, each of which represents a solid structure added to the
24 outer balloon wall. There is no support in that declaration for when
25 his conclusion is reached. He doesn't point to anything in Todd,

1 suggest any disclosure in Todd, or reason that only solid structures
2 would work in Todd.

3 JUDGE KAMHOLZ: Did you address it in the
4 deposition?

5 MR. CHAKANSKY: I don't believe -- I don't believe so.
6 We'll check as I'm talking.

7 I would like to also address a statement or misstatement
8 by Patent Owner's counsel. We have never stated that figure 4 is like
9 figure 8. What we had up -- in context, figure 4 of Todd is like figure
10 8 of Todd, and Todd is Exhibit 1008. What we have said is that the
11 purported representation of figure 8 set forth in Exhibit 2004 appears
12 closer to figure 4 cross-section.

13 In fact, I just looked at it, and the "representation of
14 figure 8" uses all the elements that are numerical elements that appear
15 in figure 4.

16 If one looks at figure 4, the elements 40/32, 40 which
17 refers to knobs, appears in Exhibit 2004's representation. As you can
18 see, these numeral elements refer to figure 4, and that's the only point
19 we're making.

20 JUDGE KAMHOLZ: I'm sorry. Restate that.

21 MR. CHAKANSKY: The point I'm making is that the
22 numerical elements are from figure 4, they are not from figure 8,
23 which deals with annular rings, and not knobs.

24 JUDGE KAMHOLZ: Your point is that Exhibit 2004 is
25 an adaptation of figure 4?

1 MR. CHAKANSKY: Yes. Just further proof of it, and it
2 has nothing to do with figure 8.

3 JUDGE KAMHOLZ: Is it fair to say that Exhibit 2004 is
4 a fair representation of Clark's view of what figure 8 is?

5 MR. CHAKANSKY: Well, it's hard to say, because he
6 never looked at it. And Clark's view of figure -- Clark's or Samuels'
7 view?

8 JUDGE KAMHOLZ: Clark.

9 MR. CHAKANSKY: Clark's view of figure 8.

10 JUDGE KAMHOLZ: What's his interpretation?

11 MR. CHAKANSKY: He doesn't -- I don't believe he
12 refers to 2004.

13 JUDGE KAMHOLZ: I didn't ask whether he refers to it.

14 MR. CHAKANSKY: Figure 2004 shows knobs on the
15 top, not annular ridges. So, I don't think it's -- it's usable in that form.

16 And another point is that much is made of the
17 incorporation in Samuels' declaration, Exhibit 1020, and -- strike that.

18 In Samuels' declaration, which is Exhibit 2002, and in
19 Clark's declaration, 2003, incorporation of verbatim quotes from
20 publications, medical publications. We do not understand the
21 relevancy, we don't think there is any relevancy to it. In any case, it is
22 impermissible, inadmissible hearsay, if they're trying to prove what's
23 being asserted in those statements. They're not under oath, and I think
24 that's about all I have to say about those statements.

1 The next thing is the motion to amend. The motion to
2 amend the claims, we believe, is deficient, in at least four areas. One,
3 there's no written support in the specification and patent claims as
4 filed for inflating -- a means for inflating the circumferential ridge.
5 There is support for means for inflating the circumferential -- the cuff,
6 but the way it's described, the structure that's in the patent
7 specification does not include any means shown structure for inflating
8 the circumferential ridge.

9 This is a means for claim, 112-6 should apply, there
10 should be some structure there showing a pipe going into the
11 circumferential ridge. What we have are statements that, well, it's all
12 connected, so if we just go ahead and we go from inflating the cuff to
13 inflating the circumferential ridge, it's the same thing, but we're just
14 going to put the language in here and that's going to make a patentable
15 distinction, which we disagree with. That's the first claim, claim 25.

16 The other two claims --

17 JUDGE RICE: Mr. Chakansky, is it Petitioner's position
18 that the amended claim requires directly inflating the ridge?

19 MR. CHAKANSKY: That's how I read it. Yes.

20 JUDGE RICE: But the word "directly" is not used?

21 MR. CHAKANSKY: One has to read it as in distinction
22 from what went before, I would think, and what is shown in the
23 patent, and what is shown in the patent, what went before, was
24 directly into the circumferential -- into the cuff.

25 JUDGE RICE: Thank you. Please proceed.

1 MR. CHAKANSKY: Now, 37 and 45 are also deficient
2 in that they violate 35 USC 316 in broadening the scope of the claim.
3 And in particular, they no longer require -- let me get it -- the inflation
4 of the cuff.

5 This is proposed claim 37, these are two elements from
6 the proposed claim 37, and once again, we have means for inflating
7 the inflatable channel, and the inflatable circumferential ridge of the
8 cuff, but we no longer have a means for inflating the cuff. That was a
9 specific requirement of the claim before amendment.

10 JUDGE KAMHOLZ: So, the claim, claim 37, just like
11 original claim 14, requires that the cuff have an inner surface and a
12 friction-enhancing outer surface, with an inflatable and deflatable
13 chamber disposed there between.

14 MR. CHAKANSKY: Um-hmm.

15 JUDGE KAMHOLZ: So, means for inflating the
16 chamber will not result in inflating the cuff?

17 MR. CHAKANSKY: Well, what I'm saying is that the
18 means for inflating the -- expressly for inflating the chamber and the
19 ridges. There's no means directly required for inflating the cuff. One
20 may result from the other, but the means is defined by what the
21 function is supposed to encompass, which is inflating the chamber and
22 the circumferential ridges. It doesn't talk about means for inflating the
23 cuff anymore.

24 JUDGE KAMHOLZ: So now inflation of a part is
25 different from inflation of --

1 MR. CHAKANSKY: I think when you're talking about a
2 "means for" structure, you know, the specification -- you have to be
3 very clear structurally as to what's happening, and I think that right
4 now we had originally means for inflating the cuff, okay, and now we
5 no longer have means -- we no longer have a means as directly just
6 inflating the cuff, we have means for inflating something connected to
7 the cuff, the inflatable chamber and the inflatable circumferential
8 ridges.

9 JUDGE KAMHOLZ: Well, means for inflating a
10 particular part.

11 MR. CHAKANSKY: Right. As opposed to the cuff.

12 JUDGE KAMHOLZ: Right, so they're specifying which
13 particular part of the cuff is being inflated.

14 MR. CHAKANSKY: Right, and it's no longer saying
15 that the means are --

16 JUDGE KAMHOLZ: I don't want to dwell on this, why
17 don't you continue.

18 MR. CHAKANSKY: Okay. Additionally, we believe
19 that the Patent Owner has not met its burden in comparing the new
20 claims, amended claims, all the claim limitations, to the general prior
21 art. He has focused for the most part on the prior art of record, and
22 according to Dr. Clark he is knowledgeable in periodicals and
23 literature in the field. The focus of both Dr. Clark's and Dr. Samuels'
24 declarations are on the inflatable ridges for the most part and not
25 every element, and we think he has not -- that they have not -- Patent

1 Owner has not met its burden of showing why the patent is distinct
2 from the rest of the general prior art.

3 Additionally, we believe that even with the amendments,
4 which now expressly -- which now require that the circumferential
5 ridge be inflatable, that that is met by, for example, Todd together
6 with Samuels '851, or Todd together with Lazarus, just as it was in the
7 early discussion.

8 JUDGE KAMHOLZ: In this context, though, are you
9 relying on Todd as teaching a hollow ridge or solid ridge --

10 MR. CHAKANSKY: In this connection, I am not -- at
11 the very least, Todd makes no differentiation whether it's hollow or
12 not. I am saying use of a circumferential ridge as a gripping means,
13 put together with the '851 disclosure or the Lazarus disclosure, would
14 result in a hollow or inflatable circumferential ridge. Or it would be
15 obvious to one ordinarily skilled in the art to construct such a thing.

16 And insofar as the references to the prior art, excuse me
17 one second, the file history, and references to distinctions made by the
18 Patent Owner to avoid the Samuels '851, and whereby they included
19 reference to a continuous circumferential ridge -- I'm sorry, to a
20 circumferential ridge continuously disposed about the inflatable cuff,
21 and where the inflatable protrusion did not contain ridges components
22 like barbs, that those are admissions regarding the claim construction,
23 and that therefore the circumferential ridge, even if it's inflatable, does
24 not necessarily have to be continuous. It could be intermittently
25 disposed, like the Blue Ridge Mountains or a mountain range are

1 ridges, a number of them, are circumferentially about the inflatable
2 cuff.

3 Additionally, the fact that -- implicit also is that the
4 inflatable protrusions were modified to include without rigid
5 components suggests and mandates that they be interpreted as
6 including rigid components, and in that case, even if Todd had rigid
7 annular rings, circumferential ridges, they would still be part and
8 parcel of inflatable protrusions.

9 And I think basically it comes down to even if Todd was
10 solid, which we don't see any proof of, other than right now the
11 statement from Dr. Samuels that they're solid, not why they're solid,
12 why they're not, is no inventive leap between solid and hollow when
13 applied to an inflatable device that's going to go into a blood vessel.

14 And as Patent Owner's counsel agreed, one of the goals is
15 to enable it to be as small as possible in the area that it presents the
16 blood vessel so it can go through. And that's all. Thank you, Your
17 Honors. Questions?

18 JUDGE KAMHOLZ: Was there anything from the Clark
19 deposition you wanted to cite?

20 MR. CHAKANSKY: Just bear with me a second.
21 Excuse me, Your Honor, we're talking about Samuels' reference to
22 Todd?

23 JUDGE KAMHOLZ: Clark.

24 MR. CHAKANSKY: Clark's? One more minute, please,
25 Your Honor.

1 This would be Exhibit 1021, the deposition transcript of
2 Todd, at page -- deposition transcript of Clark, at page 152. Okay, no,
3 actually, I will start at 150, and the question is, line 18, "Question: If I
4 can direct your attention now to 1008," which is the Todd patent,
5 figure 8. "Does element 52 point to one of the circumferential ridges
6 shown in the device in figure 8?

7 "Answer: Yes.

8 "Question: Can you show me where the patent discloses
9 that those ridges are solid?

10 "Answer: I would ask in return do you want me to find
11 where there is an inflation means of those ridges because I don't think
12 I can find an --

13 "Question: No.

14 "Answer: So, therefore, they can either be fluid or solid,
15 not both, and unless there is a description of an inflation means of
16 those ridges, then they're solid.

17 "Question: So, therefore --

18 "Answer: They can only exist in one of two states,
19 correct?

20 "Question: So your testimony is that you're assuming
21 that they're not inflatable and, therefore, they must be solid?

22 "Answer: Is there another state or other than fluid or
23 solid that those ridges could be?

24 "Question: There are many phases and states. I'm
25 asking --

1 "Answer: So they could be a gas. They could be a fluid
2 or a gas.

3 "Mr. Petruzzi: You don't need to argue with him. If you
4 want to read the patent and answer his questions, look at the figures,
5 go ahead.

6 "THE WITNESS, Clark: Okay. I'll see if I can find an
7 inflation means for --

8 "MR. CHAKANSKY: Question: That wasn't the
9 question, Dr. Clark. I'm asking you if there is any written disclosure
10 in the patent that refers to or describes the element 52, circumferential
11 ridges, as solid, which is the term that you used in answering the
12 questions from your counsel?

13 "Answer: Well, I'm going to assume that specifically
14 reading this from stem to stern will not come across the word 'solid,'
15 but there will be what the patent teaches, and all the embodiments this
16 patent teaches to, a variety of elements that are intended to confer
17 friction and/or sealing to prevent the egress of cardioplegic solution
18 outside of the coronary sinus during the arrest of the heart after the
19 insertion of a catheter into the coronary sinus solely for the purposes
20 of instilling a cardioplegic solution to allow the heart to stop to allow
21 cardiac surgery to ensue."

22 I tried to ask the question, and I -- you can see the
23 response.

24 JUDGE KAMHOLZ: Thank you, Mr. Chakansky.

25 MR. CHAKANSKY: Thank you.

1 JUDGE KAMHOLZ: Patent Owner reserved 15

2 minutes, you have more like 27.

3 MR. WHITELAW: Thank you. Okay, I would just like
4 to hit the points that were raised. One of them was that there is no
5 support for the means plus function language. I'll just put up one of
6 the claims. The Petitioner is adding the word "directly" into this
7 claim, which is simply not there. The means for injecting an inflation
8 material is covered by a structure to inspect the same as it was before
9 the amendment. The most important thing to note is that the function
10 has changed. So, we simply disagree with the addition of the word
11 "directly" and would submit that the structure is there.

12 The next point, the Petitioner was saying that we need to
13 show in the motion to amend that all the elements of the claim are
14 patentable. We respectfully submit that's incorrect on its face. We
15 really need to show one change that's novel and nonobvious. The
16 ridges were the one we focused on. Also, we focused on the
17 noncombinability of the two references.

18 The next one was regarding the amendments made
19 during prosecution. The actual amendments made were to claims 3
20 and 4, adding without rigid components and continuously disposed,
21 referring to circumferential ridge, those amendments were completely
22 eliminated from the case and are no longer there.

23 More importantly, the examiner agreed that the
24 limitations that were put in the claims were patentable in the record,
25 particularly the Samuels reference '851.

1 And then unless you have questions or my co-counsel has
2 anything further, that was all I had. Did you want to say anything?

3 MR. DIEDERIKS: I do.

4 MR. WHITELAW: Go ahead.

5 MR. DIEDERIKS: As long as we have this claim up
6 here, I would like to just add a couple of things. As far as (b), we do
7 agree that it is a means plus function language, and required to meet a
8 means plus function language is that the reference disclose the
9 identical function. The question is does Todd inject inflation material
10 into an inflatable circumferential ridge, and I submit that it doesn't.

11 The second thing here that I would like to --

12 JUDGE KAMHOLZ: Just before you go to the second
13 point, do you have any case you can cite in support of that proposition
14 that the identical function must be disclosed?

15 MR. DIEDERIKS: If I can, we can pull up the MPEP,
16 that's where it comes from, being a former examiner, I remember
17 quoting that, but I will pull that up for you.

18 JUDGE KAMHOLZ: I am familiar with that portion of
19 the MPEP, I don't believe it cites a case.

20 MR. DIEDERIKS: Oh, it may not, but it says the
21 application of a reference against a means plus function limitation
22 requires that the reference perform the identical function, and it uses
23 the word "identical." That's what really gets -- it's not something
24 that's similar, it's not something that might have some of the aspects,
25 the identical function.

1 JUDGE KAMHOLZ: I'm asking you for a case that I
2 may rely on.

3 MR. WHITELAW: I can't get the Internet up.

4 JUDGE KAMHOLZ: I should say that we can rely on.

5 MR. DIEDERIKS: Can we follow up on that, because I
6 don't have the MPEP with me.

7 JUDGE KAMHOLZ: You have 23 minutes.

8 MR. DIEDERIKS: Well, maybe we will have to
9 disregard that part of it, then, because I can't provide the MPEP that
10 quick. Unless we have Internet access. No? Okay.

11 The other thing with respect to this limitation is that the
12 way I would hope that this would be looked at is if we're talking about
13 inflation material, this reminds me of inflation material, you're
14 shooting water into a house, the cuff is the house. We amend it to say,
15 you're shooting the water into the living room of the house. You're
16 still shooting it into the house. You're still inflating that cuff. There's
17 some kind of insinuation that because we're now inflating the ridge,
18 we might not be inflating the cuff.

19 I pointed out earlier that section (a) sets forth that the
20 circumferential ridge is part of the cuff. When you inflate the
21 circumferential ridge, you inflate the cuff. There's no taking any
22 limitation out of there, it's adding a specific -- it's basically you're
23 specifying that it also does. I could say if I shot water into the house,
24 I don't hit the living room. I'm saying you actually do hit part of it,

1 you're still injecting it into the house. So, I just want to make that one
2 thing clear.

3 And then the last is, without a doubt, no matter how you
4 interpret any of these limitations, they have to be consistent with the
5 written description. It has to be consistent with what's disclosed in the
6 specification. And I pointed out in one of the charts all the limitations
7 that refer to the ridges, and in each of those, they referred to
8 protruding ridges and inflatable ridges. There's nothing inconsistent
9 with our position on that.

10 And I believe that that's it. I'm going to give him one last
11 shot to see if he's pulling it up or not.

12 MR. WHITELAW: I'm sorry, I can't pull it up that
13 quick.

14 MR. DIEDERIKS: Sorry, can't get the MPEP. Thank
15 you very much.

16 JUDGE KAMHOLZ: Thank you. The hearing is
17 adjourned.

18 **(Whereupon, at 2:43 p.m., the hearing was concluded.)**

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