

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PENUMBRA, INC.,
Petitioner,

v.

RAPIDPULSE, INC.,
Patent Owner

IPR2024-01261
Patent 11,406,402 B2

Record of Oral Hearing
Held: December 10, 2025

Before ROBERT L. KINDER, DAVID COTTA, and
JAMIE T. WISZ, *Administrative Patent Judges*.

IPR2024-01261
Patent 11,406,402 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

ELIOT D. WILLIAMS, ESQ.
Baker Botts L.L.P.
700 K Street, N.W.
Washington, D.C. 20001
(202) 639-7700
eliot.williams@bakerbotts.com

ON BEHALF OF THE PATENT OWNER:

CHARLES H. SANDERS, ESQ.
Latham & Watkins LLP
200 Clarendon Street
Boston, MA 02116
(617) 948-6022
charles.sanders@lw.com

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P R O C E E D I N G S

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JUDGE WISZ: Good morning. Today we will hear arguments in IPR2024-01261 concerning U.S. Patent Number 11,406,402. I am Judge Wisz. And I'm joined today by Judge Kinder and remotely by Judge Cotta. Let's start with appearances, beginning with Petitioner.

MR. WILLIAMS: Good morning, Your Honor. Eliot Williams of Baker Botts for Petitioner.

JUDGE WISZ: Okay. And Patent Owner?

MR. SANDERS: Good morning, Your Honors. Charles Sanders on behalf of Patent Owner.

JUDGE WISZ: Thank you. As set forth in our hearing order, each party will have 60 minutes to present their arguments. And just so you know, we each have a copy of all the demonstrative exhibits that you provided. But for the benefit of those attending by video, please identify clearly and specifically each demonstrative reference by slide number so everyone can follow along and for clarity of the record.

So Petitioner, you will proceed first and you may reserve time for rebuttal. Would you like to reserve any time for rebuttal?

MR. WILLIAMS: Yes, Your Honor. I'd like to reserve 20 minutes for rebuttal.

JUDGE WISZ: 20 minutes. You can start whenever you're ready.

MR. WILLIAMS: Okay. Great. Thank you. And may it please the Board. We have a lot to get through, so I'm just going to get into it. The Patent Owner here is claiming a catheter system for ingesting a thrombus

1 that has a vacuum and a pressure, or sometimes called a vent source, that are
2 connected by valves under control of a controller. Slide 4, Petitioner's
3 demonstrative shows kind of an overview figure from the patent with the
4 vent and the vacuum being shown there connected to the catheter.

5 Slide 3 is the text of Claim 1. This is the main independent claim.
6 There are some method claims but they incorporate the system of Claim 1,
7 so essentially all 20 claims here depend from Claim 1. I guess one thing to
8 note about the claims, obviously, as I just mentioned, there is recited
9 -- specifically, a vacuum source, a vacuum valve, a vent fluid of some sort, a
10 vent valve, and a controller that's controlling those two valves.

11 Petitioner has asserted two sets of grounds shown in Slide 5. The
12 first set of grounds is based on Yang, as combined with Mullins, as well as
13 some other references. And the second set, Grounds 4 through 6, are based
14 on Ofek, also with Mullins and then some additional references. And we'll
15 get into those details in a few minutes.

16 But I did want to first start with claim construction. And for now, I
17 just want to talk about the claim construction of the term control and
18 limiting. The dispute here is, essentially, Patent Owner says that these
19 claims require distal flow, whereas Petitioner's view is the claims just mean
20 what they say. In particular, all that's required here is you have control over
21 that distal flow and it is limited. There is no recitation here that distal flow
22 is actually required.

23 Now, if you look at how Patent Owner is interpreting the claims
24 that's shown on Slide 16, they essentially, in terms of -- for the term control,
25 they essentially say what this means is that the controller has to cause fluid
26 flow in and out from the distal end of the catheter. It's insufficient to merely

1 control it, it has to actually occur, is the Patent Owner's argument. But that
2 quite simply is just not what the claim says.

3 Similarly, if we look at the limiting claim -- I'll get back to that in
4 just a second. But just to give the other context here for the other term at
5 issue is the limited to a positive amount of exit flow. And then there's some
6 dependent claims that add further limitations to this, which we'll get into.
7 Again, in our view -- Petitioner's view, this is just plain meaning. The claim
8 means what it says. It's limited to a positive amount of exit flow. If you're
9 underneath that limit, then you've satisfied the claim.

10 The Patent Owner, again, takes the view that there actually has to
11 be some exit flow in order to be within the scope of this claim, which we
12 disagree with because that is not what the claim says. So --

13 JUDGE WISZ: Just a quick question on that one. So it's limited to
14 a positive amount of exit flow. And then, for example, in Claim 3, that's
15 0.001 milliliters to approximately 1 milliliter. So the way that you're reading
16 the claim, could that claim have been written as limited to a positive amount
17 of exit flow from 0 to 1 milliliter? What is the purpose of the lower limit
18 there if there can be no positive exit flow?

19 MR. WILLIAMS: Yeah. I think that is correct. It could have
20 been 0. I mean, approximately 0.001 milliliters, for all intents and purposes,
21 is 0. And we can talk about Patent Owner's expert's testimony on that point,
22 which I think is essentially conceding that it's sort of an arbitrary rounding
23 issue that needs to be applied to understand what that claim means, which
24 would raise all sorts of indefiniteness problems if Patent Owner's
25 construction were correct.

26 Instead, we think, yeah, the exact limitation here is that there's a

1 limit and anything in or under that limit is satisfactory. Now, could you
2 have a controller that limited the positive exit flow to, in this case, let's say,
3 half of a milliliter? Where none occurred, would the controller, you know,
4 be satisfying the limitation? I don't see why not. There's nothing -- again,
5 this is a claim that's directed to a limitation that the controller is applying.
6 It's not requiring that you get close to that limit or that you get up to that
7 limit.

8 So that's our view. I'll talk more about that in a second. Let me
9 just back up and talk about control. In general, what we'd say about these
10 two constructions the Patent Owner is proposing is that they're improperly
11 rewriting the claims. They're inconsistent with the specification. I'll show
12 you that in a second. They're inconsistent with how skilled artisans
13 understand these terms. As I just alluded to, the construction that Patent
14 Owner is proposing likely creates some indefiniteness problems for these
15 claims that would be avoided if Petitioner's construction were accepted.

16 So talking about -- one thing that I think is helpful, just as an
17 introduction to this claim construction problem, is looking at the family as a
18 whole. So Slide 28 has our summary of the other patents in this same
19 family. And as you see, there's a number of them. We've identified some of
20 them here. They're not all identified in this ticker chart, but each one of
21 them we've given an identification code. So RP-1, RP-2, you'll see them
22 there listed along as the patent family listings in the right-hand column.

23 The point is that there are some patents in this family that do
24 expressly recite that reverse flow is caused or that there's an exit flow that
25 occurs or that you cause an exit flow. So the Patent Owner had the language
26 available to them to include a requirement that actually does require distal

1 flow occur. These claims do not use that language. These claims are
2 broader. Of course, they would cover the possibility that distal flow occurs.
3 But that is not a requirement of these claims as Patent Owner lists in their
4 proposal. I think the file history makes that perfectly clear.

5 The other thing I just point out on Slide 21 is the specification
6 itself discusses of course embodiments where substantially no liquid exits
7 the distal end of the catheter. There's, you know, repeated sections from the
8 specification shown there on Slide 21 that make clear that there's nothing in
9 the specification to suggest that these claims require forward flow -- or
10 sorry, I should say exit flow to occur outside the distal end because it's clear
11 that inventor had in mind the possibility that there would be no flow exiting
12 and still be within the scope of his invention.

13 JUDGE WISZ: So Patent Owner's position on that, I believe, is
14 that the specification talks about how the flow of fluid forward is an
15 exemplary embodiment, which is in contrast to other embodiments where no
16 forward flow occurs.

17 MR. WILLIAMS: Yeah. Yes. So the inventors used -- they were
18 lexicographers, as you recall, we had some prior IPRs in this family that
19 some of the panel members have already been involved in. Those patents
20 involved the claim term forward flow. And that is a defined term in the
21 patent that has a particular definition. In that case, the actual claim term was
22 no forward flow. And the spec made clear that although the claim said no
23 forward flow, that didn't mean that there was no exit flow. So there was
24 some exit flow that could occur. What they were describing there was
25 forward flow.

26 So I think in terms of those different embodiments, it's true there is

1 an embodiment that specifically says there is no forward flow. But even in
2 that case, there was essentially an upper bound put on what the exit flow
3 could be and still be within scope of those claims. So we don't think these
4 two embodiments are necessarily mutually exclusive.

5 And we don't think there's anything in the patent that makes clear
6 to a person skilled in the art that when they used the term control in the
7 claim, what they meant was cost. That was just not the way those terms are
8 used. And it doesn't seem like there's nothing in the specification that would
9 suggest that's what those terms are meant to mean either.

10 Speaking of how persons of skill in the art talk about these terms,
11 we'll just start with -- on that point, start on Slide 23. First thing to note is,
12 again, you know, Mr. Brown's testimony about this in his declaration and his
13 deposition was very clear about how a person of ordinary skill in the art
14 would understand control. It just means to have some effect on.

15 That's confirmed by Grey, which is a prior art reference shown on
16 Slide 23, which again actually defines how persons of skill in the art
17 understand the term control, which just means to have an effect on or having
18 an influence on that's predictable. And as, again, Mr. Brown points out in
19 his declaration, at the bottom of Slide 23, there's a basic commonplace
20 example. When you say that you have a flood control device, that doesn't
21 mean that a flood must occur, right? In fact, the point of that device is the
22 opposite. So there's no reason to think that, you know, the adverse outcome
23 that the device is meant to control has to actually occur in these claims.

24 I'll just mention on Slide 24 -- I'm not going to go into great detail
25 on this, we do cover it in the reply brief. But, you know, it is our view that
26 Petitioner's -- sorry, Patent Owner's construction does create ambiguity

1 about what would be within the scope of the claims, whereas Petitioner's
2 construction resolves that clearly.

3 With respect to limiting in particular, again, we make the same
4 -- Mr. Brown makes the same point. It's when you hear the term limiting,
5 what your -- what you understand is that there is an upper limit that must be
6 satisfied but anything less than that would still be within the scope of your
7 limitation. So if you have a statutory speed limit on your car at 55 miles an
8 hour, then going zero would still be within the scope of that limitation.

9 And then lastly, on Slide 26, this is some of the cross-examination
10 testimony of Patent Owner's expert where we started to probe into some of
11 these questions about, you know, how else would a person of skill in the art
12 -- what would it mean to them, this claim, if some forward flow is required,
13 given the problems with trying to understand the particular limitations here
14 in the claim. And as you see, the Patent Owner's expert was unable to
15 essentially give a very clear definition about what would satisfy these claims
16 in the absence of applying Petitioner's construction.

17 So in short, in our view, none of these claims require exit flow to
18 occur. You just have to control or limit that exit flow, which could include
19 none. But let me move on -- because even if we accept Patent Owner's
20 construction, it actually doesn't matter to the outcome of this case.

21 Let's start with Slide 14. We'll talk about our prior art Mullins. So
22 Mullins is in all of the grounds. It's combined with Yang in the first set of
23 grounds and Ofek in the second set of grounds. It's relied on primarily in the
24 petition for its control features because it does go into great detail about how
25 these catheter valves could be controlled in order to ensure that you're
26 effectively aspirating the clot by first breaking it up and then ingesting it into

1 the system.

2 The important thing to note, here on Slide 29, is there's a few
3 places in Mullins where it actually makes explicit that the clot can be
4 expelled, right? So for instance, the first section on the top of Slide 29 talks
5 about how this sort of cyclical pressure can ingest and, if required, expel at
6 least some of the clot whereby there is deformation on the clot to improve
7 efficiency of aspiration and prevent clogging of the catheter.

8 And again, in the next section for Mullins, at column 26, it again
9 talks about essentially the same thing. If you look at the pictures, the figures
10 of Mullins, they are I think particularly helpful on this point. So I'm going
11 to turn to Slide 30 to talk about those for a moment.

12 And as you'll see on these pictures, as you go from 47(g) to (h),
13 what's happening there is the clot has been ingested. So starting at 47(g), the
14 clot has been partially ingested into the catheter. At the distal end of the
15 catheter, there is a fairly lengthy section of the clot that's been pulled in. But
16 at that point, the system has decided that it can't. The vacuum is no longer
17 going to be effective. And so it reverses the pressure and begins to
18 essentially push on that clot.

19 And as you'll see, as you move to 47(h), the clot is then pushed out
20 of the catheter. So at least some of the fluid that was in the catheter in 47(g)
21 has now exited the catheter in 47(h). And again, if you look over to the right
22 column, the right section of the slide, 47(k) and 47(l), some similar things
23 are going on. In 47(k), now we've got sort of a large section of the clot that's
24 been adjusted into the lumen of the catheter. And then there is a reversal
25 that happens to push that fluid column back out of the catheter. And then as
26 you see there, the clot has begun to break up. And then there's a clear fluid

1 path in that 47(1). You'll see 47(1), at the bottom of that lumen, where, you
2 know, fluid is coming in and out of that lumen while the maceration and
3 ingestion cycles are happening.

4 So that's what Mullins is about. There's clear exit flow going on in
5 all these embodiments. They're part of the combination. Slide 40 has a nice
6 discussion from Mullins about how this works. I'm not going to read the
7 whole thing, but that section on 27:18-35 is I think very helpful in
8 understanding exactly what's being shown in these figures and makes very
9 clear that what's going on there is you're pushing distally to that clot. You're
10 expelling some of it, but you don't want to lose contact with it, so it drifts
11 away. So you keep that clot sort of finely controlled in its positioning near
12 the distal end. But it is clear there is some exit flow to make that happen.

13 Also, I'll just -- I'll mention, we don't necessarily, you know, rely
14 on this -- we don't need to rely on this, obviously, to prevail. But I'll just
15 point out that both Yang and Ofek do also have some discussion that would
16 suggest there is exit flow.

17 For instance, Slide 34, which is talking -- which is a section from
18 Yang, explains how it uses axial reciprocation at the distal end, meaning if
19 you look at the very distal end, there's going to be movement going
20 proximally and distally along that axis. And it's being performed there in
21 order to dislodge or break up an obstruction. As Mr. Brown said, a person
22 of skill in the art reading that would understand that there must be some exit
23 flow happening if there's this axial reciprocation occurring at the distal end
24 of that catheter.

25 Similarly, Ofek is -- we have some relevant sections of Ofek on
26 Slide 36. In Ofek, what happens is there's a high-pressure injection of fluid.

1 And as it explains in that section, when you inject that high pressure
2 impulse, you're using it to clear the lumen after an occlusion is formed
3 therein; meaning you've got something that's inside your lumen, some piece
4 of clot, you're going to put high pressure to clear that.

5 As Mr. Brown says, when a person of ordinary skill in the art reads
6 that, what they're understanding is that this is flow going out, right? If it's a
7 high-pressure injection to clear a lumen, it's not sucking it in, it's pushing it
8 out, at least to some extent. So again, he's -- that testimony, I think, further
9 confirms that all three of these references talk about some amount of distal
10 flow. Mullins is obviously very explicit about it.

11 Unless there's any questions about that, I want to move to some of
12 the dependent claims. Now, talking about the particular exit flow values,
13 this is -- so Slide 39 has, I think, a summary. We have Claims 3 and 4.
14 There's some summary limitations in 14 and 16 through 16 and 17. So these
15 particular limitations, as we point out, you know, the prior art doesn't say
16 exactly how much distal flow is occurring when those -- when that cyclic
17 process takes place.

18 Mr. Brown has testified that a person of skill in the art would
19 understand that all of these claim ranges were very obvious ranges to
20 experiment with in terms of how much fluid you would want as a skilled
21 artisan to eject from the lumen, you know. Ejecting a milliliter of liquid
22 from these lumens would very likely, you know, be dangerous, so you'd
23 want to do less than that, as he testifies. But more importantly, he also -- so
24 just in general, without even any, you know, quantitative analysis, his view
25 is that these claim ranges are all well within the range of what a person of
26 ordinary skill in the art would have experimented with and concluded are the

1 right ranges to use in implementing the features.

2 But he went further and did a numerical analysis based on what's
3 actually disclosed in the references. Those charts are of course in his
4 opening declaration, for instance, starting around paragraph 215 of Exhibit
5 1005 and there's again another one at 295. His analysis was based on, you
6 know -- the assumptions he relied on came from the references themselves.
7 And what he showed is applying these just very simple basic assumptions
8 with the fluid flow equations everyone agrees applies here, you get, you
9 know, certainly the ranges that are claimed.

10 So there's nothing inventive about the particular ranges. They
11 haven't shown any criticality to these ranges. To the extent there are any
12 criticality to these ranges, those would have been very obvious to a person of
13 skill in the art who understands that what you're trying to do is, as Mullins
14 explains, you know, dislodge that clot but not sort of lose contact with it.

15 Okay. I was going to move now to this issue of predetermined
16 cycle which is in Claim 1. This is Slide 45 I'm looking at with the text,
17 relevant text, from Claim 1 here. Essentially, what the dispute is, is Patent
18 Owner's arguing for some unstated negative limitation in this claim, to say
19 that what predetermined cycle means is that there is no sensor used to tune
20 the valve timings when the system is performing its cycle.

21 In our view, that is -- there's absolutely no support for that in the
22 specification. There's certainly no support for that in the claims. So we
23 think it's just an inappropriate restriction. In our view, a cycle is just a cycle.
24 When you read the claim, what's required is a cycle of valve states. So one's
25 on, one's off. Then you move to a second state, then the third state, then a
26 fourth state, and then you repeat that cycle. So you cycle through which

1 valves are opened and closed at the various time. That is all this claim
2 requires.

3 As Mr. Brown has explained, there is obviously no limitation that
4 restricts the use of sensors in the specification. In fact, to the contrary, the
5 specification itself talks about the use of sensors for exactly this purpose.

6 Slide 48 has the argument from our reply on this as well as Mr. Brown's
7 testimony. The relevant section from the specification is on column 44, line
8 23, approximately.

9 What it says is by knowing the time delay and the distance
10 between the sensors, the speed of the wave can be calculated. By knowing
11 the distance from the most distal sensor to the tip of the catheter, the time it
12 will take for the wave to travel to the distal tip can be calculated. This
13 information can be used by the controller to time the valves properly.

14 So again, the specification itself makes clear that sensors can be
15 used to control the valve timing. It doesn't change the sequence. The
16 sequence is still A to B to C to D. You know, you have a vent state, you
17 have a vacuum state, you have a closed state. That cycle doesn't change.
18 But their timings can be tuned by a sensor. There's nothing that prevents
19 that from being within the scope of the claims at all.

20 All that the Patent Owner presents at the core of this construction
21 is an ambiguous statement by the examiner in the file history, which the
22 Patent Owner himself repudiated. He said he didn't concede. This is from
23 Exhibit 1004, which is the file history page 29. It says the applicant does not
24 concede the examiner's characterization of the terms of the claims and the
25 prior art are correct. So there's certainly no disavowal here. There's no clear
26 restriction that would suggest you need to add a negative limitation because

1 of what happened during file history.

2 Going back and looking at what the examiner's conclusion was, it's
3 actually very hard to tell exactly why the examiner thought Garrison was
4 distinguishable. He does mention a sensor, but I don't -- it's not clear to me
5 that that's what he was actually relying on. I think he was just more
6 generally saying -- I mean, Garrison -- this whole section of Garrison, which
7 is mostly about the catheter and not about this control feature, the whole
8 section of Garrison that's relevant is two paragraphs and neither section
9 really explains that there are valves, how they're cycled, what the states are.

10 So I think the examiner was just saying none of that is present in
11 those two paragraphs in Garrison, which could very well be correct. But if
12 it's not, then, you know, examiner here is -- you know, examiners can err,
13 that's why the PTAB exists. So I don't think there's anything in that, you
14 know, short section of the file history that would conclusively say the Board
15 should here inject a negative limitation into this claim that Patent Owner
16 itself didn't bring in.

17 In terms of the prior art applicability to this claim, I think there's
18 no doubt that the prior art all has these cycles of valve states. I'll talk of
19 course about the double off state in a second, which is I think the main one
20 that's disputed. But in general, they all talk about a progression of valve
21 cycles; certainly, Yang and Ofek do. And as we explained in the petition,
22 applying Mullins' techniques would have been an obvious way to control
23 those valves in order to achieve what Mullins describes as, you know,
24 clearing the catheter using those pulses and vacuum cycles.

25 I don't think I need to cover that. Let me just move -- before I get
26 to the double-closed state, let me also touch on the Claim 11 method claim

1 arguments. So Slide 57 is our sort of beginning of that discussion. So the
2 issue here is that Claim 11 requires -- but there's sort of two issues that
3 Patent Owner has raised. I'll just sort of lump them together because I think
4 this is what they're arguing in the Patent Owner response. And of course, if
5 I hear something different, I'll respond to that in my rebuttal time.

6 But I think they have two arguments, one is that, in general, for
7 Ofek Claim 11, there's no discussion that Ofek has actually used -- he
8 doesn't ever say that you position the catheter near a thrombus you're trying
9 to extract. So that's, I think, their argument about Ofek. That argument
10 doesn't apply to the Yang grounds, best I can tell.

11 But in either case, I think assuming that's the argument, I think
12 Patent Owner is just ignoring the combination that we actually have in the
13 petition because we explained in the petition the combination in both cases
14 involves Mullins. And as we explained, you would combine the things to
15 carry out the functionality described in Mullins, which is performing a
16 thrombectomy. So to perform a thrombectomy, you need to position the
17 catheter near the thrombus you're trying to extract. That I don't think is a
18 particularly controversial position.

19 I think the other set of arguments that are being made here have to
20 do with -- by the Patent Owner, have to do with the assumption that if
21 Mullins' sensor were not being used, then you wouldn't have a reasonable
22 expectation of success of carrying out these method claims, which I think is
23 what they're claiming. The petition relies on Mullins' techniques to do its
24 aspiration that in some -- that may involve Mullins' sensor; it may not. I
25 think Mullins discloses both.

26 But even if it did, even if we have to rely on Mullins' sensor,

1 there's nothing wrong with that. As we talked about, the claims don't
2 exclude the use of a sensor and they concede by using -- they appear to
3 concede that using Mullins' sensor does not create any problems of
4 reasonable expectation of success. So I think in both cases, these method
5 claim arguments just don't quite work.

6 Is there anything else I want to say about that? I don't think so. So
7 let me just turn in my remaining time to the off-off state and then I'll maybe
8 touch briefly on secondary considerations.

9 Okay. The off-off state, this is Slide 66. Okay. So these claims
10 -- where this term appears in these claims, what seems to be required is you
11 have some state where the valves go through a position where both of them
12 are off at some point. So both the vacuum and the vent are turned off.

13 First thing I just want to point out about these claims is there's no
14 requirement here of how long the state has to last in the overall cycle.
15 There's no restriction about that. Patent Owner is making some argument
16 about purposefulness, that somehow this has to be a purposeful state. I don't
17 have any idea how a person of skill in the art would know if their double-
18 closed state is purposeful as opposed to accidental.

19 If I had a device sitting on my desk and it accidentally went
20 through a double-closed state, would I be infringing or not? The Patent
21 Owner doesn't explain how I could tell that. And there's nothing in the claim
22 that would explain how to figure that out either.

23 So all we need to look for is a double-closed state, and we have
24 that in the prior art. First, with respect to Yang -- by the way, on that
25 purposeful state, Slide 67 has some testimony from Patent Owner's expert
26 about that, where he essentially conceded that the claims don't have this

1 restriction in timing. But let me just turn to where it is present in the prior
2 art.

3 So this is best understood, I think, on Slide 69, where we have the
4 actual figures from Yang and the text that Yang has about the sequence of
5 valve states that are being shown in these figures. So as you see here, and
6 starting in Figure 25A, what's happening is that the vacuum is on, but this
7 vent -- or what he calls here atmosphere -- is off, right? So all that's being
8 applied to the catheter, there is vacuum. In B now, we have both valves on.
9 In step C, we leave the atmosphere, the vent valve on, but we've turned off
10 the vacuum valve.

11 And then the specification of Yang explains at this point, another
12 cycle from 25A to C begins by closing the release valve 2514. So that's the
13 atmosphere or vent valve that he's talking about. So as Mr. Brown explains,
14 a person of ordinary skill in the art reading that would understand what's
15 happening is, okay, now you're going to move from 25A back up to 20
16 -- sorry, from 25C back up to 25A. And the first thing you do is to close the
17 vent valve. The vacuum valve at that point is already closed. So what he
18 points out is that in doing that, you would have either necessarily or at least
19 obviously gone through the double-closed state. Because either Yang itself
20 is saying the first thing you do is close off the atmospheric valve, which
21 would create a double-closed state.

22 And to the extent that -- you know, the only other possibility that
23 Patent Owner seems to be arguing here is that maybe these things happen in
24 parallel. And as Mr. Brown points out, a parallel approach to this would be
25 a bad idea and instead, a POSITA would be more likely to do a serial
26 switching these valves in order -- in particular in the order that would have

1 created a double-closed state for many reasons. He explains, obviously, all
2 of those in his declaration.

3 By doing that, what you would create, as shown on Slide 70, we've
4 shown you what the valve states would look like as it goes through that
5 double-closed state. On the bottom there, that's the figure labeled 25-DC,
6 which is from Mr. Brown's declaration. If Mr. Brown does give obviously
7 many -- as I said, many reasons why a person of ordinary skill in the art
8 would have been motivated to perform the switching in that way.

9 For instance, at Slide 71, he explains how this approach would
10 allow you then to give the full force of the switch vacuum when you move
11 into step 25A so that it's not being diluted by the continued presence of vent
12 fluid coming into the system. He also explains, for instance, in Slide 72,
13 how doing the valves serially in that way would create more predictability in
14 the system because parallel operations could create an unknown state. You
15 wouldn't know whether the vent and the vacuum were connected at any
16 particular point during that transition. Whereas if we do them in serial,
17 you're sort of guaranteeing yourself some states that the controller could rely
18 on, creating overall system reliability.

19 There's many other reasons. I'm not going to cover them all that he
20 raises in the declaration that we mentioned in the petition and in the reply.
21 But I think that's, you know, more than enough to establish that it would
22 have been at least obvious to perform a double-closed state with Yang.

23 With respect to Ofek -- there's a couple arguments we make with
24 respect to Ofek. I'll just sort of -- they're both sort of alluded to on Slide 75.
25 I'll just mention one of them here, which is Ofek expressly says that in
26 connecting between vacuum and vent, you can use what he calls a three-way

1 valve. That's the top box there on Slide 75 from Ofek, column 5, line 26.

2 And as Mr. Brown explains on paragraph 76, with a three-way
3 valve, you would sort of guarantee yourself an off-off state because in
4 moving your three-way valve from one state to another, you would enter an
5 in-between state where neither the vent or the vacuum are connected as
6 you're transitioning between those two states.

7 The last thing I'll mention is that even if the Board were to
8 conclude that that's not clear enough from the three-way valve discussion
9 that's actually in Ofek, we also have the Rubenstein Ground 2 and 5.
10 Rubenstein is relied on primary -- this is Slide 79 that I have on the screen.
11 Rubenstein's relied on essentially for -- Rubenstein has a sort of similar
12 setup where there's a vacuum pump and a mist source that is used in
13 different -- at different times in sort of a cycle to clear out the catheter. But
14 the relevant thing that we're relying on it for in particular is that the valves it
15 uses are these, you know, rotary valves that connect the vent and the vacuum
16 to the catheter.

17 As we explained and Mr. Brown explains, it would be obvious to a
18 person of skill in the art when implementing this combination to use valves
19 like in Rubenstein, where you would have these rotary valves that connect
20 these two different states -- sorry, that connect these two different sources to
21 the lumen, to the catheter itself. We do in the demonstratives on Slide 84,
22 and these are in Mr. Brown's declaration as well, starting on Slide 84, going
23 through to 85 and then 86, you can see we've got sort of a manual animation
24 here put on the screen of how those valves turn and how when they do turn,
25 you create a period where, you know, neither the vacuum or the vent is
26 connected to the catheter, which is therefore double-closed state.

1 Okay. The last thing I just want to briefly mention and then I'll
2 reserve --

3 JUDGE WISZ: Oh, before you move on to that --

4 MR. WILLIAMS: Yeah.

5 JUDGE WISZ: -- I did want to circle back to Claim 11.

6 MR. WILLIAMS: Okay.

7 JUDGE WISZ: I just want to make sure I heard you correctly.

8 MR. WILLIAMS: Okay.

9 JUDGE WISZ: Did you say that a person of ordinary skill in the
10 art would have had a reasonable expectation of success whether or not they
11 were using the sensor from Mullins?

12 MR. WILLIAMS: We think so, but yeah, I mean, we make that
13 argument in the reply. I mean, as I stand here today, I'm just focusing on
14 Mullins with a sensor because there's nothing that -- there's no reason to
15 exclude sensors from these claims.

16 JUDGE WISZ: Okay.

17 MR. WILLIAMS: So yeah, I mean, we do think that a person of
18 skill in the art would have reasonable expectation of success either way.
19 But, you know, I don't even think Patent Owner disputes that they would
20 with this sensor.

21 JUDGE WISZ: So without the sensor, what is your response to
22 Patent Owner's argument about the variability of the clots, the sizes, makeup
23 of them, that might -- you know, one of skill in the art might not think a
24 predetermined cycle without the use of a sensor would be able to
25 successfully remove the clot?

26 MR. WILLIAMS: Yeah. I mean I think our answer to that is,

1 again, the level of skill in the art here is a combination of, you know, a
2 device engineer and a medical doctor. And so I think in that situation you've
3 got a lot of brains at the table using this device, not just the ones that are in
4 the controller itself. But the doctor can decide which -- you know, whether
5 to turn the thing on or whether or not to turn the thing on and which modes
6 -- whether you should cycle through the modes again. So even a
7 preprogrammed set of cycles, the doctor can determine if it's working or not
8 and it would still be an effective device to be using. And that's I think the
9 argument.

10 JUDGE WISZ: Thanks.

11 MR. WILLIAMS: On secondary considerations, I mean this is
12 really Patent Owner's burden to make this case. Again, they've identified
13 one of, like, the seven objective indicia factors relevant here, this long-felt
14 need. Again, we don't think there's any nexus to the claimed invention
15 because everything in this claim is already in the prior art as we've shown.
16 There's been no commercialization by Patent Owner that they can point to.

17 So yeah, I mean this idea is old, it's in a lot of patents as we've
18 talked about. So the fact that there may have been at the time still a
19 commercial need for the device doesn't mean that the objective indicia here
20 are showing that obviousness. It's just a matter of getting this device to
21 market.

22 And nothing about Patent Owner's invention, nothing in these
23 claims, is what is turning the tide here. But I'll wait to see what Patent
24 Owner has to say about that. I will just reserve the remainder of my time
25 unless that Board had any other questions they wanted me to cover.

26 JUDGE WISZ: No, thank you. And before you get started, would

1 you like to reserve any time for surrebuttal?

2 MR. SANDERS: Yes, Your Honor. I would like to reserve 15
3 minutes, please.

4 JUDGE WISZ: Okay. Start whenever you're ready.

5 MR. SANDERS: Thank you, Your Honor. I want to set the stage
6 here. This is not an IPR where the claims rise and fall together. There are
7 important differences among the claims and there are three sets of claims
8 that I'm going to discuss.

9 Claim 1, the problem with Petitioner's position is that the prior art
10 here and the prior art combination set forth, do not disclose a predetermined
11 cycle to control fluid flow in and out from the distal end of the catheter.
12 Claim 11 is the method of using the system of Claim 1 to actually perform
13 removing thromboembolic material using the predetermined cycle, thereby
14 controlling fluid flow in and out. Claim 11 clearly requires you to have fluid
15 flow in and out as part of the method. Claim 1, of course, is a system claim
16 that requires components configured to do things.

17 Then there are the dependent claims that require specific amounts
18 of positive amounts of exit flow within specific ranges. Those claims are
19 patentable for the additional reason that Patent Owner has not put forward a
20 basis to find that those particular ranges of positive exit flow are obvious.
21 On the off-off claims that Petitioner discussed, I'm happy to address any
22 questions, but otherwise, we'll rely on our briefing as to those claims.

23 I'd like to go forward to Slide 10, please, and I'll start with claim
24 construction. Claim 1 is a system claim that requires a controller configured
25 to control fluid flow in and out from the distal end of the catheter. Claim 11,
26 as I mentioned, is the method of using the system of Claim 1 to actually

1 remove the clot, remove thromboembolic material, that involves using the
2 predetermined cycle of Claim 1, controlling the valves, and thereby controls
3 fluid flow in and out from the distal end of the catheter. This claim is a
4 method where those steps are actually occurring to remove a clot.

5 Now, in the petition, there was no claim construction argument put
6 forward about Claims 1 or Claim 11. The only argument that was put
7 forward with respect - was with respect to the dependent claims that
8 required a positive amount of exit. This is a new argument that it came up in
9 the reply about the construction of Claims 1 and 11. Addressing that new
10 argument on the merits, what Petitioner is doing is reading out the
11 requirement to have flow out. Petitioner says -- this is on the left,
12 Petitioner's reply -- preventing flow out meets the claim.

13 If you're preventing flow out, then you only have flow in. And
14 out, in this claim, becomes superfluous, which of course is not the right way
15 to construe claims. Controlling flow in and out, my brother mentioned that
16 it requires to have an effect on. You can't have an effect on something
17 which you don't have in the first place. You have to have flow out and
18 control it.

19 And to be clear, this is different than cause. Control is different
20 than cause. You can cause an explosion. You can control an explosion.
21 Those are two very different things. But that doesn't make the words "flow
22 out" meaningless in this claim. Control requires more than cause. It is a
23 narrower term. You need to control the flow in; you need to control the flow
24 out.

25 I'm now on Slide 15. The specification here explicitly
26 distinguishes embodiments. It explicitly distinguishes the embodiments

1 where exit flow is intentional, in contrast to those where substantially no
2 forward flow occurs.

3 And Your Honors may be familiar, of course, with the two prior
4 proceedings that we had here, which had very different claims. They
5 required preventing forward flow. Those claims were directed to the second
6 set of embodiments, those embodiments where substantially no forward flow
7 occurs. The claims here are different. They require flow out. And they're
8 directed to the other set of embodiments, the ones where flow out is
9 intentional.

10 And I would mention, before I turn to the dependent claims,
11 actually staying on Slide 15 for a moment, there's also quite an explicit
12 transition in the specification between these embodiments that occurs at
13 column 41, lines 32 to 35, where the specification says, turning now to
14 embodiments that create maceration but without the forward flow. There are
15 two sets of embodiments; they're expressly distinguished. The claims here
16 are addressed to the embodiments that have forward flow, in contrast to the
17 embodiments that were at issue in the prior IPRs where forward flow is
18 prevented.

19 Turning now to the dependent claims. The dependent claims here
20 certainly have the word limited in them, but limited to what? Limited to a
21 positive amount of exit flow, an amount above zero, within specific ranges.
22 And those ranges have bottom limits. And those bottom limits are also
23 different. Claim 3 has a bottom limit of 0.001 milliliters. Your Honors may
24 remember we were talking about microliters when we were talking about the
25 definition of forward flow in the earlier IPRs.

26 Claim 4 has a much higher lower limit, right, 100 times higher.

1 Limited to amount of positive -- limited to a positive amount of exit flow of
2 approximately 0.1 milliliters, right? That's 100 microliters, much larger than
3 the amount of, you know, this very small amount of six microliters we were
4 talking about for the definition of overflow earlier. That's a lower limit,
5 Your Honors. You have to be above that, at least meet that tip to meet the
6 claim. You have to be approximately 0.1 milliliters. My friend's for -- on
7 behalf of Petitioner are arguing zero meets the claim. That's just plain
8 wrong. That's not what the claim says. And of course, there are other
9 claims that recite the positive amount of exit flow in other terms based on
10 the contents of the fluid column in the catheter.

11 We deposed Mr. Brown about these claims. And as you can see
12 here on Slide 18, he agreed the ordinary and customary meaning of positive
13 is greater than zero. He agreed that it has its ordinary meaning in the claims.
14 And he agreed a positive amount of exit flow is something that is above
15 zero.

16 Yet, now on Slide 19, Petitioner argues -- this is from their reply
17 -- a zero amount of exit flow would satisfy the claimed exit flow limit.
18 That's just plain wrong. You can see Claim 4 on the slide, it requires a lower
19 limit that is above zero, approximately 0.1 milliliters. It requires a positive
20 amount of exit flow that is something above zero, and specifically
21 approximately 0.1 milliliters to approximately 0.5 milliliters. Zero exit flow
22 does not meet these claims.

23 And going forward to Slide 21, we have on the bottom here
24 Petitioner's verb chart where they decide the word limit means that you don't
25 need to have any distal flow at all. Again, that's simply wrong. They point
26 to Claim 4 but Claim 4 has a lower limit on the amount of exit flow, 0.1

1 milliliters, same thing we were looking at before. And Petitioner's expert,
2 Mr. Brown, admitted the lower limit value in each of these Claims 3 and 4 is
3 above zero. It's the plain language of the claim. Petitioner is simply wrong
4 in saying that no exit flow meets the claim.

5 Now, I want to stay on this topic of exit flow, and I'm going to
6 come back to the predetermined issue. Let's go forward, please, to Slide 41.
7 All claims -- because Claim 1 is the only independent claim -- require
8 control of fluid flow in and out. And Claim 11 quite specifically requires
9 that you have that flow in and out and control it as part of the method of
10 removing a clot. So I can understand, Claim 1 is a system claim. The
11 system doesn't actually do anything. It can infringe as a doorstep. Again,
12 it's a controller configured to do something. Claim 11, you're actually doing
13 it. You're actually producing the flow out as part of your process of
14 removing that clot. It could not be clearer; flow out is required.

15 Now, this is what Petitioner's physician expert said about flow out
16 even as of today. It's something that persons of skill in the art seek to avoid.
17 Forward flow is something that one seeks to avoid. That was the state of the
18 art. This is Slide 43. And Petitioner's art is all consistent with that state of
19 the art.

20 Now on Slide 44, Petitioner has conceded, both it and its expert
21 have conceded, each of the three references on which they rely teach
22 preventing flow out; not having it, preventing. This is from -- this is Slide
23 45 -- Petitioner's physician's expert declaration. Petitioner's expert explained
24 that you want to reduce the risk of forward flow -- this is the same expert
25 who said you avoid it -- by maintaining levels of suction force, as described
26 in all of Petitioner's references, Mullins, Yang, Ofek, to preserve sufficient

1 levels of pressure.

2 And explain what that means. Generally keeping the overall
3 pressures exerted on the fluid within the catheter below blood pressure so
4 that the pressure in the catheter is lower than the pressure in the body so that
5 you will not have flow out because the pressure is never sufficiently high to
6 force fluid out of the catheter. And when we get specifically to the prior art
7 that Petitioner has put forward, you will not find, Your Honors, in those
8 references, any express disclosure of forward flow. It's simply not there.
9 There's no disclosure of flow out in the references themselves.

10 Let's see what their experts say about it. This is Petitioner's own
11 technical expert -- this is Slide 46 -- he was asked whether Yang discloses
12 control of flow out. He said it's unknown. I asked, why is it unknown?
13 Because he does not describe the flow out. Yang does not disclose flow out.
14 Petitioner's expert just admits it. And he doesn't -- Yang doesn't describe
15 whether his system controls flow out either. Petitioner's expert agrees with
16 us. There's simply no disclosure of flow out in Yang, let alone control it.

17 And that's not the only time Petitioner has admitted this. Petitioner
18 is telling the European Patent Office that Yang is understood. The skilled
19 reader would appreciate that the teaching of O2 -- that's Yang -- the teaching
20 is that forward flow is prevented. And yet here, Petitioner is telling Your
21 Honors exactly the opposite. They got it right in Europe. Their expert got it
22 right in his deposition. They agree with us. Yang doesn't
23 (INDISCERNIBLE) flow out.

24 And that wasn't the only time they said in the European office.
25 This was no mistake, mind you. This was their view of Yang, operating an
26 arrangement as described by the document Yang would naturally result in

1 the prevention of forward flow.

2 Moving on to Slide 49, they addressed Ofek, too, in arguments to
3 the European Patent Office. And what did they say a person of ordinary
4 skill in the art would understand about Ofek? That it is operated so as to
5 prevent forward flow of fluid, as we've seen. Yang discloses that the
6 dislodged occlusion is required not to enter the bloodstream. What does a
7 POSA take from that? It is clear that the device of Ofek is operated so as to
8 prevent forward flow of liquid from the catheter. Petitioner in Europe agrees
9 with this.

10 And what does Petitioner say here? Petitioner says Yang and Ofek
11 disclose embodiments that could be understood as -- or obvious as
12 controlling flow, distal flow out. This is Slide 50. Well, that's contrary to
13 what they told the European Patent Office. That's contrary to what their own
14 expert admitted about Yang.

15 And it wouldn't meet the legal standard for obviousness anyway.
16 They're not saying that a person of ordinary skill in the art would understand
17 the references that way. Indeed, they told the European Patent Office and
18 their expert admitted a person of ordinary skill in the art would not
19 understand them that way. They're meekly saying they could be understood
20 that way, which is not the test for obviousness. As this Board well knows,
21 the test is would, not could.

22 Turning now to Slide 51, the Mullins reference. What did they say
23 about Mullins? Here, my brother said for Petitioner that Mullins explicitly
24 teaches forward flow. You won't find that in Mullins. And here's what they
25 said to the European Patent Office about Mullins. Mullins explicitly teaches
26 preventing forward flow. That's what it explicitly teaches.

1 The skilled person would therefore be motivated to operate a clot
2 removal system with no forward flow in the manner described by Mullins.
3 They got it right in Europe. And those representations by Petitioner to the
4 European Patent Office are relevant to determine how an ordinary skilled
5 artisan would understand the prior art here.

6 This is Slide 52. This has been recognized by the Board in our
7 IPRs. Now, it wasn't just in Europe that Petitioner admitted this about
8 Mullins. This is Slide 53. Petitioner admitted that here, too, at Mr. Brown's
9 deposition. He was asked about Mullins and he clearly stated, I believe a
10 person skilled in art would be motivated to use the teachings of Mullins to
11 create a system that has no forward flow, Petitioner's own expert's words.

12 And harkening back to what I showed from Petitioner's physician
13 expert, Dr. Ross, at the start of this section, this is entirely consistent with
14 what the knowledge was in the field at the time. As Petitioner argued in
15 Europe, it would be obvious to the skilled person that it should be ensured
16 that forward flow is prevented. Why? For safety. Because you want to
17 avoid the possibility of shooting that thromboembolic material further into
18 the vasculature, potentially causing worse complications for the patient.
19 You're trying to remove it, not shove it farther in.

20 What did Petitioner do after we raised this European opposition
21 filing? And we raised it so that they could address it in their reply. We
22 raised it so their expert could consider it. We asked Mr. Brown about this.
23 All he reviewed were the claims of the European patent. He admits, on the
24 left. Is that all you reviewed of the European opposition? It is. Why is that?
25 He was not asked to review more.

26 And solely on that basis, solely looking at RapidPulse's claims in

1 Europe, he disagreed that there's any contradiction between Petitioner's
2 positions here and those the Petitioner took in Europe. He admits them, on
3 the right. The entire basis for his saying that there's contradiction was
4 reviewing the European claims, not any of the statements that I just showed
5 to Your Honors.

6 We're now on Slide 55. Mr. Brown testified that he believes it's
7 acceptable to take contradictory positions. Well, that's not permissible here.
8 That's a problem because Petitioner has to show that it can meet its burden
9 by substantial evidence. And the director has made clear that self-
10 contradictory testimony does not meet that burden.

11 Petitioner has taken exactly the opposite positions here and in
12 Europe. Petitioner here has taken positions that are opposite to its own
13 expert, as admitted at the depositions. And that's particularly significant
14 here because there is no express disclosure of flow out anywhere in these
15 references.

16 Before I turn to Claim 11, I think it's important to have the full
17 picture because we're not talking just about having whether there's flow
18 -- control of flow out in the abstract. We're talking about whether there is a
19 predetermined cycle to control flow out. So I'd like to go back now to Slide
20 23, please. And I want to address the predetermined cycle.

21 There's simply no mapping in the petition to a predetermined cycle
22 to control fluid flow in and out. The petition relies on general aspiration in
23 Yang and Ofek plus a control-based system, control based on sensor
24 feedback in Mullins. That's a variable cycle, not a predetermined one. So to
25 be clear, focusing on the claim language, we need a predetermined cycle to
26 control fluid flow in and out. It's not sufficient to have just one or the other.

1 You have to have a predetermined cycle that accomplishes that result.

2 JUDGE KINDER: This is Judge Kinder. A question about
3 Mullins. And I don't know if it was addressed like this by Petitioner, but
4 like a time zero before the sensors actually start providing feedback, what
5 would Mullins be operating under? Would that be a predetermined
6 operating state?

7 MR. SANDERS: No. At time zero, it would be operating in
8 vacuum. Because the way Mullins works is Mullins is operating in vacuum
9 until a clot starts to cork the ends of the catheter. And then that's going to
10 cause the pressure to drop within the catheter because it's -- you're now
11 -- you closed it, so it's sucking down, the pressure goes down. And when
12 Mullins detects that that reaches the lower limit, then Mullins starts to -- it
13 switches the pump to go positive until it hits the higher limit. So at time
14 zero, before you've encountered a clot, it's just remaining in vacuum. And if
15 the clot is, say, small enough that it never corks, then it would just be
16 aspirated. It would be sucked in.

17 JUDGE KINDER: Thank you.

18 MR. SANDERS: And I would mention, I want to be clear that
19 we're not saying you can't use a sensor for anything anywhere. The way
20 these systems actually work is you want to sense somehow that you're near
21 the clot with the RapidPulse system to perform the predetermined cycle.
22 With Mullins, you're actually sensing the pressure change to know that
23 you're clunking out the cork (PHONETIC), because otherwise these systems
24 are in vacuum just trying to suck out the clot.

25 So I'm on Slide 26 --

26 JUDGE WISZ: Going back to Mullins for a minute. I believe you

1 said there's no disclosure in Mullins of any flow out. So what is your
2 response to where Petitioner was pointing to the disclosure regarding
3 expelling part of a clot? Is your position there, that's not flow out?

4 MR. SANDERS: Yes, Your Honor. That is our position. And
5 quite frankly, Your Honor, that's the same position that Petitioners take in
6 Europe saying that it prevents flow out. And their expert admitted that that's
7 how one would design a system based on Mullins.

8 So what Mullins is disclosing is that you can take a clot that's been
9 sucked in to a certain extent into the catheter, and you can push part of that
10 out of the catheter. But Mullins is not saying that you had that pushed
11 completely out of the catheter, where it's separated from the catheter and
12 you've had flow out. Mullins is talking about jostling that clot within the
13 catheter to try to break it up, as opposed to doing something that is, in a
14 sense, more extreme of actually pushing it out of the catheter and having
15 flow out. There's no disclosure of that.

16 And I note that Petitioner points to the figures and labels it distal
17 flow. Those are just Petitioner's labels. There's no text in Mullins that says
18 there's distal flow. And I think this Board well knows the limitations of
19 reading things in from figures -- and I can give cites on that. See here
20 -- yeah, so the Hockerson-Halberstadt case, that's 222 F.3d 951, makes clear
21 that it's well established that patent drawings do not define the precise
22 proportions and may not be relied on to show particular sizes, which is
23 effectively what Petitioner is doing in trying to find a little space between
24 the clot and the catheter.

25 And then the Teashot v. Green Mountain Coffee Roasters case,
26 that's 595 F. Appendix 983. That is an example of a case where the Federal

1 Circuit said, all right, the figure's ambiguous, you're asking us to read a
2 certain feature into it, we're not going to do that. Well, there's no disclosure
3 of that anywhere in the patent itself. And that's -- same is true here in
4 Mullins.

5 In addition, we have the expert testimony. And the expert
6 testimony is consistent as well as the Petitioner's admissions in Europe are
7 consistent with the fact that you simply do not have flow out, out.

8 JUDGE COTTA: Explain to me just to make sure I understand
9 this. At column 27, line 18, of Mullins it mentioned the direction of fluid
10 displacement of the pump is now reversed. Can you explain to me what's
11 going on there and why that made the claim (INDISCERNIBLE)?

12 MR. SANDERS: Yeah. Happy to do so, Your Honor. So you can
13 reverse the direction of fluid flow but -- and have start to push fluid into the
14 catheter. But the catheter has a length, and the catheter has previously been
15 in suction. So you can reduce the amount of suction that's applied in the
16 catheter by introducing fluid. You could even potentially go to a positive
17 pressure if you're coked because you've got a blockage at the end of the
18 catheter, without having flow out.

19 And Your Honor may remember the Grey reference from the
20 earlier IPRs where Grey was such a reference that described what I just
21 described where you have non-zero suction force at all times, but Grey
22 would moderate that suction force by introducing fluid, introducing positive
23 pressure. So it was -- the art was consistent that you would potentially vary
24 the vacuum pressure and you can even go, as I said, somewhat positive if
25 you're coked without actually having the -- unless you go positive enough
26 to cause the clot to come off.

1 And that's what Mullins is describing. Introduction of fluid into
2 the catheter by going positive in Mullins does not equate to flow out. You
3 can see this in Yang, too. Yang discloses opening a vent while keeping a
4 vacuum on. Yang is a valve system as opposed to the pump system in
5 Mullins. But that's another way of doing the same thing where you maintain
6 an overall suction pressure while you alleviate some of that suction by
7 introducing fluid.

8 JUDGE COTTA: Thank you. That was helpful.

9 MR. SANDERS: And I'm happy to address any other questions
10 about flow out in Mullins. I'm turning now to another failing of Mullins,
11 which is not a failing of Mullins itself. It's just a very different approach
12 than the claims. Mullins uses a sensor-based approach. That's not a
13 predetermined cycle.

14 And the issue here is we're not reading predetermined out of the
15 claims, far from it. We're just giving the term meaning. What is a cycle?
16 Petitioner admits it's a complete sequence of repeating events. A cycle is
17 opening and closing the valve in a sequence, doing that repeatedly.

18 What makes a cycle predetermined? It's at the timing for opening
19 the vent valve, the timing for when the vacuum valve is open, the timing
20 when you may have those valves closed. That's fixed. As opposed to being
21 variable and using a sensor to adjust the amount of time that you open the
22 valve or when you close the valve. Those types of adjustments make the
23 cycle variable, not predetermined.

24 And I'm turning now to Slide 28.

25 JUDGE WISZ: What about Petitioner's argument that it's just the
26 order of the opening and closing of the valves and not necessarily the timing

1 that could make that predetermined?

2 MR. SANDERS: Understood, Your Honor. And that's wrong
3 because that's what a cycle is. If you change the order, you just have a
4 different cycle. You don't have the same cycle. So if you're going to have a
5 cycle, claims say cycle, you're opening and closing the valves in a sequence.
6 The difference between a predetermined cycle and a variable one, is that a
7 predetermined cycle, the timing of that sequence is fixed. In a variable one,
8 the time in which you're in particular states of that cycle can be different.

9 And in the specification -- this is Slide 28 -- it refers to a fixed
10 cycle. Your Honors will see a number of tables, including Table 1 here.
11 This shows that the timing is fixed. This is the cam angles. These are cam
12 control of the valves and it's a particular number of degrees. So as this turns
13 through, this fixes the timing of the cycle.

14 And to be clear, we're not running away from the disclosure of
15 sensor in the patent. As I said, you can have a sensor. It's simply not
16 controlling the timing of the cycle.

17 So let me go through what a sensor is used for in the clot; it's used
18 for other things. At column 32, line 55, to column 33, line 7, it's used to
19 determine when it's time to engage the predetermined cycle when you've
20 encountered the clot. At 40:66 to 41:5, it's used to detect the presence of
21 blood when you're performing the method. And at 49:9 to 29, the sensors
22 are used there to show how the pressure changes when performing the
23 claimed method. And that's graphed in Figures 50 and 51.

24 They're not being used to control performance of the claim
25 method. They're being used to show what's happening in the catheter when
26 you do perform a predetermined cycle. And my brother's refer to using

1 sensors to determine the time it will take. The time it will take can be
2 calculated. That was what was read from the specification. Yes, you can
3 use a sensor to tune the predetermined cycle, in other words, to determine
4 what your timing is going to be. But the cycle is predetermined because that
5 timing is fixed before you ever perform that cycle.

6 Turning now to Slide 29. Our point about the prosecution history
7 is that the examiner applied the meaning of predetermined according to its
8 plain, ordinary meaning, exactly as we have proposed here. This shows the
9 examiner understood its plain and ordinary meaning, too, because he
10 distinguished a predetermined cycle from a reference that disclosed
11 changing the cycle based on feedback from sensors. Just like Mullins,
12 changing the cycle based on predetermined -- excuse me, changing the cycle
13 based on feedback from sensors is not a predetermined cycle. It's a variable.

14 And this is Slide 30 now. The plain and ordinary meaning of
15 predetermined really shouldn't be in dispute here. It's been addressed many
16 times by the Federal Circuit. It's a common claim term. The plain and
17 ordinary meaning of predetermined is to determine beforehand. If you are
18 varying something after you've started performing the process, it's not
19 predetermined. Predetermined means that it's fixed prior to the operation.

20 Sure, you can use a sensor to figure out what your predetermined
21 timing is going to be. But in a predetermined cycle, you are not varying that
22 time. Otherwise, it's not a predetermined cycle anymore.

23 And of course -- this is Slide 31 -- the Federal Circuit tells us that
24 it's highly disfavored to make claim terms superfluous. Well that's what
25 Petitioner has done here with respect to predetermined. The order of
26 opening vents, closing it, opening vacuum -- that's just part of the cycle

1 itself. That's what a cycle is; it's repeating the same steps. What makes it
2 predetermined is that the timing is fixed as opposed to that.

3 And there's no question that in the petition, what Petitioner relied
4 on -- this is Slide 32 -- was Mullins' sensor feedback-based approach.
5 Petitioner repeatedly referred to it. And as shown on Slide 33, the citation in
6 the petition to the expert testimony was also expert testimony that relied on
7 using Mullins' pressure sensor for control because that's how Mullins
8 discloses performing control, using sensor-based feedback.

9 The same thing with respect to Ofek/Mullins -- this is Slide 34
10 -- relied on Mullins' sensor for performing the control and the same thing in
11 the Petitioner's expert declaration. Now, Petitioner admitted during the
12 earlier argument that it's only in reply the Petitioner has argued that you
13 don't need to use Mullins' sensor.

14 Well of course that's a new argument in reply which raises its own
15 procedural problem. There's also no explanation put forward as to how you
16 actually perform this control if you didn't have the sensors. It's conclusory.
17 It's a single sentence in rebuttal, shown here on Slide 35.

18 And it's similarly conclusory in the expert's declaration. There's
19 just no explanation anywhere -- this is Slide 36 -- in the reply declaration of
20 how you're going to accomplish control of flow out, which presents a
21 significant safety issue of potentially pushing that clot further into the
22 vasculature if you don't know what's happening because you don't have a
23 sensor.

24 Turning to Slide 37, Petitioners try to say that Mullins discloses
25 control without using sensor feedback. That's not true. The first thing that
26 Petitioner points to is this shake signal. But Mullins itself is clear. It's shake

1 signal, cycling between two pressure limits. How would you know whether
2 you've hit a pressure limit? The only way to know that is to sense the
3 pressure to know whether you've hit the limit. It's the same sensor feedback-
4 based process described throughout Mullins.

5 Turning to Slide 38, that's exactly what our expert explained, based
6 on the clear text and Mullins. And turning to Slide 39, Petitioner has
7 pointed to ratios of infused aspirate cycles that are disclosed in Mullins. The
8 ratios that are disclosed are outer limits. The ratio of the fused aspirate cycle
9 may be between one value and another value. Those are the outer limits.
10 Those represent the maximum time durations for the infused aspirate cycles,
11 not that the cycle follows some fixed ratio. Mullins never says that.

12 And even in Petitioner's reply, Petitioner is still relying on the
13 cycling between pressure limits. This is page 16 of the reply that we have
14 here, right after they're arguing about propagated in a predetermined pattern,
15 the gray text, say Mullins discloses pulse cycling between two pressure
16 limits. True, those are sense pressures to determine whether you've hit the
17 limits. That's a variable cycle, not a predetermined one. So I now --

18 JUDGE COTTA: Counsel, can you -- if I could interrupt for a
19 second, can you address how sensing a pressure limit is different from the
20 sensing that's described in the challenged patent, '402 Patent?

21 MR. SANDERS: Certainly, Your Honor. Sensing a pressure limit
22 is done in Mullins as part of the cycle to determine when you want to have
23 the vent open, when you want to be positive on the pump versus negative.
24 When you hit the lower limit and hit the higher limit, those -- that's what
25 determines the reversal. Its use is part of the cycle.

26 The distinction in the '402 Patent, sensors are disclosed not for use

1 during the cycle -- for other purposes, for determining when you're going to
2 engage the predetermined cycle, for determining what the timing will be for
3 your predetermined cycle, so you tune in advance to decide on the timing
4 and then you know that timing when the predetermined cycle is used in
5 operation in a patient. And it's disclosed for observing what the pressures
6 are in the catheter when you're performing the predetermined cycle so that
7 that information can be provided as illustrative in the patent in Figures 50
8 and 51.

9 JUDGE COTTA: I guess what I'm struggling with is how is
10 observing what the pressures are when you're performing the operation as
11 you just stated, how is that different from sensing a pressure limit in
12 Mullins?

13 MR. SANDERS: The key difference is there's no adjustment
14 being made to the cycle based on that sensed pressure. In other words, in
15 Mullins, you're sensing the pressure when it hits the limit, you reverse the
16 pump. You're actually making a change.

17 In the '402 Patent, you're performing a predetermined cycle. The
18 timing is fixed and you're just looking to see what the pressures are at
19 different points in the catheter. It shows it at the distal point and at the
20 proximal point. So that can be presented graphically in the patent to explain
21 what's going on with the within the catheter. There's no adjustment to the
22 cycle that's being performed.

23 JUDGE COTTA: Okay. Thank you.

24 MR. SANDERS: And I would submit, just to follow up on Your
25 Honor's question, there is no disclosure of varying the cycle in the '402
26 Patent based on sensor feedback. Let me be clear. But even if there were,

1 it's perfectly fine to have unclaimed embodiments.

2 Indeed, what we have here in this case is the preventing forward
3 flow embodiments are the ones that are not claimed. They were claimed in
4 the earlier IPRs. So it wouldn't change the claim language. The claim
5 language is still predetermined cycle. That doesn't change whether there is
6 an embodiment that doesn't meet that in disclosing the specification. To be
7 clear, there is none. It just wouldn't change the result if there were.

8 I'd like to turn now to Slide 56 and address Claim 11 specifically.
9 Again, Claim 11 is performing the method of Claim 1, where you actually
10 have fluid flow in and out and performing removal of a clot. So page 58
11 -- oh, Slide 58 outlines the history here. Petitioner relied on Mullins' sensor.
12 That's not a predetermined cycle.

13 There was no argument about routine optimization in the petition.
14 In reply, Petitioner shifts to a routine optimization theory. But there's been
15 no explanation, no showing, that this would have been -- it would have been
16 obvious to control fluid flow out without knowing what the pressures were,
17 without sensor-based feedback.

18 Slide 59, just showing explicitly that in the petition, Petitioner
19 relied on Mullins' sensor for a reasonable expectation of success. And
20 Petitioner is now changing its argument. Of course, that's not permitted in
21 reply. That's Slide 60. And, you know, even if we look at on the merits,
22 what is Petitioner changing it to? Slide 61, Petitioner is now arguing that
23 you would -- machine optimization, citing Grey.

24 Well, Grey is the very reference I mentioned earlier that discloses
25 always having a non-zero suction force, as was found in the earlier IPRs. So
26 if you optimize based on Grey, you don't have any flow out because you

1 always have a suction force. That's not routine optimization to arrive at
2 what is claimed. And that's consistent with what Petitioner's physician
3 expert explained earlier that you would want to avoid flow out to keep the
4 pressure in the catheter below blood pressure, citing all of the references at
5 issue here and Grey, which Petitioner raised in reply to justify the routine
6 optimization.

7 And to Your Honor's question earlier about the clot variability
8 -- Slide 63 -- this is a huge issue because clots can be very hard and dense or
9 very soft and easily broken up. This is well-known in the literature; it's
10 shown in Figure 5. And in that paper, it states that this was one of the major
11 challenges. One of the most important obstacles is the fact that clots tend to
12 differ in consistency and removability.

13 I realize, Your Honor, I'm moving into my rebuttal time. I'll
14 continue in using my rebuttal time.

15 Petitioner's arguments are classic hindsight. This is what
16 Petitioner's expert says in reply. It's hand waving. There's no reasoned
17 explanation as to how you would control fluid flow in and out with a
18 predetermined cycle. And of course, 65, the Federal Circuit has told us that
19 that is the sort of conclusory and unsupported testimony that's
20 impermissible.

21 I will skip the Ofek specific issue because Ofek is a patency device
22 since you don't need to reach it because these other arguments that I
23 presented here, they apply across all of the art. I want to turn briefly to the
24 exit flow claims, Slide 69. So we discussed earlier, Slide 70, these claims
25 require specific amounts of exit flow with lower limits. Slide 71 has the rest
26 of the claims.

1 Slide 72, just to set the baseline here, there's no disclosure of any
2 specific amount of flow out because there's no disclosure of flow out in any
3 of Petitioner's references. And as we've seen, Petitioner's admitted that in
4 Europe, Petitioner's admitted that -- expert's admitted that in his depositions
5 in this IPR, and Petitioner's physician expert has admitted that in his
6 declaration and at his deposition.

7 Now Petitioner's arguments in reply fail to meet the obviousness
8 standard. Petitioner argues what a person of skill in the art could understand
9 or what may occur. Of course, that's not the standard. That's not what a
10 person of ordinary skill in the art would understand.

11 And the Federal Circuit has told us even when there's a possible
12 arrangement that doesn't meet the legal standard here. Here, we don't even
13 have a possible arrangement disclosed in the prior art. We simply don't have
14 the disclosure of flow out.

15 And Petitioner's arguments, simply new arguments in the reply are
16 contrary to specification. Slide 75, Petitioner says include the thrombus as
17 part of the fluid column. You can't do that. Specification expressly
18 distinguishes the two. It's distinguished in the claims, in Claim 10. It's
19 distinguished in the specification. The fluid column is something different
20 than the thrombus. Taking the last quote, for example, for the thrombus to
21 accelerate, both it and the fluid column within the catheter system must
22 attain a velocity.

23 So Petitioner says the claimed exit flow values, the claim ranges,
24 are obvious by routine optimization. This is Slide 76. But this is exactly the
25 sort of hindsight reasoning that has been rejected. You can't simply say, oh,
26 those specific ranges that you claim, oh, they would have been obvious. All

1 the evidence that Petitioner puts forward is its expert's calculations, and
2 those are woefully deficient. They don't account for many critical aspects of
3 an aspiration thrombectomy system.

4 First, the whole point of what we've been discussing here is how
5 you deal with a clot clogging the end of the catheter. You don't have free
6 flow of blood when that happens; it's clogged. Petitioner assumes that you
7 have free flow of blood. That's exactly wrong for what we're talking about
8 in this proceeding.

9 Petitioner assumes that you have the same pressure for aspiration
10 and for infusion. Essentially, you have a very low vacuum. If you're going
11 to have positive pressure, you're going to be very careful that you don't want
12 to shoot the clot into the vasculature.

13 You don't have instantaneous reversible flow in the catheter.
14 Petitioner's expert essentially treats the catheter as if it's a lead pipe of no
15 length. It has a length. It takes time for fluid to flow. You can introduce
16 fluid into a catheter from the proximal end, and that fluid may never come
17 out the distal end because the catheter is in vacuum and you're relieving the
18 vacuum. That has a length and the length matters. It's also not a lead pipe.
19 The catheter is compliant.

20 And when you suck down on it because it's clogged and the
21 vacuum is engaged, that sucks down the catheter. That leads to a higher
22 negative pressure. That's the whole way Mullins works, is detecting that
23 negative lower pressure limit is reached. Petitioner's expert ignores that.
24 Petitioner's expert also ignores the water hammer effect that they rely on
25 elsewhere.

26 And finally, just to touch very briefly on objective indicia, I just

1 wanted to note here, the evidence that we're relying on is not ordinance. It's
2 Petitioner's evidence. These are the videos that Petitioner submitted to the
3 European Patent Office to tell them what the state of the art was. And right
4 in their own videos, it says that variable or cyclical suction wasn't unmet.

5 Thank you, Your Honors. I'll reserve the rest of my time for
6 rebuttal.

7 MR. WILLIAMS: Let me just begin by pointing out I think many
8 of the arguments Patent Owner made are based on ignoring an important
9 distinction between what forward flow is and what flow out or exit flow is.
10 So exit flow is the thing that's claimed here. Forward flow is the bad thing
11 that pushes the clot too far away where you're no longer able to engage it.

12 Pointing to what happened in Europe and trying to find some
13 inconsistency there is just completely pointless because the claims there are
14 all about -- and all the testimony is about forward flow, and everyone agrees
15 you don't want forward flow. Forward flow is too much exit flow. So all
16 that testimony, there's nothing inconsistent about it from what we're
17 presenting here; we're not hiding anything.

18 Mr. Brown's testimony was not inconsistent. He explains this. He
19 explains that exact point I just made as to why it's not inconsistent and
20 Patent Owner just ignores it. Almost all of their arguments are based on that
21 improper distinction. They're just trying to conflate those two things in a
22 way that I think is clearly false and gives a complete misimpression of
23 what's actually happening.

24 Let me begin -- I'll just take through the issues that my counterpart
25 raised, starting with claim construction. So there's nothing superfluous
26 about our construction. Control is the thing this claim requires. And we are

1 not saying you don't have to control it. We're not saying you don't have to
2 control exit flow. We're saying you can control exit flow by not allowing it,
3 just like a flood control device controls a flood by not allowing it. It's
4 exactly the same point, and it's not even a very far-removed point that
5 analogy I just drew, because both of them obviously have to do with
6 hydrology laws. So again, nothing superfluous about our construction.

7 And, you know, Patent Owner's argument that somehow we're
8 reading out controlling, it's just not true. You could control forward flow
9 -- sorry, you control exit flow by having none of it and still satisfy the
10 claims.

11 Okay. Again, as explained, regardless, all of the grounds in this
12 case actually do have forward flow. Let me cover that first, and then I'll
13 come back to the patent point. Okay. Yeah. This is Slide 40 that I'm
14 looking at. Judge Cotta, I don't know, he can't see the slides in the room,
15 right, Your Honor? They can show him?

16 JUDGE WISZ: I don't think he can see them in the room.

17 JUDGE COTTA: I actually can see the slides.

18 MR. WILLIAMS: Oh, great.

19 JUDGE WISZ: Oh, OK.

20 MR. WILLIAMS: All right. Perfect. So Slide 40 is the one that
21 has the summary from Mullins in terms of his discussion of exit flow. This
22 discussion that we have reproduced on Slide 40 from column 27 is obviously
23 highly, you know, important to this issue of whether there is forward flow
24 because Mullins is just not - I'm not just relying on the dimensions of the
25 drawings. I'm relying on the exact text of Mullins, which explains exactly
26 what's going on in these figures. So as he said, okay, so you're going to

1 reverse the direction of fluid displacement. Now, recall, Mullins doesn't
2 exactly have two valves. Mullins has a pump that's reversible so it can be a
3 suction pump, or it can be a pressure pump. So it can suck and it can blow.
4 Either one, you pick which way you want to go.

5 And what Mullins says when you do that is when you pressurize it,
6 you increase the pressure into the catheter. The load which was applied to
7 ingest the clot will be reduced. So you got a vacuum that's reduced that
8 unloads the clot. Then the pressure -- well, actually, he says -- allows some
9 of -- or all of the clot to be pushed distally towards the catheter tip, 47(h),
10 okay?

11 So when you look at the figures, you see what that means. In the
12 state where you've got a catheter that's clogged with this thrombotic
13 material, some of it is leaving the endpoint of that catheter. So there was
14 -- some of that fluid was inside the catheter and when you start pushing it,
15 now some of that fluid is outside the catheter. That is all this claim requires,
16 even under Patent Owner's construction, right? The figures about that are
17 unambiguous, and the text is unambiguous as well.

18 During this unloading, the clot is macerated, becomes free. The
19 pressure is further increased until a high limit is reached. And in one
20 embodiment, this high limit is defined such that the ingested clot may not be
21 completely expelled from the catheter.

22 Okay. Well, that's the discussion of forward flow that I alluded to
23 earlier, right? That's the bad thing. You want a little bit of fluid to come out
24 but not so much that you're losing contact with the clot. You got to keep it
25 in your sphere of influence there, at the end of the catheter. And that's
26 what's shown in 47(l), as you see there, you know, the clot there has begun

1 to break up. You know, we pushed parts of it outside the catheter. We still
2 retained a little bit of it in the catheter so that now we can suck it back in and
3 further macerate it. That's how Mullins works.

4 So even under Patent Owner's construction, Mullins is meeting all
5 of the elements. There's nothing ambiguous about this text. We're not
6 reading into the figures. That's exactly what they show. It's exactly what the
7 text says.

8 Okay. I don't really -- I was going to cover Mullins. I don't think I
9 have to. I mean I think for purposes of understanding, you know, our
10 combination and how it's teaching the forward flow, Slide 40 is more than
11 sufficient to get you there.

12 In terms of the European patent proceeding, I think I've already
13 explained that. That has to do with a completely different claim element
14 involving forward flow. And yeah, it's absolutely true, no one suggests that
15 Mullins is telling you to blow that clot so far out that you lose contact with
16 it. That would be ridiculous. Mullins is saying you're going to have a little
17 bit of exit flow, you're going to need that to macerate the clot, and then
18 you're going to suck it back in -- so a little bit but not so much that you lose
19 contact with it.

20 I guess this would be a good point to maybe address one of the last
21 things that my counterpart raised, which had to do with -- whether the clot is
22 actually fluid. So I think his argument is that what's shown there is
23 somehow not fluid because it's thrombotic fluid material, you know. That is
24 obviously a very different way of talking about clots than a person of
25 ordinary skill in the art would use.

26 So if you look at Slide 33, this is an excerpt from, you know, one

1 of the texts in the field talking about blood clots. What it tells you there is
2 that blood, even when clotting, has a viscosity of -- blood clots obviously
3 have a much different viscosity than blood that's not clotting and certainly
4 much different viscosity than water, which is Newtonian fluid; blood is not.

5 But the point is, everyone understands that even clotting blood is a
6 type of fluid. That's exactly what these patents are all directed to is
7 extracting, pulling in blood clots and completely aspirating them through the
8 lumen. So it makes no sense if that wasn't considered -- if the blood clot
9 itself wasn't considered fluid. I mean, these clots are not rocks. I mean,
10 they're -- if anything, they're maybe gelatinous, but they're still fluid.

11 Moreover, as Mullins -- as you see here on Slide 40, again from
12 Mullins, even if we were to exclude thrombotic material, which is kind of
13 the crosshatched thing shown in the figure, there's still fluid being pushed in
14 and out. At least as you get into that Figure 47(l) (INDISCERNIBLE)
15 where the clot has started to break up. Now you've got pieces of fluid and
16 clot under Patent Owner's sort of arbitrary dichotomy that they've sort of
17 proposed on you here.

18 Even if you were to accept that, both pieces are still in lumen, both
19 are still being pushed out and pulled back in during this process shown from,
20 you know, 47(k) to 47(n) there. The clot is being broken up to where you
21 now got interspersed fluid that's coming in and out. So even under that
22 reading, they're just wrong that Mullins doesn't teach this.

23 Okay. Let me go to the predetermined cycle point in respect to the
24 sensor. So this I did want to go back to just look at the patent for a second.
25 So I think either my colleague misspoke about what the patent teaches, or
26 maybe he doesn't understand what this patent is actually teaching.

1 So I read to you earlier the section that's in column 44, starting
2 around line 9, that's on the screen here. I don't know if you'll be able to read
3 it. But it talks about the proximal and distal pressure measurement devices,
4 690. This is at line 19 on the right-side column there. This is column 44 on
5 the right. I know that's cut off. So it talks about the pressure transducer. It
6 tells you who it's manufactured by, then it tells you how to use it. And when
7 you get to line 28 and 29, it says the information -- this is the information
8 from that transducer -- can be used by the controller to time the valves
9 properly to stop the pressure pulse.

10 Okay. Now, what I heard counsel for Patent Owner say is, oh, this
11 is all about setting up the timing before you do the process. This isn't a
12 dynamic process where you change the timing as you're going, but in fact, it
13 absolutely is. So if you go to, for instance, column 48 of the patent, which
14 -- if I can get my cursor on the screen and show you. Okay, here we go.
15 We'll just start here. This is around -- this is in column 48. It's around line
16 -- the paragraph starts around line 19. But the point of this paragraph is to
17 set up this idea of tuning.

18 This is what the Patent Owner calls tuning the valving sequence.
19 Like in line 35, you see that, right? The controller and the valving sequence
20 be tuned as a system so it's important that the system be tuned. And then if
21 you go to the very next column, 49, and continuing this discussion about
22 tuning the system, you see around line 7, tuning can happen statically or
23 dynamically. Okay. So a statically tuned system, maybe you're going to
24 tune all the valid timings before you do anything. Set that up, get a program
25 in your timings, and then you never take any other action.

26 Okay. Fine. Maybe that's what he's alluding to. But that's not the

1 only thing you can do. You can also do it dynamically. And then if you get
2 down to line 15, you'll see where -- in line 49, it says a dynamically tuned
3 system is in comparison tuned during operation. So you're again changing
4 the valve timings during operation based on these pressure sensors. That's
5 exactly what Mullins is doing.

6 So unless they're somehow saying that this embodiment is outside
7 the scope of the claim somehow, I don't see how they're drawing any
8 distinction between what Mullins and the spec says. It's exactly the same
9 thing. This idea that they're talking about, Mullins had it exactly way
10 earlier.

11 Okay. We'll --

12 JUDGE COTTA: Counsel, if I can interrupt very quickly. Is there
13 anything that ties the disclosures you were just discussing about -- in the
14 '402 Patent, about using sensors to a predetermined cycle?

15 MR. WILLIAMS: Well, only insofar as this tuning that we just
16 talked about is talking about the valve timings. So in terms of what the
17 predetermined cycle is, no, there's nothing in the spec that is going to give
18 you any more clarity than that. As you see, if you go down a bit further in
19 49, the sequence is discussed. And so I'm assuming -- this should be on the
20 screen, but it's column 49 -- sorry, line 30 to line 35. There's this valve
21 sequence that's being discussed, which is one is open, the other is closed,
22 you know. You move from these various states of one's open, then the
23 other's closed.

24 I mean, more or less, the cycle is you want a vacuum state, you
25 want a vent state, and then you're going to have transition states in between.
26 That's the cycle, and that's what's being discussed here. That's also what's in

1 our prior art.

2 There's no notion that predetermined cycle can't be adjusted, right?
3 That the timings of the valves can't be adjusted any more than a life cycle of
4 the butterfly is not the same for every butterfly. I mean, we know what the
5 stages are, but it doesn't mean everyone is going to be born at the same time,
6 is going to be in a cocoon for the same amount of time. I mean, those things
7 can vary and still have a predetermined cycle, just like you can have a
8 predetermined cycle for how long one valve is open based on what's going
9 on in the system.

10 The last point that was made had to do with the specific -- these
11 dependent claims that have specific ranges on how much flow out is
12 acceptable, what your limit should be for the amount of flow out. And as we
13 point out and what Mr. Brown did is take a very conservative approach to
14 say, okay, if you did Mullins -- if you did this combination, that patent, the
15 Petitioner is proposing, using what we know about the catheter from Yang or
16 Ofek and applying Mullins' techniques, how much flow out could you
17 conceivably have? And it is a big range. It is within the limits that Patent
18 Owner has claimed.

19 So the point is -- and, you know, Mullins itself specifically teaches
20 you, you should be experimenting, by the way. Mullins teaches you that all
21 these things should be -- the pressure limit should be experimented with by a
22 person of skill in the art to get the real numbers that you would use. So the
23 whole point of Mr. Brown's analysis is just to show there's nothing special
24 about these claim ranges. They are the obvious ranges that a person of skill
25 in the art would have been looking at when conducting a system like this.
26 Because everyone agrees what you want to do is have a little bit of motion

1 on the -- in the distal tip of the catheter but not so much that you lose contact
2 with the device.

3 And finally, the point that he was assuming that this was a lead
4 pipe of no length is just false. Mr. Brown used real flow data conducted
5 empirically in the literature on catheters. It was with water, not blood. And
6 so he had to make adjustments to the numbers to account for that difference.
7 But it wasn't some theoretical catheter that had no size. I don't think I had
8 anything else unless the Board had any questions about Patent Owner's
9 presentation that you wanted me to address.

10 JUDGE WISZ: I have one question going back to claim
11 construction.

12 MR. WILLIAMS: Mm-hm.

13 JUDGE WISZ: So Claim 1 uses the term fluid flow in and out
14 from the distal end and then some of the dependent claims, for example,
15 Claim 3 talks about limited to a positive amount of exit flow. So whereas
16 Claim 1 is talking about fluid flow, Claim 3 is talking about exit flow. Do
17 you see a distinction there in interpreting the claims, construing the claims
18 because those different terms are used?

19 MR. WILLIAMS: There is certainly potential ambiguity insofar as
20 the Patent Owner wasn't explicit about what that distinction was, if any.
21 We've interpreted exit flow to mean flow out, which seems consistent with
22 the kind of language of Claim 3, when Claim 3 talks about a positive limit
23 on exit flow before the fluid is drawn back into the catheter lumen. That's
24 what we're assuming.

25 You could read these claims the other way and say flow, you
26 know, that exit flow is somehow flow passing into the catheter from the

1 vessel. It is potentially ambiguous, but we've read exit flow there to mean
2 flow out of the catheter, you know, back into the vessel. So approximate
3 flow -- you know, distal flow, the other way around, sorry.

4 JUDGE WISZ: Okay.

5 MR. WILLIAMS: Thank you, Your Honor.

6 JUDGE WISZ: Thank you.

7 MR. SANDERS: Go to Slide 70, please. So I heard in rebuttal
8 that the distinction that Petitioner was drawing with the European
9 proceedings is that they involved claims that recite preventing forward flow,
10 just like the earlier IPRs that were at issue here. This Board previously
11 construed forward flow as 6 microliters or less. If that's Petitioner's
12 distinction, then Claim 4, there's no question, it's patentable because it
13 requires a lower boundary of 100 milliliters, approximately 100 milliliters of
14 exit flow.

15 And to Your Honor's question about flow out and exit flow, yes,
16 flow out is exit flow. Do we agree? Those have the same meaning.

17 Now I'd like to go to Slide 40 of Petitioner's presentation. This is
18 the slide about Mullins that was raised on rebuttal. And I encourage Your
19 Honors to look very carefully at the passage. It talks about the load being
20 reduced in the catheter so that some or all of the clot will be pushed distally
21 toward the catheter tip. It talks about the clot becoming more free within the
22 catheter. There is no disclosure there of flow out from the distal end of the
23 catheter. It's all about the clot within the catheter being moved within the
24 catheter more towards the distal tip. There's no disclosure of outward flow
25 of fluid.

26 There's no question that those two things are different. We go

1 back to our presentation. As I showed earlier, the specification and the
2 claims -- I'm not talking about the slide here, but the specification and the
3 claims expressly distinguish the thrombus from the fluid flow that's
4 distinguished in Claim 10. It's distinguished in the specification. It's also
5 even distinguished in -- if we look at -- can we have, please, Claim 11?
6 That's on -- we'll go to Slide 12. Slide 12. Yes. It recites the
7 thromboembolic material separate from the flow of fluid that goes back -- if
8 we go back to Slide 11, go back to Slide 11 -- that's recited in Claim 1.

9 The thrombus is not the fluid flow; it's something distinct. It's
10 distinct in the claims. It's distinct in specification. And if we could go
11 forward, please, to Slide 51. Again, this isn't just Patent Owner saying what
12 Mullins discloses. It's Petitioner, too. Petitioner said to the European Patent
13 Office, Mullins explicitly teaches changing a level of vacuum at the distal
14 end of the catheter to prevent clogging and preventing forward flow to
15 reduce the risk of distal embolization.

16 According to the claim construction that Petitioner prevailed on
17 with this Board in the earlier IPRs, that's preventing 6 microliters of forward
18 flow. Well, as I said previously, submit that what they're really saying here
19 is any forward flow at all but at least Claim 4 is patentable.

20 And I would like to address the portions of the specification to
21 which Petitioner pointed on rebuttal in addressing the sensor. Petitioner
22 pointed to column 44 first of the paragraph that begins at line 19. And what
23 is stated there in that paragraph is that the time it will take for the wave to
24 travel to the distal tip can be calculated. This is at lines 26 to 27. This
25 information can be used by the controller to time the valves properly to stop
26 the pressure pulse. This is talking about the tuning operation.

1 As I mentioned before, you can use the sensor to determine what
2 your predetermined timing will be. And Petitioner raised a new argument
3 here, in column 49, about static versus dynamic tuning. To the extent
4 Petitioner is saying that dynamic tuning means that you use the sensor to
5 perform adjustments to the cycle timing during operation of the cycle, that is
6 indeed an unclaimed embodiment. Because what is claimed here is a
7 predetermined cycle, just as we have in this IPR, claims that are directed to a
8 different set of embodiments than the earlier IPRs. The earlier IPRs were
9 focused on the embodiments that prevented flow out.

10 The claims here are focused on embodiments that require -- and
11 indeed independent claims even require specific amounts of flow out with
12 lower limits. And there's none described in any of the references, nor has
13 Petitioner put forward a reason why you would have those claim ranges.

14 I'm happy to address any other questions that Your Honors may
15 have.

16 JUDGE COTTA: I do have one quick question if you don't mind.
17 Could you explain for me what's going on in Mullins Figure 47(l) and
18 specifically whether there's any fluid flow out?

19 MR. SANDERS: Yes. We bring up Exhibit 1008, Mullins, and go
20 to 47(l) so we can all have that in front of us. Next page -- there we go, yes.
21 So in figure 47(l), this is in conjunction with the explanation in the text of
22 Mullins that the clot is being pushed more distally within the catheter.
23 There's no disclosure that there's flow out here. What Petitioner is reading in
24 from this figure is that because there's a little gap between the big clump of
25 clot in the catheter, that there must be some flow out. That's not described in
26 the text, and that's contrary to what they told the European Patent Office.

1 But also, if you look at the figure, there's not just a big clump of
2 clot. There's other clumps of clot that are further within the catheter. Those
3 may still be blocking the flow. And that's the point of Mullins saying that
4 you're pushing the clot more distally toward the end of the catheter, not that
5 you're pushing it all the way out of the catheter and having flow out.

6 JUDGE COTTA: Thank you.

7 MR. SANDERS: Thank you very much --

8 JUDGE WISZ: Thank you.

9 MR. SANDERS: -- for your time, Your Honor.

10 JUDGE WISZ: Thank you very much for your helpful
11 presentations today. This matter is now submitted to the panel for
12 determination and preparation of the final written decision. We're
13 adjourned.

14 (Whereupon, the above-entitled matter went off the record at 1:54
15 p.m.)

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PETITIONER:

Eliot Williams
Jeremy Taylor
Mark Oda
BAKER BOTTS L.L.P.
eliot.williams@bakerbotts.com
jeremy.taylor@bakerbotts.com
mark.oda@bakerbotts.com

PATENT OWNER:

Charles Sanders
Brent Watson
Raghav Bajaj
LATHAM & WATKINS LLP
charles.sanders@lw.com
thomas.watson@lw.com
raghav.bajaj@lw.com