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1 with some devices. It could be possible to do an
2 intervention and -- and radiation at the same time. I
3 think that's a possibility, certainly. Not with every
4 device.

5 MR. BROWN: Q. Well, am I correct that, when
6 you use the word "treatment," that refers at least to
7 the use of an interventional device to reduce stenosis
8 in an artery?

9 A. Generally, that's what I mean, yes.

10 Q. And when you use the term "post-treatment,"
11 you're referring to the use of a device to prevent or
12 minimize what's called restenosis?

13 A. That's correct, yes.

14 Q. So the purpose of the treatment is to, in
15 effect, open the blockage in the artery, and the purpose
16 of the post-treatment is to try to minimize any
17 subsequent -- a reduction in the diameter of the artery?

18 A. That's correct.

19 Q. Now, in your patent, what role does the amount
20 of radiation released in the treatment area play in
21 achieving the goal of post-treatment?

22 MR. TEIXEIRA: Rob, I would caution you,
23 before you answer, to read the patent.

24 THE WITNESS: Well, do we -- I don't -- we do
25 talk about control at some point in here, but I --

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1 MR. TEIXEIRA: Why don't you take a look at
2 the patent again.

3 THE WITNESS: Well, I have to...

4 MR. TEIXEIRA: Unless --

5 MR. BROWN: Q. You're certainly welcome to
6 refer to the patent, Mr. Hess, but I'm -- I'm asking the
7 question really based on your experience with using
8 devices that include radioactive elements or material.

9 A. Okay. In that context, I think -- I haven't
10 found it back. That's a term that translates from
11 another language. In this setting, one would be
12 concerned about the amount of radiation because you do
13 not want to provide large amounts of radiation that will
14 kill cells, because, unlike soft tissue oncology
15 procedures, you're dealing with a -- a pressure vessel,

16 a very critical pressure vessel, a tubular organ that
17 has pressure within it --

18 Q. You're referring to the artery?

19 A. The artery, and it's pulsating, so it's
20 subject to fatigue, and if you kill enough cells, the
21 artery will rupture, so there's an appreciation that
22 it's somewhat unlike other uses of radiation in nuclear
23 medicine.

24 Q. So are you saying that you have to be
25 concerned about not using too much radiation?

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1 A. Or too little.

2 Q. All right. What happens if you use too little
3 radiation?

4 A. You get restenosis, presumably, and, in fact,
5 you do.

6 Q. So then what -- what is done to -- to get the
7 appropriate amount of radiation to the artery?

8 A. Well, there are numerous ways of doing that,
9 and it -- exposure time is one way, and limiting
10 exposure time is -- can be done in many ways, and it
11 will depend on the particular isotope that you're
12 working with and the energy delivered by that particular
13 isotope.

14 Q. So are there any structures that -- identified
15 in your patent that play a role in ensuring that you get
16 the right amount of radiation to the artery?

17 A. Yes, some of them contemplate shielding as a
18 means of doing that.

19 Q. Can you identify for me what you're referring
20 to?

21 A. I'm going to go by the figures, rather than
22 the text. Figure 5 certainly would provide a means of
23 shielding, to some degree. It depends on the materials
24 you choose as well. Figure 6 as well.

25 Q. Let's back up a second.

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1 In Figure 5, what is the shielding, or how is
2 it identified?

3 A. Well, the shield -- there's a shielding effect
4 by this wire wound member when you withdraw the

5 radioactive source inside of it.

6 Q. You're referring to number 50?

7 A. 50, that's correct.

8 Q. All right. And then what was the next figure
9 you referred to?

10 A. I think Figure 6, if I remember the text, and
11 I can go read it, if you like, but I think that's a
12 window --

13 MR. TEIXEIRA: Rob, rather than guess, just
14 read the text.

15 THE WITNESS: All right. I've got to look at
16 Figure 6.

17 I think that's a window that closes.

18 There's a -- this window can be opened and
19 closed, presumably, by a cover of some sort, and,
20 depending on the materials chosen, would offer a degree
21 of shielding.

22 MR. BROWN: Q. And by "this window," you're
23 referring to what in Figure 6?

24 A. Well, it's -- I think it's 66. I'll take a
25 look. Window 66, yes.

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1 Q. All right. Any other structures in your
2 patent, in the figures, that are used to control the
3 amount of radiation to which the artery is exposed?

4 MR. TEIXEIRA: Rob, I would ask you to read
5 the patent again.

6 THE WITNESS: Uh-huh.

7 MR. TEIXEIRA: And specifically, if I can
8 speed this up, you might want to look at column 3, from
9 line 15.

10 THE WITNESS: Column 3, line 15, Figure 1. I
11 was just looking at that.

12 Yes, I think Figure 1 would, again, depending
13 on the materials you choose, would provide a measure of
14 shielding.

15 MR. BROWN: Q. And how would that happen?

16 A. The -- the dose means is 22, I think, a wound
17 housing 22 within the lesion site...sheath 24.

18 Yeah, so the radioactive dose is contained
19 here --

20 Q. I'm sorry. The what is contained?

21 MR. TEIXEIRA: You need to refer to the
22 numbers, Rob, for the court reporter.

23 THE WITNESS: The radioactive source -- let me
24 find it again.
25 Housing 22 contains a dose means 30. Okay.

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1 So this housing contains a dose means 30, and is
2 retractable within the sheath, which is, I believe, 10.
3 No, that's the whole thing.
4 MR. BROWN: Q. Is the sheath 24?
5 A. Let's find out.
6 Sheath 24, yeah.
7 Q. All right.
8 A. So it's retractable within that sheath, and,
9 again, depending on the choice of materials, a more or
10 less degree of shielding could be provided.
11 Q. So is the radioactive material contained
12 within some structure which is a wire wound housing 22,
13 and then that is retractable within another --
14 A. Wire wound housing --
15 Q. 24.
16 A. A sheath, and I don't know -- wire wound
17 retractable sheath 24. Yeah, so that's a wire wound
18 retractable sheath 24, so it's -- yeah, it's
19 contained -- the source is contained within a housing,
20 and the housing is within the --
21 Q. Sheath?
22 A. Right.
23 Q. So you, in effect, have two layers of
24 insulation in that embodiment?
25 A. No, not really. Not really, because there is

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1 a window -- window in the sheath that holds the -- I
2 thought there was a window.
3 Q. Is that window cut-out 32? Is that what
4 you're referring to?
5 A. What line is that?
6 Q. Line 3, about -- I'm sorry. Column 3, line
7 38, roughly.
8 A. I didn't get that far yet.
9 Window cut-out 32. Window cut-out 32, so
10 there's -- the source is within that sheath, but -- but
11 can be exposed by opening the window of 32, or the

12 artery can be exposed by opening the window 32.
13 Q. All right. So in -- in Figure 1, how does one
14 control for the amount of radiation that's released to
15 the artery?
16 A. Can do it in several ways, or it has several
17 components, let's say. With this window closed, the
18 source is shielded to some degree, but -- depending on
19 the isotope, and the particles coming off that isotope,
20 it may be more or less shielded. If it's withdrawn
21 inside the sheath, it is more shielded, and if it's
22 removed from the artery, there is no more radiation, so
23 there are sort of multiple possibilities of limiting the
24 radiation with a device like this.
25 Q. And then, looking at the -- the version of the

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1 device in Figure 5, how is the amount of radiation
2 released to the artery controlled?
3 A. Again, there's a degree of shielding when you
4 retract it within that sheath, and the time of exposure
5 until you remove the entire device.
6 Q. And then with respect to Figure 6, how does
7 one control for the amount of radiation released to the
8 artery?
9 A. There's a -- a closable window that would
10 provide a degree of shielding, and -- and time of
11 exposure, removal of the device.
12 Q. If we look at claim 1 of the '168 patent, can
13 you describe for me the sequence of steps that are used
14 as part of the claimed method?
15 A. You want me to read it to you, or --
16 Q. No. Let's just walk through it.
17 Am I correct that the first step is reducing
18 the annular stenosed area within an artery?
19 A. That's what's contemplated here, yes.
20 MR. TEIXEIRA: And again, you're asking this
21 from his point of view as a lay person?
22 MR. BROWN: Right, and the identified
23 inventor.
24 MR. TEIXEIRA: That's fine.
25 MR. BROWN: Q. So is that first step what

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8 means.
9 So positioning means can be any means of
10 getting a radioactive source to the lesion.
11 MR. BROWN: Q. Well, that's just -- that's
12 just a recitation of the language out of the claim,
13 isn't it?
14 MR. TEIXEIRA: Object to the form. He's a lay
15 person.
16 MR. BROWN: Well, he can read as well as any
17 of us.
18 MR. TEIXEIRA: That's fine, but he doesn't
19 have to agree to your characterization.
20 THE WITNESS: I just read it.
21 MR. BROWN: Q. Am I correct that what you
22 read is just the same language that appears in the
23 claim?
24 A. And? I don't know what that means.
25 Q. Well, what I want to know is: Where do you

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1 describe any structures that accomplish this -- the
2 purpose of the post-treatment and that are not either a
3 catheter over a guidewire or a device that surrounds a
4 motion wire?
5 A. And my answer is at line 39, column 2, the
6 summary of the invention.
7 Q. Anything else?
8 A. No.
9 Q. And am I correct that --
10 MR. TEIXEIRA: Rob, why don't you read the
11 patent before you answer that.
12 MR. BROWN: Q. Am I correct --
13 A. You mean does it appear elsewhere? I believe
14 it probably does. I think this kind of language -- I
15 haven't memorized this. I never will memorize this, but
16 I think that kind of language exists in the -- in the
17 description as well. If you like, I'll go and try and
18 find it.
19 Q. Well, I'm interested in what other structure
20 you can identify for me in the patent that accomplishes
21 the purpose of the invention.
22 MR. TEIXEIRA: Rob, I would ask you to read
23 the whole patent, then.
24 THE WITNESS: So if we refer to column 4, it's
25 probably starting at line 7, okay, these materials may

1 be incorporated into and delivered in a solid, liquid,
2 or gaseous form, and the delivery of such forms is
3 considered within the scope of the invention, so that's
4 a description of various other forms -- various forms in
5 which the isotope can be found, and that it can be
6 delivered in those forms.

7 MR. BROWN: Q. Does it tell you how --

8 A. And we don't have a drawing -- and we don't
9 have a drawing of a gaseous isotope or a liquid isotope,
10 but it is claimed within the scope of the invention, and
11 the delivery of such forms or the transport of such
12 forms of the isotope would require a positioning means
13 which is operatively connected to them which is
14 appropriate for those forms of the isotope.

15 Q. Well, my question is: What is there in column
16 4, line 10 through 12, that tells you what structure is
17 used to accomplish the purpose of the invention?

18 A. This -- the structure is described as the
19 isotope in any one of those physical forms, and -- and
20 any one of those particular forms of the isotope
21 operatively connected to a positioning means.

22 Q. So what is the structure disclosed at column
23 4, line 10?

24 A. The structure disclosed here is the form in
25 which the isotope may be delivered or the physical form

1 in which the isotope may be delivered to the lesion
2 site.

3 Q. That being solid, liquid, or gas?

4 A. Correct.

5 Q. But does this passage disclose the structure
6 by which those radioactive materials may be delivered?

7 MR. TEIXEIRA: Objection. Asked and answered.

8 THE WITNESS: Not in this paragraph, but that,
9 in combination with the -- the source being operatively
10 connected to a positioning means describes -- I'm not
11 sure of the question I'm answering anymore -- describes
12 other devices, basically.

13 MR. TEIXEIRA: Counsel, whenever it's time for
14 a bathroom break...

15 MR. BROWN: Q. So, again, you're referring
16 back to the language in the claims for the --

17 A. Well, I'm not done yet.

18 Q. All right.

19 A. There may be more in here, but I'm just
20 saying -- all I'm saying is that describes other forms
21 that aren't disclosed in the figures, or could be
22 incorporated in the figures.

23 Q. Well, can you identify any other structure in
24 the patent that accomplishes the purpose of the
25 invention and is not either a catheter over a guidewire

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1 or a device surrounding a motion wire?

2 A. I think I did that.

3 Q. Have you completed your review of the patent?

4 A. No, I think I've done that by saying it could
5 be in these forms, and it has to be operatively
6 connected in any of those forms to a positioning means,
7 any positioning means, any means of operatively
8 connecting it.

9 Q. I'm looking for language in the patent that
10 discloses a structure other than a catheter over a
11 guidewire or a device surrounding a motion wire that
12 accomplishes the purpose of the invention. You've
13 identified for me a passage at column 4, lines 10
14 through 12, and a passage at column 2, roughly lines 37
15 to 41.

16 Are there any other passages in the patent --

17 A. I have to read the rest of it to -- to see,
18 but in my mind, that -- that describes a broad array of
19 methods, mechanisms, of getting an isotope to a lesion
20 site beyond a guidewire or -- or a -- whatever the other
21 term was.

22 Q. All right. And my question, again, is: In
23 addition to those two passages, is there any other
24 passage in the patent --

25 A. I have to -- I have to finish reading the

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1 patent.

2 Q. -- that discloses a structure that
3 accomplishes the purpose of your invention and is not

4 either a catheter over a guidewire or a device
5 surrounding a motion wire?

6 And we can take a break now, if you want to.

7 MR. TEIXEIRA: Why don't you finish. We'll
8 come back, and you can finish reading the patent and
9 answer his question.

10 THE VIDEOGRAPHER: This marks the end of tape
11 number 1 in the deposition of Robert Hess.

12 Going off the record. The time is 10:52.

13 (Whereupon, a recess was taken.)

14 THE VIDEOGRAPHER: Back on the record.

15 Here marks the beginning of tape number 2 in
16 the deposition of Robert Hess. The time is 11:09.

17 MR. BROWN: Q. Mr. Hess, let me restate the
18 question that I asked before the break.

19 Can you direct me to any language in the '168
20 patent that discloses a structure other than a catheter
21 over a guidewire or a device surrounding a motion wire
22 that accomplishes the purpose of the invention?

23 You've identified already a passage at column
24 4, lines 10 through 12, and a passage at column 2,
25 roughly lines 37 to 41. Are you able to identify any

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1 additional language in the patent that discloses such a
2 structure?

3 A. I will have to continue going through the --

4 Q. Please do.

5 A. If we look at column 4, starting at line 66,
6 through column 5, line 7, contemplates different
7 structures as well.

8 Q. Does it disclose any structure other than a
9 catheter over a guidewire or a device surrounding a
10 motion wire?

11 A. Well, it says, "Having indicated above
12 preferred embodiments of the present invention, it will
13 occur to those skilled in the art that modifications and
14 alternatives can be practiced within the spirit of the
15 invention. It is accordingly intended to define the
16 scope of the invention only as indicated in the
17 following claims," and referring back to the previous
18 two references, that means that it is any means of
19 delivering a radioactive source, which is either a
20 liquid, a solid, or a gas, operatively connected to a
21 positioning means.

14 claim contemplates advancing an isotope to a -- to the
15 site of a lesion and extracting it from the site of the
16 lesion and the artery using a positioning means which is
17 operatively connected to the dose means, and whatever I
18 can imagine -- whatever way I can imagine doing that is
19 within the scope of this claim.

20 Q. So in your view, the positioning means for
21 advancing the radioactive material can be different from
22 the positioning means for removing the radioactive
23 material?

24 A. I would like to believe that this is broad
25 enough to allow that if I wanted to do it.

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1 Q. What does the -- let me back up.
2 Do you know how a person working in the field
3 of radiation therapy would construe the term
4 "radioactive dose"?

5 MR. TEIXEIRA: Objection. Foundation.

6 THE WITNESS: I can't say that -- there are
7 many ways to measure -- there are several ways to
8 measure radioactive dose. I don't know what the
9 standard is in -- in -- you mean nuclear medicine,
10 oncology, for example? I'm not sure what you mean by
11 that.

12 MR. BROWN: Q. My question is simply how a
13 person working in the field of radiation therapy would
14 construe the term "radioactive dose."

15 MR. TEIXEIRA: I'm going to object.
16 Foundation.

17 MR. BROWN: Q. Do you know? You can tell me.
18 If you don't know, tell me you don't know.

19 A. No, I don't know. In fact, I mean, you can
20 talk about the emitted dose or the absorbed dose, and
21 I'm not quite sure at this point in time what the
22 convention is.

23 Q. Well, what does the term "radioactive dose"
24 mean to you?

25 A. It means -- it means a quantity of energy that

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1 is emitted by a radioactive source and -- and/or the
2 effect that that has on some material, the absorbed

3 dose. It can -- it can mean a number -- it can mean a
4 number -- or there are a number of different ways of
5 interpreting or measuring dose, and, in general, you
6 have to choose a -- a parameter that you want to measure
7 and -- and -- and then build your data around that.

8 Q. Well, does -- does it refer to some quantity
9 of radiation?

10 MR. TEIXEIRA: Objection. Asked and answered.

11 THE WITNESS: If it's absorbed dose, it will
12 depend on the -- the source, the particle, the energy of
13 that particle, and the material that's being --
14 that's -- that's absorbing the dose. It depends on all
15 those things, and the attenuation within -- you have
16 blood in the artery. There will be an attenuation, or
17 you have -- or it's going through the wall of a balloon
18 or something, where there's an attenuation factor, which
19 varies with the energy of the particle and the particle
20 type, and it's not a particularly simple thing.

21 MR. BROWN: Q. All right. So can you
22 identify for me the factors that, in your view, impact
23 radiation dose?

24 A. I think I just did. It's the particle, the
25 energy of the particle, and attenuation of any other

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1 materials in the way, and the reactivity of the
2 material that is being -- the radiation is being applied
3 to.

4 Q. Does it also depend on the length of exposure?

5 A. As well as the time, sure.

6 There may be other things that I've missed as
7 well.

8 Q. Now, in what way does a radioactive dose
9 depend on the length of time the tissue is exposed to
10 the radiation?

11 A. More time, more dose.

12 Q. How does the radioactive dose depend on the
13 level of radioactivity of the material?

14 A. More particles, more dose, more energy,
15 basically.

16 Q. So the higher the radioactivity of the
17 material, the higher the dose for a given period of
18 time?

19 A. Not necessarily. It depends also on what's
20 being emitted.

21 Q. Well, all other things being equal.
22 A. Yes. I mean, if you're talking about where it
23 is in its series of decay, yes, a given isotope, yes,
24 that's correct.
25 Q. And does the dose also depend on whether the

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1 radioactive material is a solid, liquid, or gas?
2 A. It may.
3 Q. Does it -- does the dose depend on whether the
4 radiation emitted is alpha, beta, or gamma?
5 A. Clearly, it does, and in conjunction with
6 other factors.
7 Q. What is the difference between alpha, beta,
8 and gamma radiation?
9 A. Alpha is a very large particle. It's -- is
10 easily absorbed, easily shielded. It would probably not
11 be a good choice in this setting because generally you
12 have enough fluid around that you probably wouldn't get
13 any dose through the artery wall. Beta is essentially
14 an electron, has medium penetration, depending on the
15 energy of the particle, has significant mass, so that it
16 gives up energy pretty readily. Gammas are extremely
17 penetrating, and tend to be used in areas where either
18 the -- the material to be irradiated is quite thick or
19 you can expect a lot of attenuation due to interstitial
20 materials.
21 Q. Now, according to the '168 patent, does it
22 matter whether you use alpha, beta, or gamma radiation?
23 MR. TEIXEIRA: Object to the form.
24 THE WITNESS: Fundamentally, it shouldn't
25 matter, but one or the other form will generally be

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1 found to be more desirable, given the structure and what
2 you're trying to do and half-life of the isotope, and at
3 the end of the day, you want to deliver a certain amount
4 of energy to the stenosed region to -- to prevent
5 proliferation of the cells, and getting the energy there
6 depends on a -- a large number of factors.
7 MR. BROWN: Q. Well, then, how, according to
8 the patent, does one control for the amount of radiation
9 that's released to the area of reduced stenosis?

10 MR. TEIXEIRA: Objection. Asked and answered.

11 THE WITNESS: The patent doesn't tell you how
12 to do that. It tells you you should do that, I believe.

13 MR. BROWN: Q. Am I correct that it is
14 important to control the amount of radiation released to
15 the area of reduced stenosis?

16 A. In -- in my belief, yes.

17 Q. And that's in order to ensure that you get the
18 desired response in terms of minimizing restenosis?

19 A. Without causing damage. The -- the issue is
20 to get enough -- sufficient radiation to the site to
21 control the smooth muscle cells, but without causing
22 significant damage to the artery.

23 Q. Now, does the term "radiation" or "radioactive
24 dose" imply anything about which radioactive material is
25 used?

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1 A. No. It implies that a radioactive source is
2 used.

3 Q. Does the term "radioactive dose" imply
4 anything about the form of the material, that is,
5 whether it's solid, liquid, or gas?

6 A. Not necessarily, no.

7 Q. Does the term "radioactive dose" imply
8 anything about the shape of the material?

9 A. Not necessarily, no.

10 Q. Do you see the term, quote, radioactive dose
11 means, end quote, in claim 1 of the '168 patent?

12 A. In which line?

13 Q. Claim 1.

14 A. Claim 1, "advancing a radioactive dose means,"
15 yes.

16 Q. All right. What does the term, quote,
17 radioactive dose means, end quote, mean in the context
18 of claim 1?

19 A. It means -- it means something capable of
20 emitting radioactivity.

21 Q. What's the function of the radioactive
22 material that's part of the radioactive dose means?

23 A. To -- to emit radiation.

24 Q. What's the purpose of emitting the radiation?

25 A. To deliver a certain amount of energy to the

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1 stenosed region.
2 Q. And what is the purpose of delivering a
3 certain amount of energy to the stenosed region?
4 MR. TEIXEIRA: Objection. Asked and answered.
5 THE WITNESS: To control the proliferation of
6 smooth muscle cells.
7 MR. BROWN: Q. What are the possible
8 materials disclosed in the patent that can be used to
9 perform the function of releasing radiation?
10 MR. TEIXEIRA: Rob, I'll ask you again to make
11 sure that you read the patent.
12 THE WITNESS: I know it's in here somewhere.
13 MR. BROWN: Q. I can direct you to column 4,
14 lines 7 through 9.
15 A. Column 4, 7 through 9.
16 MR. TEIXEIRA: I think you would also want to
17 look at the lines preceding that.
18 THE WITNESS: And the question is: What are
19 the --
20 MR. BROWN: Q. The question is: What are the
21 possible materials disclosed in the patent that can be
22 used to perform the function of releasing radiation?
23 A. Well, if you take the isotopes that are listed
24 there together with radioactive materials, including but
25 not limited to, it's anything that's radioactive.

1 Q. All right. Now, you refer specifically to
2 Radon 222; am I correct?
3 A. Yes.
4 Q. What form of radiation is that, or radioactive
5 material?
6 A. I don't know. I don't remember what form
7 that's found in.
8 Q. Do you remember whether it emits alpha, beta,
9 or gamma radiation?
10 A. No, at this point.
11 Q. What about Gold 198? Is it alpha, beta, or
12 gamma?
13 A. The same answer. I don't -- I don't recall at
14 this time.
15 Q. What about Strontium 90? Do you remember
16 whether it's alpha, beta, or gamma?

17 A. I don't recall at this time, no.
18 Q. What about Radium 192? Do you remember
19 whether it's alpha, beta, or gamma?
20 A. I don't recall.
21 Q. What about Iodine 125? Do you remember
22 whether it's alpha, beta, or gamma?
23 A. No, I don't recall.
24 Q. Do you remember which of these radioactive
25 materials are solid, which are liquid, and which are

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1 gas?
2 A. No, I don't recall at this time.
3 Q. What are the possible forms of the radioactive
4 material disclosed in the patent?
5 A. Do you mean solid, liquid, or gas, or -- yes.
6 I'm sorry. Did you --
7 Q. Let me try to clarify.
8 Am I correct that the forms of radioactive
9 material disclosed in the patent are solid, liquid, and
10 gas?
11 A. They may be. I don't -- I don't know what
12 natural forms those are found in, but the contemplation
13 is that they may be incorporated into or delivered in a
14 solid, liquid, or gas, not that they're found in those
15 natural forms necessarily.
16 Q. Now, looking at the figures in the patent, can
17 you tell me the form of the radioactive element
18 disclosed in each of the figures?
19 A. Let me see about Figure 3.
20 So what is the question, now? What are we
21 answering here? What am I answering?
22 MR. TEIXEIRA: Do you need the question read
23 back?
24 THE WITNESS: Yeah.
25 MR. BROWN: Q. I'll state the question again.

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1 Can you tell me the form of the radioactive
2 element disclosed in each of the figures of the '168
3 patent?
4 A. Well, I suppose there are certainly, in the
5 case of the stent, there are multiple possibilities. In

20 Q. So does the phrase, quote, radioactive dose
21 means, end quote, say anything about the possible
22 materials that could be used?

23 A. Yes. It says it has to be a radioactive
24 material.

25 Q. Other than that, does it tell you anything

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1 about the type of radioactive material?

2 A. No, it's not defined.

3 Q. Does the phrase, quote, radioactive dose
4 means, end quote, tell you anything about the possible
5 forms of the radioactive material?

6 A. The patent tells you about the potential
7 forms. That phrase doesn't.

8 Q. Does the phrase, quote, radioactive dose
9 means, end quote, tell you anything about the possible
10 shapes of the radioactive material?

11 A. I don't think so.

12 Again, I'm just thinking, is there an isotope
13 that -- that has to be in a particular shape to
14 function? I don't think that's the case, quite
15 honestly. It may be. I'm not aware of it.

16 Q. So is it accurate to say that the phrase,
17 radioactive dose means, end quote, doesn't tell you
18 anything about the kind of radioactive material, the
19 form of the radioactive material, or the shape of the
20 radioactive material?

21 MR. TEIXEIRA: Objection. Form.

22 THE WITNESS: It doesn't define it, but it
23 tells you that it's a radioactive material, and it's my
24 belief that you can, within the scope of this patent, it
25 can be in any of the forms of solid, liquid, or gas, and

Hess claim construction

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1 it can be any radioactive material which has sufficient
2 properties to accomplish the -- the control of the
3 smooth muscle cells, and it can be in any form which is
4 appropriate, and that's called design engineering, I
5 guess. You have to consider all those things.

6 MR. BROWN: Q. But am I correct that the
7 phrase itself, quote, radioactive dose means, end quote,
8 tells you none of those things?

15

---o0o---

16 AFTERNOON SESSION

1:17 P.M.

17 THE VIDEOGRAPHER: This marks the beginning of
18 tape number 3 in the deposition of Robert Hess. The
19 time is 1:17.

20 EXAMINATION BY MR. BROWN (RESUMED):

21 MR. BROWN: Q. Mr. Hess, I want to talk with
22 you about the term or phrase, quote, positioning means,
23 end quote, as that phrase is used in the '168 patent.
24 Let's look at the use of that phrase in the '168 patent.
25 Could you look first at column 2, lines 38 to 41.

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1 Do you see at that location the use of the
2 phrase, "positioning means"?

3 A. Yes, I do.

4 Q. Does the use of that phrase at column 2, lines
5 38 to 41, shed any light on how that phrase should be
6 construed? Does it tell you there what "positioning
7 means" is intended to mean?

8 A. It's not defined, no.

9 Q. Would you please look at column 3, lines 33
10 through 35, and tell me whether you see a reference to
11 "positioning means" at that cite.

12 A. Yes, I do.

13 Q. Am I correct that the patent reads, at that
14 cite, quote, A radioactive dose means 30 is movable by
15 advancing or retracting catheter shaft 26 which may be
16 referred to as a positioning means, end quote?

17 A. I see that, yes.

18 Q. So how is "positioning means" defined in that
19 sentence?

20 A. "Positioning means" is defined -- a
21 positioning means is defined as a catheter shaft in
22 that -- in that sentence, which also implies that there
23 are other positioning means, because that is a
24 positioning means.

25 Q. All right. Would you please look at column 4,

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1 lines 17 through 20, and tell me whether you see a
2 reference to "positioning means" at that cite.

3 A. A device including "a positioning means 52

4 which is a motion wire providing slidable motion of the
5 radioactive dose means."
6 Q. So you just read from the patent?
7 A. That's what I read, yes, from the patent.
8 Q. All right. So am I correct that, at column 4,
9 lines 17 through 20, the positioning means is defined as
10 a motion wire?
11 A. That's correct.
12 Q. Is the term or phrase "positioning means" used
13 in the patent to describe anything other than a catheter
14 shaft or a motion wire? And now I'm referring to the
15 written description portion of the patent.
16 A. I don't know.
17 Q. Well, would you please take a look. I've
18 tried to identify for you the places where I found the
19 term, but for you to be satisfied, feel free to take a
20 look.
21 Have you had an opportunity to read through
22 the patent, Mr. Hess?
23 A. Yes, I have.
24 Q. All right. Let me rephrase my question or
25 repeat my question.

Hess claim construction
page 94

1 A. Yes.
2 Q. Is the phrase "positioning means" used in the
3 written description portion of the patent to describe
4 anything other than a catheter shaft or a motion wire?
5 MR. TEIXEIRA: Objection to form.
6 THE WITNESS: Well, I'd refer you in -- I
7 would refer you to column 5, lines 3 through 7, "Having
8 indicated above preferred embodiments of the present
9 invention, it will occur to those skilled in the art
10 that modification and alternatives can be practiced
11 within the spirit of the invention. It is accordingly
12 intended to define the scope of the invention only as
13 indicated in the following claims."
14 MR. BROWN: Q. All right. My question again,
15 is: Is the phrase, "positioning means," is that phrase
16 used in the written description portion of the patent to
17 describe anything other than a catheter shaft or a
18 motion wire?
19 A. And my answer is: When you take those two
20 references and couple that with the last paragraph
21 before the claims, that is the sum total of the

22 definition of "positioning means."
23 Q. All right. And would you agree that that last
24 paragraph before the claims says nothing about -- or
25 does not use the term "positioning means"?

Hess claim construction
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1 A. The words are not there, "positioning means."
2 Q. Now, do you have any reason to think that a
3 person of ordinary skill in the art would think of a
4 fluid when reading the term "positioning means"?
5 A. I believe that's possible, yes.
6 Q. Why?
7 A. Because there are numerous -- numerous
8 examples where fluids or gases have been used to
9 position things.
10 Q. Are there any in the patent?
11 A. Well, what I meant by that is there are
12 numerous examples in other fields where that's been
13 done.
14 Q. Are there any in the patent?
15 A. Refer you again to column 5, 3 through 7.
16 Q. And again, that paragraph doesn't use the term
17 "positioning means"; correct?
18 A. The words are not there.
19 Q. Is there any other language in the written
20 description portion of the patent that you'd point to to
21 support a construction of the phrase "positioning means"
22 to include a -- a fluid?
23 MR. TEIXEIRA: I would ask that you read the
24 patent again.
25 THE WITNESS: Sorry?

Hess claim construction
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1 MR. TEIXEIRA: I'd caution you to read the
2 patent before answering the question.
3 THE WITNESS: The question is? I'm sorry.
4 Again.
5 MR. TEIXEIRA: Can you read back the question,
6 please, Leigh?
7 MR. BROWN: I'll restate it.
8 Q. Other than the last paragraph preceding the
9 claims, is there any other language in the written
10 description portion of the patent that you'd point to to

11 support a construction of the phrase "positioning means"
12 to include the use of a fluid?

13 A. Refer you to, again, to column 4, 9 through
14 12, where the radioactive source can be incorporated
15 into or delivered in a solid, liquid, or gaseous form,
16 together with the last paragraph before the claims.

17 Q. But with respect to column 4, lines 8 through
18 10, would you agree that that language is directed to
19 the different forms that the radioactive material may
20 take, that is, solid, liquid, or gas?

21 A. And the delivery of such forms. We're not
22 talking about just the forms it can take. We can say --
23 it says that can be "incorporated into or delivered in a
24 solid, liquid, or gaseous form, and the delivery of such
25 forms is considered to be within the scope of the

Hess claim construction
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1 subject invention."

2 Q. All right.

3 A. "Delivered" means, to me, "delivered."

4 Q. Well, let's see if we can break it down.

5 The language, quote, these materials may be
6 incorporated into or delivered in a solid, liquid, or
7 gaseous form, end quote --

8 A. Right.

9 Q. -- would you agree that that language is
10 directed to the different forms that the radioactive
11 material may take?

12 A. I don't think it limits it at all.

13 Q. Does it say anything about how it's delivered?

14 A. Yes, it does. It says it's delivered in a
15 liquid, solid, or gaseous form.

16 Q. The radioactive material is delivered in a
17 liquid, solid, or gaseous form; correct?

18 A. Or delivered in a liquid, solid, or a gas.

19 Q. Well, the language says, quote, these
20 materials may be incorporated into or delivered in a
21 solid, liquid, or gaseous form, end quote; correct?

22 A. Uh-huh.

23 Q. And the "form" in that sentence is referring
24 to the form of the radioactive material, isn't it?

25 MR. TEIXEIRA: Object to the form of the

Hess claim construction
page 98

1 question.

2 THE WITNESS: But it also says that it -- that
3 it's delivered in that form, which -- which means --
4 which means it's brought to the site of the lesion in --
5 in that form.

6 MR. BROWN: Q. The radioactive material is
7 brought to the site of the lesion in a solid, liquid, or
8 gaseous form; correct?

9 A. And -- and it can be delivered in a solid,
10 liquid, or a gas.

11 Q. Where does it say that?

12 A. That's what it says to me.

13 Q. The phrase, "these materials," would you agree
14 that that is referring to the radioactive materials?

15 A. Yes.

16 Q. So when the sentence reads, quote, These
17 materials may be incorporated into or delivered in a
18 solid, liquid, or gaseous form --

19 A. Uh-huh.

20 Q. -- end quote, am I correct that the form
21 that's being referred to is the form of the radioactive
22 materials?

23 MR. TEIXEIRA: Objection. Asked and answered.

24 THE WITNESS: No, that's -- that's really not
25 correct, because that implies that it is the natural

Hess claim construction
page 99

1 state of the radioactive material, and this means --
2 what this means is that you can take a radioactive
3 material which is, for example, not in a liquid form,
4 and put it in a liquid, and deliver it that way, and
5 that, taken with the last paragraph before the claims,
6 would certainly allow you to do that.

7 MR. BROWN: Q. So you're construing the term
8 "form" to refer to not only the form of the materials,
9 but to the -- the manner in which the materials are
10 delivered?

11 MR. TEIXEIRA: Objection. I don't believe he
12 testified to that.

13 THE WITNESS: Sorry. I didn't hear that.

14 MR. TEIXEIRA: I said objection, you didn't
15 say that.

16 MR. BROWN: Q. Is that what you're
17 testifying?

18 A. Try that again.
19 Q. Are you contending that the use of the word
20 "form" at column 4, lines 8 through 10, refers not only
21 to whether the radioactive material is a solid, liquid,
22 or gas, but also to the manner in which the radioactive
23 material is delivered to the treatment site?
24 A. Or the vehicle, taken together with the last
25 paragraph before the claims.

Hess claim construction
page 100

1 Q. So you're saying "form," in -- at column 4,
2 lines 8 through 10, is not limited to the form of the
3 material, the radioactive material?
4 A. I think we've said that before. It doesn't
5 necessarily matter if the radioactive material is found
6 in its natural state, in a solid or a liquid or a gas,
7 because what this contemplates is you could take
8 radioactive material in any form and combine it with a
9 solid, a liquid, or a gas, and deliver it.
10 Q. But my question is whether this sentence
11 addresses at all the manner of delivery, or does it only
12 refer to the form of the radioactive material?
13 A. It says delivered, so I think it addresses --
14 taken together with the last paragraph before the
15 claims, I think it certainly means the manner in which
16 it's delivered, yes.
17 MR. TEIXEIRA: Are we talking about the
18 complete sentence, or up to gaseous form, comma?
19 MR. BROWN: Q. We're talking about, quote,
20 These materials may be incorporated into or delivered in
21 a solid, liquid, or gaseous form, end quote.
22 Correct, Mr. Hess?
23 A. Uh-huh.
24 MR. TEIXEIRA: For the record, that's not the
25 complete sentence.

Hess claim construction
page 101

1 THE WITNESS: Well, let's see what the
2 complete sentence says.
3 MR. BROWN: Counsel, you have continually,
4 throughout this deposition, engaged in improper
5 objections, and if you continue to do so, we're going to
6 take it to the judge because --

7 MR. TEIXEIRA: Be my guest.
8 MR. BROWN: -- you know very well that your
9 objections have been improper --
10 MR. TEIXEIRA: They have not.
11 MR. BROWN: -- your speaking objections
12 throughout.
13 MR. TEIXEIRA: If you have a problem with it
14 we can go to the Court, but all I'm saying is that your
15 question does not incorporate the complete sentence.
16 MR. BROWN: There was no reason for that
17 comment, Counsel. My question was clear. You're simply
18 trying to coach the witness.
19 MR. TEIXEIRA: I'm not trying to coach the
20 witness, and I resent that, and if you have a problem,
21 you can take it to the Court.
22 Rob, you can go ahead and answer the question.
23 Is there a pending question, Leigh?
24 (Record read as follows: "Q. We're talking
25 about, quote, These materials may be incorporated into

Hess claim construction
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1 or delivered in a solid, liquid, or gaseous form, end
2 quote.
3 "Correct, Mr. Hess?
4 "A. Uh-huh."
5 THE WITNESS: So is there a question? I'm
6 sorry.
7 MR. BROWN: Q. My question is whether the
8 sentence, quote -- or portion of the sentence, quote,
9 These materials may be incorporated into or delivered in
10 a solid, liquid, or gaseous form, end quote, addresses
11 the form of the radioactive material, or addresses the
12 manner in which it's delivered, or both.
13 MR. TEIXEIRA: Objection to form, and asked
14 and answered.
15 THE WITNESS: I think -- I think that both,
16 when taken in the context of the requirement of a
17 positioning means and the last paragraph before the
18 claims.
19 MR. BROWN: Q. I'm not sure I understood your
20 answer, Mr. Hess.
21 What did you mean by taken in the context of
22 positioning means?
23 A. Well, we're talking about in -- we're talking
24 about delivery, we're talking about positioning means,

25 and we're talking about modification and alternatives

Hess claim construction
page 103

1 could be practiced within the spirit of the invention,
2 so I think, if you put all of those things together, you
3 get distinctly that possibility.

4 Q. But my question was directed to the portion of
5 the sentence which reads, quote, These materials may be
6 incorporated into or delivered in a solid, liquid, or
7 gaseous form, end quote.

8 Is it your contention that the word "form" in
9 that portion of the sentence refers both to the form of
10 the radioactive material and the manner in which that
11 radioactive material is delivered to the treatment site?

12 MR. TEIXEIRA: Objection to the form of the
13 question.

14 THE WITNESS: It is my contention that it may
15 be both.

16 MR. BROWN: Q. Now, your counsel apparently
17 wanted to bring to your attention the fact that the
18 sentence goes on to read, quote, and the delivery of
19 such forms is considered to be within the scope of the
20 subject invention, end quote.

21 Do you see that portion of the sentence?

22 A. I do.

23 Q. Is that portion of the sentence directed to
24 the form of the radioactive material?

25 MR. TEIXEIRA: Objection to the form of the

Hess claim construction
page 104

1 question.

2 MR. BROWN: Let me rephrase the question.

3 Q. In that portion of the sentence which reads,
4 quote, and the delivery of such forms is considered to
5 be within the scope of the subject invention, end quote,
6 what is being referenced when using the phrase, quote,
7 such forms, end quote?

8 A. I'm not sure I understand the question. I
9 mean --

10 Q. What does "such forms" refer to in that part
11 of the sentence?

12 A. It means the -- it means the -- it means
13 the -- the vehicle in which the -- again, we're not

14 talking about the natural states of the radioactivity,
15 so if they're incorporated into a liquid, solid, or gas,
16 then that liquid, solid, or gas becomes -- can become
17 the vehicle that delivers the radioactive material to
18 the -- the site of the lesion.

19 Q. So are -- are you talking about the situation
20 where the radioactive material itself is the medium used
21 to deliver the material to the treatment site?

22 A. No. I distinctly said that wasn't necessary,
23 that the radioactivity -- the radioactive material does
24 not have to exist in a liquid, gaseous, or solid state
25 to be put into that medium and delivered. It's not a

Hess claim construction
page 105

1 necessary requirement that it have the same state as the
2 medium into which you're putting it.

3 Q. So if we look at the portion of the sentence
4 which reads, quote, and the delivery of such forms is
5 considered to be within the scope of the subject
6 invention, end quote, you construe the reference to,
7 quote, such forms, end quote, to include a reference to
8 the manner in which the radioactive material is
9 delivered?

10 A. It could, yes.

11 Q. Did you ever envision using a fluid to move a
12 radioactive element to the site of stenosis?

13 A. Yes.

14 Q. When?

15 A. I don't recall.

16 Q. Do you have any documents that show you, in
17 fact, possessed the idea of using a fluid to transport
18 the radioactive material to the site of stenosis?

19 A. I don't know.

20 Q. What -- what do you regard as being the
21 function of the positioning means?

22 A. The function of the positioning means is to
23 get the radioactive source to the site of the lesion
24 and -- and to remove it.

25 Q. Claim 1 of the '168 patent uses the phrase

Hess claim construction
page 106

1 "operatively connected."

2 A. Yes.