

1
2 UNITED STATES INTERNATIONAL TRADE COMMISSION

3 WASHINGTON, D.C.

4 -----X
5 In the Matter of)
6 CERTAIN STRONTIUM-RUBIDIUM) Inv. No.
7 RADIOISOTOPE INFUSION SYSTEMS,) 337-TA-1110
8 AND COMPONENTS THEREOF,)
9 INCLUDING GENERATORS)
10 -----X

11 CONTINUED

12 VIDEOTAPED DEPOSITION

13 OF ROBERT THOMAS STONE, PH.D.

14 CONFIDENTIAL BUSINESS INFORMATION

15 SUBJECT TO PROTECTIVE ORDER

16 Washington, D.C.

17 Wednesday, October 10, 2018

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22 Pages: 285 - 508

23 Reported by: Cindy L. Sebo, RMR, CRR, RPR, CSR,

24 CRR, CLR, RSA, LiveDeposition Authorized Reporter

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Bracco Ex. 2005
Jubilant v. Bracco
IPR2018-01449

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2 October 10, 2018
3 9:05 a.m.
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6 Confidential Videotaped Deposition
7 of ROBERT THOMAS STONE, PH.D. held at the law
8 offices of:
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12 Greenberg Traurig, LLP
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14 Suite 1000
15 Washington, D.C. 20037
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18 Pursuant to notice, before Cindy L.
19 Sebo, Registered Merit Reporter, Certified Real-Time
20 Reporter, Registered Professional Reporter,
21 Certified Shorthand Reporter, Certified Court
22 Reporter, Certified LiveNote Reporter, Real-Time
23 Systems Administrator and a Notary Public in and for
24 the District of Columbia.
25

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15 ELIZABETH CONNERS, law clerk, Office of
16 Unfair Import Investigations, U.S.
17 International Trade Commission
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3 I N D E X
4 - - -
5 WITNESS PAGE NO.
6 ROBERT THOMAS STONE, PH.D.
7 By Ms. Bookbinder 297, 453, 501
8 By Mr. Walker 493
9
10 - - -
11 E X H I B I T S
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13 STONE
14 DEPOSITION
15 EXHIBIT NUMBER DESCRIPTION PAGE NO.
16 Number 32 [REDACTED]
17 [REDACTED] 339
18 Number 33 [REDACTED]
19 [REDACTED]
20 [REDACTED] 359
21 [REDACTED]
22 Number 34 [REDACTED]
23 [REDACTED] 366
24 [REDACTED]
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6 EXHIBIT NUMBER	DESCRIPTION	PAGE NO.
7 Number 35	[REDACTED]	
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11 Number 36	[REDACTED]	
	[REDACTED]	
	[REDACTED]	
	[REDACTED]	386
14 Number 37	Patent Application Publication	
16	Number US 2015/0228368 A1,	
17	Bates stamped	
18	BRACCOITC00633522 through	
19	BRACCOITC00633547	388
20		
21 Number 38	Office Action Response for	
22	Application Number 14/426,208,	
23	April 5, 2018, Bates	
24	stamped BRACCOITC00633511	
25	through BRACCOITC00633521	389

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7 EXHIBIT NUMBER	DESCRIPTION	PAGE NO.
8 Number 43	[REDACTED]	
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	[REDACTED]	434
13 Number 44	[REDACTED]	
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	[REDACTED]	
	[REDACTED]	442
18 Number 45	[REDACTED]	
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6 EXHIBIT NUMBER	DESCRIPTION	PAGE NO.
7 Number 39	[REDACTED]	
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12 Number 40	[REDACTED]	
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	[REDACTED]	
	[REDACTED]	416
17 Number 41	[REDACTED]	
18	[REDACTED]	
	[REDACTED]	429
20 Number 42	[REDACTED]	
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6 EXHIBIT NUMBER	DESCRIPTION	PAGE NO.
7 Number 46	[REDACTED]	
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10 Number 47	Patent Application Publication	
12	Number US 2014/0343418, Bates	
13	stamped JDI-ITC-000188162	
14	through JDI-ITC-000188203	449
15		
16 Number 48	[REDACTED]	
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	[REDACTED]	
	[REDACTED]	
	[REDACTED]	453
20 Number 49	[REDACTED]	
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3 EXHIBITS (Continued)
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5 STONE
6 DEPOSITION
7 EXHIBIT NUMBER DESCRIPTION PAGE NO.
8 Number 50 [REDACTED] 461
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10 Number 51 [REDACTED] 464
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15 Number 52 [REDACTED] 466
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20 Number 53 [REDACTED] 472
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3 EXHIBITS (Continued)
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7 EXHIBIT NUMBER DESCRIPTION PAGE NO.
8 Number 54 [REDACTED] 475
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10 Number 55 Lemer Fax Web page, Bates
11 stamped JDI-ITC-000123196 477
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13 Number 56 [REDACTED] 489
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19 (**Exhibits Attached to Original Transcript.)
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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2
3 PROCEEDINGS
4
5 Washington, D.C.
6 Wednesday, October 10, 2018; 9:05 a.m.
7
8 THE VIDEOGRAPHER: This is the
9 videotaped deposition of Robert T. Stone
10 in the matter of Certain
11 Strontium-Rubidium Radioisotope Infusion
12 Systems, et al., in the United States
13 International Trade Commissions [sic] in
14 Washington, D.C.
15 This deposition is being held at
16 Greenberg, LLP, on October 10th, 2018, at
17 approximately 9:05 a.m.
18 My name is Martin Sherrill, and I
19 am from U.S. Legal Support. The court
20 reporter today is Cindy Sebo, also from
21 U.S. Legal Support.
22 (Sotto voce discussion with court
23 reporter and videographer.)
24 THE VIDEOGRAPHER: Okay.
25 Counsel will now state their

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 appearance for the record.
3 MS. BOOKBINDER: Julie Bookbinder
4 from Greenberg Traurig for the
5 Complainant. With me is Olena Ierega.
6 MR. WALKER: Cy Walker,
7 BakerHostetler, on behalf of the
8 Respondents.
9 MR. KOO: Brian Koo with the Office
10 of Unfair Import Investigations at the
11 U.S. International Trade Commission. And
12 with me today is Elizabeth Conners, a law
13 clerk from our office.
14 THE VIDEOGRAPHER: You may begin.
15
16 ROBERT THOMAS STONE, PH.D.,
17 after having been previously duly sworn, was
18 examined and testified further as follows:
19
20
21 EXAMINATION (RESUMED) BY COUNSEL FOR COMPLAINANTS
22
23 BY MS. BOOKBINDER:
24 Q. All right. Good morning, Dr. Stone.
25 A. Good morning.

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 Q. It's October 10th, the second day of
3 your deposition in this matter, right?
4 A. Yes.
5 Q. Okay. And you remember that your
6 affirmation from yesterday still applies?
7 A. Yes.
8 Q. Okay. Did you discuss your testimony
9 with anyone since we broke for the day yesterday?
10 A. No.
11 Q. During the course of the day
12 yesterday, did you discuss the substance of your
13 testimony with counsel?
14 A. No.
15 Q. Or with anyone else?
16 A. No.
17 Q. Okay. Yesterday, we discussed your
18 inspection of the Version 1 and Version 2 systems
19 at Jubilant in Canada, right?
20 A. Yes.
21 Q. And you had an understanding, if I'm
22 correct, that the Version 2 had been used at
23 least in Canada?
24 A. Yes.
25 Q. All right. Was Version 1 used

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 anywhere?
3 A. I am told that it -- that Version 1
4 was used at a few universities --
5 Q. Who told --
6 A. -- and --
7 Q. -- oh, sorry. Go ahead.
8 A. -- I don't recall if I asked that
9 counsel -- that question of counsel at Jubilant
10 or if it was told to me by the attorneys here.
11 Q. And that was with reference to
12 Version 1 being used at a few universities?
13 A. Yes, I -- universities, and I believe
14 it was used in trials in order to get approvals
15 for Version 2.
16 Q. Were any of those universities or
17 trials in the United States?
18 A. Not to my knowledge.
19 Q. Has the Version 1 device ever been
20 publicly available in the United States?
21 A. Not to my knowledge.
22 Q. Do you know how Version 1 was used in
23 the universities?
24 A. I do not know the details.
25 Q. Okay. Is it your understanding that

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 it was used with human patients?
3 A. Yes.
4 Q. Do you know whether images were taken
5 as a result of those uses?
6 A. I have not reviewed the details of
7 how it was used.
8 Q. And you have not reviewed any
9 documentation or testimony or any evidence
10 regarding the use of Version 1?
11 A. I don't recall any such evidence.
12 Q. Okay. Let's go back to Klein -- I
13 think you said that Version 1 was somewhat based
14 on the Klein Thesis?
15 A. Yes.
16 Q. When did the uses of Version 1 occur?
17 A. I do not know the details of when it
18 occurred.
19 Q. The Klein Thesis was prepared in
20 about 2005; is that right?
21 A. That's my understanding, yes.
22 Q. So it was sometime after 2005?
23 A. That's correct.
24 Q. And then if you recall, yesterday, we
25 looked at some e-mails indicating that the

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 Version 3 development was going on, at least in
3 2010?
4 A. I'll accept that. I'd --
5 Q. Okay --
6 A. -- have to go back and look at my
7 dates and --
8 Q. -- so the Version 1 and Version 2
9 work and use of those systems occurred likely
10 between 2005 and 2010?
11 A. That's a likely statement.
12 Q. And just to be clear, Version 1
13 predated Version 2, right?
14 A. Definitely.
15 Q. Okay.
16 So to return to your analysis of the
17 Klein Thesis with respect to the asserted
18 patents, The Klein Thesis does not disclose that
19 the infusion system is configured for the saline
20 tubing line and the eluate tubing line to be
21 routed through two tubing passageways formed in a
22 perimeter surface of the first opening, which we
23 discussed yesterday was the generator
24 compartment, wherein each of the two tubing
25 passageways has a depth configured to prevent

<p style="text-align: right;">Page 18 Page 302</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 pinching or crushing of a corresponding tubing</p> <p>3 line routed therethrough when a first door is</p> <p>4 closed over the opening.</p> <p>5 Is that correct?</p> <p>6 A. I believe that is correct.</p> <p>7 Q. And we also talked yesterday about</p> <p>8 the cart depicted in the Klein Thesis, and you</p> <p>9 stated that an external shell could have an open</p> <p>10 side, right?</p> <p>11 A. I did.</p> <p>12 Q. Okay. But the Klein Thesis does not</p> <p>13 disclose an exterior shell that extends upwardly</p> <p>14 above the platform and has a front side, a rear</p> <p>15 side, two sidewalls connecting the front side to</p> <p>16 the rear side.</p> <p>17 Right?</p> <p>18 A. I -- I'm sorry. Repeat that. That</p> <p>19 doesn't sound correct.</p> <p>20 Q. Sure.</p> <p>21 So I believe that the Klein Thesis</p> <p>22 does not disclose an exterior shell that extends</p> <p>23 upwardly above the platform and has a front side,</p> <p>24 a rear side, two sidewalls that connect the front</p> <p>25 side to the rear side.</p>	<p style="text-align: right;">Page 20 Page 304</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 figure.</p> <p>3 So I'd like to correct that</p> <p>4 testimony. That's -- the Klein Thesis was the</p> <p>5 source of that information, that there's a</p> <p>6 generator access lid on the top of the Klein</p> <p>7 cart --</p> <p>8 Q. Okay --</p> <p>9 A. -- so if we can go to --</p> <p>10 Q. -- so I want to -- yeah, let's go</p> <p>11 through this one step at a time.</p> <p>12 So you're on Page 148 of your opening</p> <p>13 report --</p> <p>14 A. That's correct.</p> <p>15 Q. -- Paragraph 327 --</p> <p>16 A. Yes.</p> <p>17 Q. -- An annotated version,</p> <p>18 Klein Thesis, Figure 2-4?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. So we've got this figure.</p> <p>21 And could you make your correction</p> <p>22 again of --</p> <p>23 A. Right. I couldn't remember where I</p> <p>24 had gotten the information that there was a</p> <p>25 generator access lid on the top. It is from the</p>
<p style="text-align: right;">Page 19 Page 303</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 A. I don't think that's correct --</p> <p>3 Q. Okay.</p> <p>4 A. -- the fact that it's an opening does</p> <p>5 not mean it's not a side. And that opening is</p> <p>6 connected via the sidewalls to the back side.</p> <p>7 Q. How do sidewalls connect an open side</p> <p>8 to anything?</p> <p>9 A. Let's take a look at the Klein Thesis</p> <p>10 and the pictures. I believe I had it on --</p> <p>11 Q. Yep.</p> <p>12 A. -- 327.</p> <p>13 Q. I think this particular element</p> <p>14 appears at Page 397 to 398, Element 1.1.a of the</p> <p>15 '869 patent.</p> <p>16 A. Understood.</p> <p>17 I'm -- so I'm looking at 327, and I</p> <p>18 noted yesterday --</p> <p>19 Q. Sorry to interrupt.</p> <p>20 The page, 327, or paragraph?</p> <p>21 A. Sorry. Paragraph 327.</p> <p>22 -- I noted yesterday that I didn't</p> <p>23 have the confirmation from the Klein Thesis that</p> <p>24 there was a generator access lid on the top, but</p> <p>25 it's clearly marked from the Klein Thesis in the</p>	<p style="text-align: right;">Page 21 Page 305</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Klein Thesis, not from the Gen 1. And it's from</p> <p>3 his cart, and it shows the generator access lid</p> <p>4 annotated in his thesis.</p> <p>5 Q. Who placed these annotations here?</p> <p>6 A. I believe that's in his thesis.</p> <p>7 Q. Let's -- okay. So I think it's</p> <p>8 Page 24 of the thesis, which . . .</p> <p>9 Keep going after that one.</p> <p>10 A. Which exhibit number?</p> <p>11 MR. WALKER: Exhibit 30.</p> <p>12 THE WITNESS: Exhibit 30, all</p> <p>13 right.</p> <p>14 Sorry. These were --</p> <p>15 BY MS. BOOKBINDER:</p> <p>16 Q. Yeah, they had to unbind them to scan</p> <p>17 them.</p> <p>18 There you go.</p> <p>19 A. Okay.</p> <p>20 Q. So you've got Exhibit 30, the</p> <p>21 Klein Thesis, at Page 24.</p> <p>22 And this is where Figure 2-4 comes</p> <p>23 from?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. So in your report, it looks</p>

<p style="text-align: right;">Page 22 Page 306</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 like some of the labels were removed, and red</p> <p>3 highlighting was added to the generator and</p> <p>4 generator access lid --</p> <p>5 A. I believe that's correct, yes.</p> <p>6 Q. All right. And what is the generator</p> <p>7 access lid label pointing to?</p> <p>8 A. It's pointing to a piece of metal</p> <p>9 that -- its edge begins there in front of a --</p> <p>10 the valve in the motor and extends toward the</p> <p>11 front of the cart.</p> <p>12 Q. Can you identify the boundaries of</p> <p>13 that piece of metal in this picture?</p> <p>14 A. Not completely, because the edges are</p> <p>15 darkened out, so it's impossible to see. But, at</p> <p>16 least, Klein felt that there was a generator</p> <p>17 access lid and labeled that in his thesis.</p> <p>18 Q. When you inspected the Version 1</p> <p>19 system, did you see the generator access lid?</p> <p>20 A. I did. And I wanted to make sure</p> <p>21 that was there. I recall asking the question,</p> <p>22 so -- my memory was foggy yesterday, but now I'm</p> <p>23 remembering I'd seen this and I wanted to make</p> <p>24 sure it was there.</p> <p>25 Q. Did you review any materials since</p>	<p style="text-align: right;">Page 24 Page 308</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 yesterday?</p> <p>3 A. I don't recall.</p> <p>4 Q. Okay. So returning to the question</p> <p>5 of the sidewalls and the front side -- if we</p> <p>6 could get back to that, which was Paragraph 973.</p> <p>7 A. I'm sorry. Paragraph?</p> <p>8 Q. Paragraph 973 on Page 397.</p> <p>9 A. Okay.</p> <p>10 Q. This is Element 1.1.a of the</p> <p>11 '869 patent relating to a specific configuration</p> <p>12 of an exterior shell that has a front side, a</p> <p>13 rear side, and two sidewalls connecting the front</p> <p>14 side to the rear side.</p> <p>15 I understand your opinion is that the</p> <p>16 Klein Thesis discloses that element?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. So then my question is, How do</p> <p>19 sidewalls connect an open space to anything?</p> <p>20 A. There's not just open space -- space</p> <p>21 on that front side; there are lips that fold in</p> <p>22 from either side as well as from the top down</p> <p>23 onto that front side.</p> <p>24 So the open space and the those</p> <p>25 sidewalls make up the front side, those lips, if</p>
<p style="text-align: right;">Page 23 Page 307</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 the deposition ended yesterday, before today, to</p> <p>3 refresh your memory about this?</p> <p>4 A. I looked at the reports that I had,</p> <p>5 yes --</p> <p>6 Q. You looked at --</p> <p>7 A. -- and I found in the report . . .</p> <p>8 Q. So you looked at your opening report</p> <p>9 that --</p> <p>10 A. Yes.</p> <p>11 Q. -- we've been discussing?</p> <p>12 Okay. But I believe you testified</p> <p>13 yesterday that when you inspected the Version 1</p> <p>14 system, the generator access lid was -- no one</p> <p>15 moved it --</p> <p>16 A. That's correct.</p> <p>17 Q. -- correct?</p> <p>18 So to confirm, in this photo, you</p> <p>19 believe this label is pointing to a section --</p> <p>20 not the whole top of the cart but a section of</p> <p>21 the cart that is movable?</p> <p>22 A. I believe that's correct.</p> <p>23 Q. Okay. Was there anything else that</p> <p>24 you discovered from your review of your reports</p> <p>25 last night that needs to be corrected from</p>	<p style="text-align: right;">Page 25 Page 309</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 you would. So those are connected by the</p> <p>3 sidewalls.</p> <p>4 Q. So the side -- are the lips that</p> <p>5 you're referring to part of the sidewalls?</p> <p>6 A. They're folded over just as a</p> <p>7 continuous sheet metal -- piece of sheet metal</p> <p>8 that would fold around could be a front side and</p> <p>9 a back side -- could be a part of it. They're</p> <p>10 extensions of the metal, but they're not on the</p> <p>11 side anymore.</p> <p>12 Q. How far does the metal need to extend</p> <p>13 from the side to be considered a front side?</p> <p>14 A. The front side -- if it folds around</p> <p>15 and extends, it's part of the front side. It's</p> <p>16 not along -- you're -- it might be part of --</p> <p>17 sorry.</p> <p>18 It might be fabricated from the same</p> <p>19 material as the sidewall, but that doesn't mean</p> <p>20 that it is "the sidewall." It has a lip, and</p> <p>21 it's now, you know, on the front side.</p> <p>22 Q. So it's your opinion that if there's</p> <p>23 a piece of material forming the sidewall that --</p> <p>24 that exists, so not an opening but material, like</p> <p>25 sheet metal or something -- and it folds at all</p>

<p style="text-align: right;">Page 26 Page 310</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 by 90 degrees, even 1-millimeter fold, you've now</p> <p>3 created a front side?</p> <p>4 A. I think that's an exaggerated way of</p> <p>5 state -- stating it. Those are obviously on the</p> <p>6 front side and connected to the top side, and</p> <p>7 they fold around to the front side, each of those</p> <p>8 lips that I referred to.</p> <p>9 It's not a miniscule thing. It's</p> <p>10 there, and it's on the front of the device. And</p> <p>11 call it -- saying it's a front side simply</p> <p>12 because it is -- has -- is a hole is a limitation</p> <p>13 that I don't see required.</p> <p>14 Q. Okay. If the sidewalls did not have</p> <p>15 a lip and the top and the bottom did not have a</p> <p>16 lip, then would there be a front side?</p> <p>17 A. They would terminate at the front</p> <p>18 side.</p> <p>19 Q. So the -- in your view, a front side</p> <p>20 could be entirely open?</p> <p>21 A. Yes.</p> <p>22 Q. And the -- so you mentioned that the</p> <p>23 sidewalls bend to make a lip and, also, that the</p> <p>24 top and bottom bend to make a lip?</p> <p>25 A. There's a -- a bottom piece of metal</p>	<p style="text-align: right;">Page 28 Page 312</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 attention to the construction of the sidewalls.</p> <p>3 I observed it, but --</p> <p>4 Q. All right.</p> <p>5 A. -- did not take notes.</p> <p>6 Q. And you can tell from this photo that</p> <p>7 the sidewalls do bend around; they're not simply</p> <p>8 a thick piece of material?</p> <p>9 A. Oh, they're definitely thin pieces of</p> <p>10 material. I was -- I looked inside, saw where</p> <p>11 the lip went backwards. And there was a thin</p> <p>12 piece of metal in the sidewall.</p> <p>13 Q. So did you pay attention to the</p> <p>14 construction on the sidewalls when you reviewed</p> <p>15 the Version 1 device?</p> <p>16 A. You just asked if I was looking at</p> <p>17 the inside and whether it -- looking --</p> <p>18 reflecting back, I know I looked inside, saw that</p> <p>19 there was an empty space between that spot and,</p> <p>20 there, that there was a lip that folded around.</p> <p>21 And whether it was affixed to it with rivets or</p> <p>22 whether it folded around, the smooth corner</p> <p>23 appears to be folded around.</p> <p>24 Q. When you refer to "the smooth</p> <p>25 corner," where in this picture can you see that?</p>
<p style="text-align: right;">Page 27 Page 311</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 that folds down from the -- the base there</p> <p>3 further on the front side, if you look at it</p> <p>4 carefully.</p> <p>5 Q. The -- the bottom folds down or up?</p> <p>6 A. That's hard to say. I'm not sure if</p> <p>7 that's a sliding-out shelf or if it's a -- a</p> <p>8 piece that folds down from the frame. I would</p> <p>9 have to disassemble it to determine.</p> <p>10 But there is a fronting piece of</p> <p>11 metal on the front side at the bottom.</p> <p>12 Q. And that is around the area of where</p> <p>13 the printer appears?</p> <p>14 A. Yes, just forward of the area of the</p> <p>15 printer and the computer.</p> <p>16 Q. I want to make sure we're looking at</p> <p>17 the same picture.</p> <p>18 You're on Page 399 or 398, or</p> <p>19 another -- what page are you on?</p> <p>20 A. I'm on 399.</p> <p>21 Q. 399.</p> <p>22 Okay. When you reviewed the</p> <p>23 Version 1 device, did you observe the -- the</p> <p>24 construction of the sidewalls?</p> <p>25 A. I did not pay a great deal of</p>	<p style="text-align: right;">Page 29 Page 313</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 A. The smooth corner's at -- on the</p> <p>3 left-hand side. It appears to be a smooth corner</p> <p>4 that's folded around, and it's a -- a normal</p> <p>5 means of construction.</p> <p>6 Q. And you're -- are you referring to</p> <p>7 the -- the -- what appears in this photo on</p> <p>8 Page 399 to be the top left corner, so above and</p> <p>9 to the left of what appears to be a keyboard on</p> <p>10 the shelf? Is that the smooth corner?</p> <p>11 A. I would say left and extending up to</p> <p>12 the top, there are folded-over lips on each of</p> <p>13 those sides, in my opinion.</p> <p>14 Q. On all four corners of the -- the</p> <p>15 perspective of the cart that we got in this</p> <p>16 photo?</p> <p>17 A. That's what it appears.</p> <p>18 Q. Okay.</p> <p>19 A. And regardless, there is material on</p> <p>20 the front that is connected via sidewalls to the</p> <p>21 back.</p> <p>22 Q. And to be clear, it's your opinion</p> <p>23 that that material on the front is a disclosure</p> <p>24 of the front side in the patent claims?</p> <p>25 A. That material in the front is on the</p>

<p style="text-align: right;">Page 30 Page 314</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 front side of the cart.</p> <p>3 Q. I believe you testified yesterday,</p> <p>4 also, that in your opinion, a cabinet structure</p> <p>5 can have an open side, right?</p> <p>6 A. I did.</p> <p>7 Q. Okay. How do you define the boundary</p> <p>8 of the inner space of the cabinet structure that</p> <p>9 you say is disclosed in the Klein Thesis from the</p> <p>10 surrounding area?</p> <p>11 A. I would assume that it stops -- no.</p> <p>12 I'm back to making an assumption.</p> <p>13 I would define it as stopping when it</p> <p>14 reaches the boundary of the front side.</p> <p>15 Q. How do you define the boundary of the</p> <p>16 front side?</p> <p>17 A. You stop having more material out</p> <p>18 front -- front.</p> <p>19 Q. What if you are in a space where</p> <p>20 there is no material, for example, again, in this</p> <p>21 Figure 2-3 from the Klein Thesis, the area where</p> <p>22 the -- it looks like a computer mouse is sitting</p> <p>23 on the middle shelf?</p> <p>24 Is that --</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 32 Page 316</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 the edges, where is the boundary of the interior</p> <p>3 space for that mouse?</p> <p>4 A. It's sitting in the interior space on</p> <p>5 a shelf that's enclosed within the cart.</p> <p>6 Q. And where does the space end if you</p> <p>7 were moving in the -- in the front direction --</p> <p>8 if you're moving towards what you say is the</p> <p>9 front side, doesn't an interior space need to</p> <p>10 have a boundary?</p> <p>11 A. Why?</p> <p>12 Q. What defines an interior space from</p> <p>13 the rest of the atmosphere?</p> <p>14 A. It's enclosed by the edges of the --</p> <p>15 of the cart.</p> <p>16 Q. So it's your view that the space is</p> <p>17 enclosed even though a side is open?</p> <p>18 A. I didn't say that. I said the space</p> <p>19 is enclosed by the edges of the cart, not that</p> <p>20 the cart is necessarily closed.</p> <p>21 Q. Sure, you're right. I misspoke about</p> <p>22 that.</p> <p>23 So the interior space is enclosed by</p> <p>24 the edges?</p> <p>25 A. I would call it interior so long as</p>
<p style="text-align: right;">Page 31 Page 315</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Q. Okay. So there is no material in the</p> <p>3 front direction in front of the computer mouse on</p> <p>4 the middle shelf, right?</p> <p>5 A. That shelf, if you look at it, is a</p> <p>6 pullout shelf. It's a shelf; it's not part of</p> <p>7 the exterior portion of the cabinet.</p> <p>8 So I'm not sure that your -- what</p> <p>9 your question is pointing at.</p> <p>10 Q. Sure.</p> <p>11 So I'd like to understand -- so this</p> <p>12 same claim element, 1.1.a, that is reproduced on</p> <p>13 Page 397, we were focusing on the first part</p> <p>14 about the sidewalls and such. The element</p> <p>15 continues to state, Wherein the platform and the</p> <p>16 exterior shell collectively defined an interior</p> <p>17 space of the cabinet structure.</p> <p>18 So I'd like to understand your</p> <p>19 opinion that this device has an interior space</p> <p>20 and what the boundaries of that interior space</p> <p>21 are in the Klein Thesis.</p> <p>22 A. The boundaries of the interior space</p> <p>23 are the edges of the front of the -- the cabinet.</p> <p>24 Q. And then in the example of the</p> <p>25 location of the mouse, which is not near any of</p>	<p style="text-align: right;">Page 33 Page 317</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 it's enclosed by the edges. I would not call it</p> <p>3 interior at that point if it goes -- extends</p> <p>4 beyond the edges.</p> <p>5 Q. And that is your opinion even though</p> <p>6 the edges are exactly what they -- what you said,</p> <p>7 edges.</p> <p>8 They do not extend across the</p> <p>9 entirety of the front side; they are only edges?</p> <p>10 A. That's correct.</p> <p>11 Q. Okay. We began to talk yesterday</p> <p>12 about the Bracco Manual, which is Exhibit 31.</p> <p>13 The -- in your opinion, the</p> <p>14 Bracco Manual does not anticipate any of the</p> <p>15 asserted claims, right? It does not contain</p> <p>16 every element of any of the asserted claims?</p> <p>17 A. I believe that's correct.</p> <p>18 Q. Okay. And the CardioGen-82 system</p> <p>19 that you expected and photographed also does not</p> <p>20 anticipate any of the asserted claims, right?</p> <p>21 A. I -- I believe that is correct.</p> <p>22 Q. Okay. And yesterday, you testified</p> <p>23 that it was a case-by-case basis in your report</p> <p>24 to understand whether you're relying on the</p> <p>25 CardioGen-82 system that you inspected or the</p>

<p style="text-align: right;">Page 34 Page 318</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Bracco Manual for your obviousness opinion,</p> <p>3 right?</p> <p>4 A. I believe that we cite the</p> <p>5 Bracco Manual in all of those instances.</p> <p>6 Q. I think, yesterday, we went through</p> <p>7 the exercise of tracking back where you cited an</p> <p>8 internal paragraph for CardioGen-82, and it was</p> <p>9 actually a photograph of the system rather than a</p> <p>10 page of the manual.</p> <p>11 I think that is when you said it's</p> <p>12 case by case that we need to check each citation.</p> <p>13 Does that sound right?</p> <p>14 A. That sounds right --</p> <p>15 Q. Okay.</p> <p>16 A. -- I'd like to do a readback, but</p> <p>17 that sounds like we used it to verify that what</p> <p>18 was in the manual was accurate.</p> <p>19 Q. What do you mean by that?</p> <p>20 A. Well, we looked at the manual to see</p> <p>21 what was there, to see if it was an accurate</p> <p>22 description, as well as our photographs, and used</p> <p>23 that as the basis, I believe, is how I've done</p> <p>24 that.</p> <p>25 Again, look at my -- if you'd cite</p>	<p style="text-align: right;">Page 36 Page 320</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Q. All right. So separate and apart</p> <p>3 from how the FDA may consider all of these things</p> <p>4 in a bundle together with respect to the patent</p> <p>5 analysis, where we need to identify specifically</p> <p>6 each prior art reference that you're relying on,</p> <p>7 you are relying on a combination of the device as</p> <p>8 a physical thing and the manual for your opinion</p> <p>9 that the claims are obvious?</p> <p>10 A. I rely on the CardioGen-82 system as</p> <p>11 prior art, and I substantiate the things that</p> <p>12 I've done by looking at the manual and</p> <p>13 referencing it to demonstrate that that device</p> <p>14 was prior art.</p> <p>15 Q. So I think, then, that takes us back</p> <p>16 to the discussion yesterday, that it just depends</p> <p>17 on what you cite for each element?</p> <p>18 A. Let's go element by element and see</p> <p>19 what's there.</p> <p>20 Q. All right. So if we go to</p> <p>21 Paragraph -- on the same page -- 1668.</p> <p>22 And you discuss the CardioGen-82</p> <p>23 Infusion System in that paragraph, right?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. But then the next page, the</p>
<p style="text-align: right;">Page 35 Page 319</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 some particular instance, I'd be glad to go over</p> <p>3 it with you.</p> <p>4 Q. Sure. So let's turn to Page 605 of</p> <p>5 your report.</p> <p>6 And this is the first page of your</p> <p>7 opinions regarding the asserted claims being</p> <p>8 obvious in view of a CardioGen reference.</p> <p>9 In the title of this section, All</p> <p>10 Asserted Claims are Rendered Obvious by the</p> <p>11 CardioGen-82 Infusion System, which reference or</p> <p>12 combination of references are you referring to?</p> <p>13 The Bracco Manual, the CardioGen device or both?</p> <p>14 A. Infusion system, as defined by the</p> <p>15 FDA as a product, is the device itself, all of</p> <p>16 its accessories and labeling.</p> <p>17 So trying to separate to say it's</p> <p>18 just what we looked at is the cart versus the</p> <p>19 label -- those are one and the same, as far as</p> <p>20 the FDA is concerned. And they describe the</p> <p>21 entire system.</p> <p>22 So it's completely acceptable to use</p> <p>23 either one of those and be, at least with regard</p> <p>24 to one Government agency, discussing the same</p> <p>25 thing.</p>	<p style="text-align: right;">Page 37 Page 321</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 figure that's described in Paragraph 1668 is</p> <p>3 actually from the Bracco Manual, right?</p> <p>4 A. That's correct.</p> <p>5 Q. So can we be sure that your citations</p> <p>6 to infusion system are the device and citations</p> <p>7 to the manual are the manual, or are -- do you</p> <p>8 use them interchangeably? I -- I just want to be</p> <p>9 sure we understand --</p> <p>10 MR. WALKER: I think this had been</p> <p>11 asked and answered. I really do. I think</p> <p>12 he said that -- go through, see what he</p> <p>13 cites; that's what he relies on --</p> <p>14 MS. BOOKBINDER: Sure.</p> <p>15 Well, I'd like to ask him about</p> <p>16 this specific citation at Paragraph 1668.</p> <p>17 MR. WALKER: And he told you.</p> <p>18 I mean, it says it right there,</p> <p>19 right --</p> <p>20 MS. BOOKBINDER: Well, I --</p> <p>21 MR. WALKER: -- I don't understand</p> <p>22 where you're going.</p> <p>23 MS. BOOKBINDER: -- I'd like to</p> <p>24 hear it from -- from Dr. Stone to</p> <p>25 understand --</p>

<p style="text-align: right;">Page 38 Page 322</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 MR. WALKER: He told you.</p> <p>3 MS. BOOKBINDER: -- what his -- his</p> <p>4 --</p> <p>5 MR. WALKER: It's asked and</p> <p>6 answered.</p> <p>7 MS. BOOKBINDER: -- evidence is.</p> <p>8 THE WITNESS: I said I rely on the</p> <p>9 Bracco system, 82, and that I use the</p> <p>10 manual as illustrations to what's in the</p> <p>11 thing. Because it would be quite</p> <p>12 difficult to take a picture and show all</p> <p>13 of those components at once, whereas the</p> <p>14 manual and the literature that backed it</p> <p>15 up have been available for quite some</p> <p>16 time.</p> <p>17 There's no reason to suspect that</p> <p>18 the manual is inaccurate in portraying</p> <p>19 what was in the device. It makes it</p> <p>20 clear.</p> <p>21 BY MS. BOOKBINDER:</p> <p>22 Q. What literature are you referring to?</p> <p>23 A. The manual.</p> <p>24 Q. I think -- you said the -- the manual</p> <p>25 and the literature that backs it up. I want to</p>	<p style="text-align: right;">Page 40 Page 324</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 you what it is.</p> <p>3 Q. All right.</p> <p>4 And then in the last paragraph of</p> <p>5 this element, Therefore, it is my opinion that</p> <p>6 the CardioGen-82 Infusion System teaches the</p> <p>7 subject matter, you do not have an additional</p> <p>8 paragraph like we saw yesterday in your</p> <p>9 discussion of the Klein Thesis of other</p> <p>10 references redundantly teaching something.</p> <p>11 And I don't believe I saw a paragraph</p> <p>12 like that in any of your CardioGen discussion.</p> <p>13 Do you know if that's accurate?</p> <p>14 A. Let's go -- I want to go paragraph by</p> <p>15 paragraph. I don't remember every citation in</p> <p>16 this -- in this particular case.</p> <p>17 Q. Do you know why, at least in the</p> <p>18 elements that we have looked at so far in your</p> <p>19 discussion of CardioGen, you do not have the</p> <p>20 additional discussion of, you know, redundant</p> <p>21 references in the CardioGen section?</p> <p>22 A. Because in building a case for</p> <p>23 obviousness, not every element of every claim has</p> <p>24 to be in each of the references.</p> <p>25 So we use the particular key</p>
<p style="text-align: right;">Page 39 Page 323</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 understand --</p> <p>3 A. Sorry. I haven't -- I don't -- I</p> <p>4 haven't cited to other literature --</p> <p>5 Q. Okay.</p> <p>6 A. -- but there would be other</p> <p>7 literature available.</p> <p>8 So let's ignore the other literature</p> <p>9 and just stay with the manual.</p> <p>10 Q. Sure thing.</p> <p>11 Let's go to Paragraph 1793.</p> <p>12 So this is Element 1.0 of Claim 1 of</p> <p>13 the '826 patent, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Okay. And you're giving the</p> <p>16 opinion that CardioGen-82 discloses the subject</p> <p>17 matter. You describe it as an "infusion system"</p> <p>18 and cite the manual.</p> <p>19 So we understand, here, you're</p> <p>20 relying on the manual, right? It says what it</p> <p>21 says?</p> <p>22 A. It says what it says --</p> <p>23 Q. Okay.</p> <p>24 A. -- the manual describes what the</p> <p>25 system is, whereas the system doesn't really tell</p>	<p style="text-align: right;">Page 41 Page 325</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 component; in this case, the Bracco Rb-82. And</p> <p>3 where it's needed to show that something else</p> <p>4 makes it obvious, we add that.</p> <p>5 Q. But you didn't -- with respect to the</p> <p>6 CardioGen-82 section, you did not believe that</p> <p>7 you needed these redundant references that you</p> <p>8 needed in the Klein Thesis section?</p> <p>9 MR. WALKER: Objection.</p> <p>10 Again, I don't think he ever said</p> <p>11 he needed them --</p> <p>12 THE WITNESS: I never said --</p> <p>13 right. I never said I needed those; I</p> <p>14 made a statement.</p> <p>15 BY MS. BOOKBINDER:</p> <p>16 Q. Okay. If you -- if you didn't need</p> <p>17 them in the Klein Thesis, why did you include</p> <p>18 them?</p> <p>19 A. Supporting material; only that.</p> <p>20 Q. Okay. You discussed yesterday that</p> <p>21 the CardioGen-82 system and Bracco Manual --</p> <p>22 neither of them disclose a computer, right?</p> <p>23 A. Excuse me. The manual is a part of</p> <p>24 the system. I don't see a differentiation here.</p> <p>25 The system con -- consists of several components</p>

<p style="text-align: right;">Page 42 Page 326</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 in order to be operable. The manual is part of</p> <p>3 the system --</p> <p>4 Q. Okay.</p> <p>5 A. -- so that's a differentiation that</p> <p>6 should not be made.</p> <p>7 Q. Well, as your counsel pointed out,</p> <p>8 you cite -- you make very specific citations in</p> <p>9 your report. So I want to use the citations that</p> <p>10 you have made and to have a clear record about</p> <p>11 this.</p> <p>12 So I'll go ahead with the question</p> <p>13 of -- to confirm we discussed yesterday, neither</p> <p>14 the system that you viewed and photographed nor</p> <p>15 the manual disclose a computer, right?</p> <p>16 A. They do not.</p> <p>17 Q. Okay.</p> <p>18 And for those claim elements that</p> <p>19 require computers, your opinion that one a person</p> <p>20 of ordinary skill would look to other references</p> <p>21 to meet that claim element, right?</p> <p>22 A. A person of ordinary skill would</p> <p>23 use -- look to other references, plus the</p> <p>24 knowledge of a person of ordinary skill in the</p> <p>25 art at the time of the inventions that we're</p>	<p style="text-align: right;">Page 44 Page 328</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Q. Okay. So is that something that</p> <p>3 should be corrected in this section of your</p> <p>4 report?</p> <p>5 A. The Klein Thesis discloses the</p> <p>6 components that would be necessary to do so. He</p> <p>7 doesn't actually track the volume of saline</p> <p>8 remaining; however, he does teach components that</p> <p>9 would be utilized in that, and it would be</p> <p>10 obvious to a person of skill in the art to</p> <p>11 combine that.</p> <p>12 Q. And, actually, you do point it out</p> <p>13 here in Paragraph 2034, at the top of Page 739:</p> <p>14 The Klein Thesis does not identify the volume of</p> <p>15 saline remaining in the saline reservoir as one</p> <p>16 of those alerts.</p> <p>17 So why are you looking to the</p> <p>18 Klein Thesis to combine with CardioGen for a</p> <p>19 limitation about tracking volume of saline</p> <p>20 remaining?</p> <p>21 A. Again, CardioGen doesn't have a</p> <p>22 computer; it doesn't have a touchscreen. Klein</p> <p>23 did. He tracked volumes that were actually going</p> <p>24 into other applications, so he could have readily</p> <p>25 tracked the total remaining volume. It would be</p>
<p style="text-align: right;">Page 43 Page 327</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 referring to, would certainly look to a computer</p> <p>3 to solve a problem instead using a programmable</p> <p>4 logic array.</p> <p>5 Q. Okay. Specifically, if we can talk</p> <p>6 about claim elements relating to tracking the</p> <p>7 volume of saline. We can turn to Paragraph 2023.</p> <p>8 It's Element 11.3 of the '826 patent.</p> <p>9 A. Yes.</p> <p>10 Q. So this is one of the computer</p> <p>11 elements where a computer is not disclosed by</p> <p>12 CardioGen, so you make a combination with the</p> <p>13 Klein Thesis, Duchon and Tate; is that correct?</p> <p>14 A. Give me a moment to look.</p> <p>15 Q. Um-hum.</p> <p>16 (Whereupon, the witness reviews the</p> <p>17 material provided.)</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MS. BOOKBINDER:</p> <p>20 Q. Now, yesterday you testified that the</p> <p>21 Klein Thesis itself does not teach the tracking</p> <p>22 of volume of saline.</p> <p>23 Do you recall that?</p> <p>24 A. The remaining volume of saline, it</p> <p>25 did not.</p>	<p style="text-align: right;">Page 45 Page 329</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 obvious to a person of skill in the art to add</p> <p>3 that feature to Klein based on the other prior</p> <p>4 art that we cite.</p> <p>5 Q. So you were looking to Klein for the</p> <p>6 computer and the touchscreen and the certain</p> <p>7 amount of tracking ability, though not for this</p> <p>8 specific component?</p> <p>9 A. It had the ability; it did not add</p> <p>10 that feature.</p> <p>11 Q. So then you move on after Klein to</p> <p>12 discuss an international standard as well as</p> <p>13 Tate, the Medrad Intego manual and Duchon, right?</p> <p>14 This is how your report continues?</p> <p>15 A. I'll read all of this, if you want</p> <p>16 to, and find it, or you can point me to. It is</p> <p>17 your choice.</p> <p>18 Q. It's just as we continue through this</p> <p>19 one claim element --</p> <p>20 A. Yep.</p> <p>21 Q. -- and in Paragraph 240 [sic], you</p> <p>22 conclude, It is my opinion that the</p> <p>23 CardioGen-82 Infusion System, when modified as</p> <p>24 taught by the prior art, meets this subject</p> <p>25 matter.</p>

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2 Right?

3 A. I do.

4 Q. So what specific modifications are
5 you suggesting be made to the CardioGen-82 system
6 based on the four -- five other prior art
7 references that are discussed in this section of
8 your report?

9 A. Well, for example, even the
10 CardioGen-82, had it had a -- a computer with a
11 touchscreen, it always withdrew a given volume
12 via a syringe and then pumped that volume out.
13 It would be trivial for a person of skill in the
14 art to track the total amount of volume that had
15 been extracted from the saline bag and know what
16 the remainder is based on the initial volume of
17 the bag; that's a simple computational factor
18 that could be -- that could have been done.

19 Q. But that's not the opinion you gave,
20 that CardioGen could be modified by just the
21 knowledge of skill in the art. You added five
22 additional references in the section of your
23 report, right?

24 A. To demonstrate that a person of skill
25 in the art would readily do that, yes.

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2 Q. And to be clear, are you giving the
3 opinion that CardioGen needs to be combined with
4 all five of those references to reach the claim
5 element that we're talking about, or is it a
6 pick-and-choose situation?

7 I would like to understand --

8 MR. WALKER: Objection: compound.

9 BY MS. BOOKBINDER:

10 Q. -- the actual combination that you're
11 proposing.

12 A. There's more than one combination.
13 Each of those systems that we talk about have a
14 tracking volume. [REDACTED]

15 [REDACTED]
16 [REDACTED]
17 These are simply additional pieces of
18 information that demonstrate what a person of
19 skill in the art would have known at the time,
20 and would readily have used almost any one of
21 those or been motivated to combine those in order
22 to come up with a -- a system that would track
23 that saline volume. There's a standard that says
24 it should be done. There are devices that
25 actually do it. It would have been obvious to do

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 so.

3 Q. Okay. So -- go ahead. Are you --

4 A. I'm done.

5 Q. Okay. So I'd like to break down
6 the -- you say there -- there's more than one
7 combination.

8 So is it your opinion that
9 CardioGen-82 and the Klein Thesis, just those two
10 together, would meet an 11.3 of the '826 patent?

11 A. No.

12 As I've said, the Klein Thesis did
13 not track the volume remaining in the thesis --
14 or in the device, but it could've -- in the
15 saline source, but it could've done so readily.

16 Q. Okay. So, then, is it your opinion
17 that CardioGen-82 and [REDACTED]
18 [REDACTED] those two references together, would meet
19 Element 11.3?

20 A. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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2 I believe you made a claim. You're
3 trying to break it down as though there was just
4 one of those that I need to combine or maybe one
5 or two. It's a complete grouping of disclosures
6 here -- or descriptions that form my opinion that
7 says it would be obvious to one of skill in the
8 art to make the modifications that have been
9 referenced to perform that function.

10 Q. I think as -- as your report reads,
11 it suggests that all five references need to be
12 combined, because of your conclusion paragraph in
13 the section that when CardioGen is modified as
14 taught by the prior art meets the subject matter.

15 So if your opinion is that it's all
16 five, then I understand that; if that is not your
17 opinion, then I would like to understand
18 specifically what combinations led to your
19 conclusion in Paragraph 2040.

20 A. I think we made it very clear. Klein
21 has the computer and touchscreen. The
22 international standard, IEC 62366, requires the
23 user to be aware of the amount of consumables
24 remaining in a medical device. That's a reason
25 at the time of this invention that a person of

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 skill in the art would have known to attempt to
3 do so.
4 Combining that with Tate, which
5 demonstrates how much is available, would have
6 satisfied that. Combining that or being
7 motivated by Duchon discloses allowing the
8 user -- alerting the user when a volume of saline
9 remains is below a predetermined level, so he has
10 to know what the level is.

11 And [REDACTED]

[REDACTED]

14 They're not all required. They all
15 demonstrate that a person of skill in the art
16 would know to do so.

17 [REDACTED]

[REDACTED] Though he doesn't
19 necessarily say a computer touchscreen. I don't
20 recall that. But I do know that Klein does have
21 a computer touchscreen.

22 So it was obvious to a person of
23 skill in the art to make the modification to
24 track. And as I said, it would simply be a
25 software modification in Klein.

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 Q. Okay. So to understand the
3 combination, you got CardioGen-82, which uses
4 saline to perform an elution; you are combining
5 with the Klein Thesis, which has the computer and
6 touchscreen, in view of the IEC 62366 that gives,
7 in your view, a person of skill in the art a
8 reason to attempt to track a volume of saline
9 remaining; and then you would go to one of Tate
10 or Duchon or [REDACTED] to accomplish
11 Claim Element 11.3 of tracking the volume of
12 saline remaining in the CardioGen system and
13 providing an alert?

14 A. I believe what I said was that if I
15 look at Klein, his system had the capability,
16 though it was not implemented, because of the use
17 of a constant -- I'm sorry -- of a metered
18 pump -- that is, the peristaltic pump -- and he
19 actually tracked volumes for other purposes. He
20 simply did not track the volume remaining.

21 If I combined Klein with the
22 international standard, I would have all that I
23 needed to have -- to do, I would -- and it would
24 be obvious to make that change.

25 Others had already made tracking of

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 the volume a part of their systems. It just
3 shows, again, that a person of skill in the art
4 would have known to do that.

5 So you're asking if it's necessary.
6 Any one of those would have been -- would have
7 demonstrated the -- that it could have been
8 modified to do that.

9 Q. Okay.

10 So, again, to understand the
11 combination that you're pointing to, you've got
12 CardioGen-82; in view of the Klein Thesis with
13 the computer and touchscreen and, in your view,
14 the capability to do certain things; and then the
15 IEC standard.

16 So it's those three references, in
17 your opinion, combined meet Element 11.3?

18 A. That's one combination.

19 Q. Okay. And, then, what is the next
20 combination that you are relaying on this element
21 in your report?

22 MR. WALKER: I think he's
23 explained this --

24 THE WITNESS: I've explained this
25 several times.

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2 THE COURT REPORTER: Hold on, sir.
3 Sorry?

4 MR. WALKER: Objection: asked and
5 answered.

6 THE WITNESS: You're trying to
7 break it down as though there's separate
8 items. These are -- all, in combination,
9 indicate an awareness, means of doing it,
10 that people were doing to and that it's
11 motivated to do. And I demonstrated at
12 least one way that it could easily be done
13 just with the hardware of Klein.

14 BY MS. BOOKBINDER:

15 Q. Okay. Let's go to Claim 13, which is
16 at Paragraph 2087.

17 Yeah.

18 So the CardioGen system that you saw
19 and the Bracco Manual do not disclose an infusion
20 system configured for the saline tubing line and
21 the eluate tubing line to be routed through two
22 tubing passageways formed in a perimeter surface
23 of the first opening, wherein each of the two
24 tubing passageways has a depth configured to
25 prevent pinching or crushing of a corresponding

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 the tubing and fishing it out would be less

3 ergonomic, less easy to do than would having a

4 circuitous routing that a lid could close down,

5 and once you have a lid closed down, you have a

6 risk of pinching.

7 Q. So making a change to the circuitous

8 path also adds the pinching issue?

9 A. No. Not having a circuitous path

10 that's a trough would have a pinching issue.

11 Q. So I'm not sure I'm -- I'm opining

12 you here. We were talking about being in the

13 column wouldn't have pinching because there's not

14 a lid, but you said it could kink at the bend; is

15 that --

16 A. Kink at the bend or wherever you put

17 the lid on it if you don't have a path that makes

18 sure the tubing stays in place while the lid is

19 closed, because you've got to put it down from

20 the top somehow.

21 Q. Where is the lid in the -- in the

22 configuration that you're describing?

23 A. Well, if you look at the -- there's a

24 path from the syringe pump that goes down. You

25 have a shielded syringe pump on the --

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 Q. I'm sorry, Dr. Stone --

3 THE COURT REPORTER: I'm sorry.

4 You have a what?

5 BY MS. BOOKBINDER:

6 Q. -- what page are you? I'm sorry.

7 A. I'm sorry.

8 If I go over to the Bracco Manual,

9 and if you look at the diagram that we have of

10 the Bracco Manual, there is the Hanger 4 -- I'm

11 on Page 6 -- 764 or 765, the same diagram,

12 without being a flow diagram.

13 So you have a shielded area for the

14 syringe pump that over -- overlies the column

15 where the tubing goes down to the generator and

16 back up from the generator, and that all needs to

17 be shielded. You have to run the tubing through

18 that. There's no path that holds it. There's

19 the weight of the tubing. To me, that's not a

20 very ergonomic way of doing it, and it's all

21 doing linear shielding.

22 Tate shows a manner that I believe is

23 superior to that, and that is troughs in the

24 shielding for the tubing to go through, which

25 will prevent -- which provides adequate shielding

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 and yet prevents kinking --

3 Q. What do you mean by --

4 A. -- and pinching.

5 Q. -- "linear shielding"?

6 A. It means there's a source and there

7 is a path to the outside where one could get

8 exposed without it going -- following a

9 circuitous path, straight-line shielding.

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 Q. Sure. So you -- you gave an opinion

20 in your report that we've discussed that a person

21 of ordinary skill would modify the CardioGen-82

22 in view of Tate to meet Claim 13 because it's

23 your view that the trough layout is superior to

24 the CardioGen layout.

25 Have I captured that correctly?

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2 A. I believe that's correct.

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 Q. We spoke a fair amount about the

11 doors in '869, Claim 1, yesterday with respect to

12 the Klein Thesis.

13 I understand from your report it's

14 also your opinion that the CardioGen-82 system or

15 manual lids meet that same claim element?

16 A. Yes.

17 Q. All right. And then let's look at

18 that opinion which begins at Paragraph 2255 on

19 Page 821.

20 So we're at Element 1.3 of the '869

21 patent. And to confirm, you explain from the

22 CardioGen-82 system and Bracco Manual that it has

23 a lid, right?

24 A. Yes.

25 Q. Then you continue, on the next page,

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 that it would be obvious, in view of Tate, to

3 have a door to meet that limitation, right?

4 A. Yes.

5 Q. All right. Why would a person of

6 ordinary skill be prompted to change the

7 CardioGen-82 design, which you believe has a lid

8 that meets the door limitation, to have the Tate

9 configuration?

10 A. Tate does meet the limitation. The

11 Bracco 82, in my opinion, does with its lid. If

12 one argues that it does not, then Tate certainly

13 discloses that. So in view of Tate, then one

14 would certainly meet that limitation of having a

15 lid which -- through which one could vertically

16 access the components under discussion.

17 Q. So is this an opinion similar to what

18 we discussed yesterday in the Klein Thesis, that

19 you would at the hearing, for example, present

20 both opinions to the Judge as equally valid

21 obviousness opinions?

22 A. I believe they're equally valid, yes.

23 Q. And to be clear, it's CardioGen-82 by

24 itself or Tate by itself or CardioGen-82 in view

25 of Tate?

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2 A. If one rejects the concept that a lid

3 is a door, then Tate certainly supplies the

4 answer. And it would be obvious to combine Tate

5 with the CardioGen-82. And that's 2261. My

6 opinion is that the CardioGen-82 Infusion System,

7 when modified as taught by the prior art, meets

8 this subject matter.

9 Q. And when you say "prior art" in 2261,

10 you're referring to Tate in the preceding

11 paragraphs?

12 A. I am.

13 Q. Okay. And this -- this is another

14 example where you have discussed a couple of

15 references, and you gave an explanation, for

16 example, on Paragraph 2260 why, in your view, a

17 person would combine them, but you do not include

18 similar language to the Klein Thesis section of

19 other references that "redundantly teach"

20 something?

21 A. I didn't say the same words; that's

22 correct.

23 Q. And now that we have seen a few

24 elements from the CardioGen-82 section, do you

25 feel confident that you don't use that

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 "redundantly teach" language in this section?

3 A. No --

4 Q. Okay.

5 A. -- I'm not confident that I don't use

6 that.

7 Q. Okay. And you don't recall, one way

8 or another, without going through the elements?

9 A. No, I do not.

10 Q. Okay. If you recall yesterday, when

11 we spent some time in the Klein Thesis

12 section talking about the doors at length, you

13 pointed to Klein Thesis itself as well as Tate,

14 and then you also had [REDACTED]

15 [REDACTED]

16 Do you recall that?

17 A. Yes.

18 Q. Okay. [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 Q. Is there -- what -- what is the

23 reason that you use it in the Klein Thesis and

24 not in CardioGen for the same limitation?

25 A. No particular reason. I think we had

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 adequate information presented here.

3 Q. So it -- it's your understanding --

4 you were instructed by counsel in the beginning

5 of your report -- and we can take a look -- of

6 certain legal premises that you needed to apply?

7 A. Yes.

8 Q. And, specifically, why don't we look

9 at Paragraph 37?

10 And this paragraph comes under a

11 header above Paragraph 34 for Obviousness, right?

12 A. Yes.

13 Q. Okay. So in Paragraph 37, you give

14 your understanding that in making a combination

15 of references for obviousness, there needs to be

16 a reason to prompt a person of ordinary skill to

17 combine the references, right?

18 A. Yes.

19 Q. Okay. And you applied that premise

20 in your obviousness analysis?

21 A. Yes.

22 Q. Okay. And in addition, at

23 Paragraph 38, you explain your understanding that

24 to find the invention obvious in light of a prior

25 art combination, the prior art combination must

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 that's not an inventive step.

3 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

8 [REDACTED]

9 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

22 Q. Okay. Did the system described in
23 the Klein Thesis -- if it was built as described
24 with an offboard dose calibrator, would it have
25 worked as intended?

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 MR. WALKER: Objection: vague.

3 THE WITNESS: What do you mean by

4 "worked as intended"?

5 BY MS. BOOKBINDER:

6 Q. Well, could you refresh me on what

7 the dose calibrator was used for in the

8 Klein Thesis -- the offboard dose calibrator?

9 A. It was used to determine, A, the

10 accuracy of the onboard radiation detector that

11 was utilized to actually administer a dose; and,

12 B, it was utilized to determine Strontium

13 breakthrough to determine if the level of

14 Strontium compared to the level of Rubidium was

15 exceeding the threshold.

16 Q. Okay. And if someone actually built

17 a system as described in the Klein Thesis with

18 that offboard dose calibrator, would the system

19 have -- have worked and would the dose calibrator

20 have performed the functions that you described?

21 A. Again, the Klein Thesis was a

22 prototype; it was not a product. Apparently,

23 other systems were built that were very similar,

24 the so-called Version 1. Apparently, it worked.

25 So I don't have to speculate. Apparently, it

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 worked and was utilized.

3 Q. And then what would prompt a person

4 of skill in the art to go through all this

5 trouble with adding lead and cost and weight to

6 move the dose calibrator onboard?

7 A. If you look -- we have the

8 motivations to combine that we've spoken of.

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 There would be motivation to combine

14 in order to be similar to the devices that were

15 utilized -- that were still being utilized in

16 those departments.

17 Is it an engineering challenge? Yes.

18 But it's not an inventive challenge. You're just

19 dealing with weight and shielding.

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 Q. My question is a little different,

25 why someone would go through all of this trouble

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 to put the --

3 MR. WALKER: Objection --

4 BY MS. BOOKBINDER:

5 Q. -- dose calibrator onboard.

6 MR. WALKER: -- characterization.

7 THE WITNESS: What I said was, in

8 general, what she stated was that she had

9 known of other PET systems and that theirs

10 looked old fashioned compared to it; that

11 it was even commented on by -- by users.

12 And, yes, that initial question was

13 relating to computers and the look but

14 also the convenience of having an onboard

15 calibrator rather than to have to position

16 the cart at one location to do daily

17 calibration and breakthrough testing, as

18 opposed to having it all on a cart. It's

19 a convenience factor.

20 MR. WALKER: Excuse me. I said

21 characterization, not speculation. Sorry.

22 THE COURT REPORTER: You have to

23 let him finish, though.

24 THE WITNESS: I'm sorry.

25 THE COURT REPORTER: Thank you.

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2 BY MS. BOOKBINDER:

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 Q. Okay. So other than Ms. Gelbach and

10 that invention at that time, do you have any

11 other evidence that someone of skill in the art

12 who was not the inventor would have been prompted

13 to move a dose calibrator onboard?

14 A. I believe we referenced other PET

15 products that had a dose calibrator onboard. So,

16 yes, a person of skill in the art would be

17 motivated to do so.

18 Q. What are the other PET products that

19 had a dose calibrator onboard?

20 A. [REDACTED]

21 [REDACTED] we have the Tate patent.

22 Q. And both the [REDACTED] and the

23 Tate patent are directed toward FDG systems, not

24 elution systems with a generator, right?

25 A. They directed toward PET imaging

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 using the same energy and using
3 radiopharmaceuticals. They simply do not have
4 the generator as their source; they have a
5 predeveloped isotope and injected material as
6 their source.

7 Q. And because they don't have a
8 generator and they have the predeveloped source,
9 they don't need the dose calibrator to perform
10 breakthrough tests, right?

11 A. No; they need it to perform the
12 accuracy test for their radiation measuring
13 device during administration of the
14 radiopharmaceutical.

15 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2

3

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2

[REDACTED]

10 Q. You testified -- I think yesterday --
11 in your view, that computerizing processes that
12 were already being done is not patentable, right?

13 A. I believe I referred -- I -- to a --
14 in the patent -- sorry -- the patent history
15 file for some of the patents that one of the --
16 they were told that by someone in the Patent
17 Office.

18 Q. Okay. Do you agree with that
19 statement from the Patent Office?

20 A. I believe that that is a valid way of
21 looking at things, yes, that that's -- certainly
22 today, that's obvious to do.

23 - - -
24 (Stone Deposition Exhibit Number 37,
25 Patent Application Publication

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 Number US 2015/0228368 A1, Bates
3 stamped BRACCOITC00633522 through
4 BRACCOITC00633547, marked for
5 identification, as of this date.)

6 - - -
7 - - -
8 (Stone Deposition Exhibit Number 38,
9 Office Action Response for
10 Application 14/426,208, Bates
11 stamped BRACCOITC00633511 through
12 BRACCOITC00633521, marked for
13 identification, as of this date.)

14 - - -
15 BY MS. BOOKBINDER:

16 Q. So we're going to mark two documents
17 together, 37 and 38.

18 So Exhibit 37 is marked
19 BRACCOITC00633522 to -547, and Exhibit 38 is
20 marked BRACCOITC00633511 to -521.

21 A. I see that.

22 Q. Okay. And you have not seen these
23 documents?

24 A. No, I've not.

25 Q. Okay. So I'd like to point you to --

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2 first, to show you how these line up.

3 So Exhibit 38 is Office Action

4 Response for Application 14/426,208.

5 Do you see that?

6 A. I see that.

7 Q. Okay. And Exhibit 37 is the

8 publication of that application, right?

9 A. Yes.

10 Q. Okay. I'd like to talk with you

11 about Exhibit 38 -- I've given you Exhibit 37,

12 you know, if you need to --

13 A. Okay.

14 Q. -- review it.

15 And, also, you can see on Exhibit 37,

16 the applicant is Jubilant and the inventors

17 include Etienne Lefort, [REDACTED]

18 as well as Drs. Dekemp and Klein, right?

19 A. Yes.

20 Q. All right.

21 So in the Office Action Response, on

22 Page 8 of 11.

23 Could you read the middle paragraph,

24 please, the As noted previously, and let me know

25 when you've read that?

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 (Whereupon, the witness reviews the

3 material provided.)

4 THE WITNESS: As noted

5 previously --

6 BY MS. BOOKBINDER:

7 Q. Oh. You --

8 A. I don't have to read it out loud?

9 Q. -- you can read it to yourself.

10 A. Thank you.

11 Q. Sure.

12 (Whereupon, the witness reviews the

13 material provided.)

14 THE WITNESS: I've read it.

15 BY MS. BOOKBINDER:

16 Q. Okay. Were you previously aware that

17 Jubilant, itself, has been making arguments to

18 the Patent Office that, you know, quality control

19 procedures are actually not obvious, including

20 the claimed step of halting operation of a

21 strontium-rubidium generator in response to user

22 interruption of a quality control assessment?

23 A. Since I've not seen this before, no,

24 I was not aware of that.

25 Q. Okay. So you were not informed

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 through any other means?

3 A. No.

4 Q. Okay. Having read this paragraph on

5 Page 8 of Exhibit 38, does that change your

6 opinions at all with respect to the alterations

7 of the Klein and CardioGen references in terms

8 of, you know, computerizing processes?

9 A. No, it does not.

10 Q. Okay. Yesterday, we talked about the

11 relevance of the length of the tubing in these

12 systems, right, that it's important because of

13 the decay of the Rubidium eluate in the system?

14 A. The length of the tubing needs to be

15 considered; and, yes, we did talk about it.

16 Q. Okay. In your report, where you

17 suggest modifying the Klein Thesis and the

18 CardioGen system to have the generator at a

19 certain height relative to the waste bottle, did

20 you consider whether the length of tubing would

21 change in making that change?

22 A. It did not need to consider whether

23 it would change; it needs to be considered in

24 determining what the dose to the patient is, but

25 that doesn't -- that would require no significant

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 experimentation. It's a straightforward

3 computation.

4 Q. Could you please explain why -- could

5 you explain further your testimony just now of --

6 that the tubing length would not change or

7 wouldn't need to be considered?

8 I didn't quite follow that.

9 A. I didn't say that.

10 Q. Okay. If you could clarify that

11 please.

12 A. Well, I said that if it were changed,

13 it would not be a significant factor with regard

14 to overall performance because that would be

15 taken into account by the control parameters,

16 knowing what the flow rate was. For example, the

17 tubing might change and one -- I would not

18 increase the flow rate.

19 Let's just go beyond that. It's a

20 simple engineering calculation to determine what

21 would need to be changed in order to give the

22 same dose to the patient; it's straightforward.

23 Q. Did you discuss that calculation or

24 dosing adjustment that may need to be made in

25 your report?

<p style="text-align: right;">Page 114 Page 398</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 breakthrough test is passed. I believe that's</p> <p>3 the only reasonable interpretation of that</p> <p>4 wording.</p> <p>5 Q. What is done with the breakthrough</p> <p>6 calculation in the CardioGen system?</p> <p>7 A. The user makes the decision as to --</p> <p>8 I'm sorry. I -- I -- I need to look back at the</p> <p>9 CardioGen manual and the figures, because I don't</p> <p>10 want to speculate from memory --</p> <p>11 Q. Okay.</p> <p>12 A. -- so . . .</p> <p>13 MR. WALKER: I believe the manual</p> <p>14 is 31.</p> <p>15 (Pause.)</p> <p>16 THE WITNESS: I don't think -- yes.</p> <p>17 Thirty-one.</p> <p>18 (Whereupon, the witness reviews the</p> <p>19 material provided.)</p> <p>20 THE WITNESS: Right.</p> <p>21 So there's no way for a user to</p> <p>22 enter -- or the -- the breakthrough level.</p> <p>23 And if I go to Page 31, it says, Patient</p> <p>24 administration may be performed only after</p> <p>25 successful completion of daily</p>	<p style="text-align: right;">Page 116 Page 400</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Q. Okay. But the CardioGen-82 system</p> <p>3 doesn't have a shielded well onboard the cart</p> <p>4 either, right?</p> <p>5 A. It does not.</p> <p>6 Q. And it also doesn't have a computer</p> <p>7 with a touchscreen display?</p> <p>8 A. It does not.</p> <p>9 Q. So the CardioGen-82 does not present</p> <p>10 a screen reminding user to insert an eluate</p> <p>11 reservoir in the shielded well onboard the cart,</p> <p>12 right?</p> <p>13 A. No, it does not.</p> <p>14 Q. So turning to Duchon, that reference</p> <p>15 also does not have a shielded well onboard the</p> <p>16 cart or an eluate reservoir or a touchscreen</p> <p>17 display, right?</p> <p>18 A. No, Duchon discloses tracking</p> <p>19 numerous process parameters and provides warnings</p> <p>20 when bottles need to be replaced.</p> <p>21 Q. Then at Paragraph 755, you point to</p> <p>22 what you characterize as "programming equipment"</p> <p>23 that was well known and understood at the time?</p> <p>24 A. Yes.</p> <p>25 Q. So, again, I'd like to understand,</p>
<p style="text-align: right;">Page 115 Page 399</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 calibration, Strontium-82/85 breakthrough</p> <p>3 procedures and the first wash (elution)</p> <p>4 disposal.</p> <p>5 So it's all up to the user to</p> <p>6 control whether or not they do an</p> <p>7 administration after a breakthrough has</p> <p>8 failed its limits.</p> <p>9 BY MS. BOOKBINDER:</p> <p>10 Q. Yesterday, I believe you confirmed</p> <p>11 that the Klein Thesis itself does not disclose</p> <p>12 presenting on the touchscreen display a screen</p> <p>13 reminding the user to insert the eluate reservoir</p> <p>14 in the shielded well onboard the cart. And you</p> <p>15 emphasized that's because there is no eluate</p> <p>16 reservoir in a shielded well onboard the cart in</p> <p>17 the Klein Thesis, right?</p> <p>18 A. That's correct.</p> <p>19 Q. Okay. So let's take a look at that</p> <p>20 claim element, which is 9.2 from the '826 patent.</p> <p>21 It's on Page 331 of your report.</p> <p>22 So for this element, you suggest</p> <p>23 combining the Klein Thesis with the CardioGen-82</p> <p>24 system and the Duchon patent; is that right?</p> <p>25 A. Yes, I do.</p>	<p style="text-align: right;">Page 117 Page 401</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 what combination are you proposing to meet this</p> <p>3 claim element when you give your conclusion in</p> <p>4 Paragraph 757 that It would have been obvious to</p> <p>5 modify the Klein cart to include a reminder to</p> <p>6 insert the eluate reservoir in the shielded well</p> <p>7 and giving your opinion that the Klein cart, when</p> <p>8 modified as taught by the prior art, meets the</p> <p>9 subject matter?</p> <p>10 A. The CardioGen-82 has a shield that</p> <p>11 contains the warning label, Elution test vial</p> <p>12 shield for use with the CardioGen-82. So that</p> <p>13 shield is a well into which the bottle is -- the</p> <p>14 test vial is actually inserted. Placing it on</p> <p>15 the cart, Duchon says to remind users when fluids</p> <p>16 need to be replaced -- or -- or emptied.</p> <p>17 So that, to me, its obvious whether</p> <p>18 it's on the cart or off the cart; they had the</p> <p>19 warning, and to put it on the cart instead of</p> <p>20 having to move it off the cart, as is</p> <p>21 currently -- as -- as the 82 -- sorry -- the</p> <p>22 CardioGen-82 did, would be an obvious change to</p> <p>23 be doing it onboard the cart instead of off the</p> <p>24 cart.</p> <p>25 They still had a shielded well, and</p>

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 physically moving it and making it a part of the
3 cart would be an obvious change.
4 Q. Does the Klein Thesis itself have a
5 shielded well that's not onboard the cart?
6 A. He has a waste container in a
7 shielded well; he does not have the test vial.
8 Q. Klein does have --
9 A. But he says --
10 Q. Yeah.
11 A. -- he says that the test vial for the
12 dose calibrator must be changed between elutions.
13 The person of skill in the art would have been --
14 would have considered it obvious to expand the
15 operational parameters that Klein system tracks,
16 to include -- well, that's not with regard to
17 that particular claim. But they do have a test
18 vial, and it was eluted into the test vial in a
19 shielded well.
20 Q. So Klein has a test vial; it's just
21 not onboard?
22 A. It's not explicitly onboard.
23 Q. Okay. So if Klein has a test vial
24 that's not onboard, why do you need to combine
25 Klein with CardioGen-82, which also has a test

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 vial not onboard?
3 A. Just showing what all the person of
4 skill in the art would have known, that people
5 knew that you would use shielded test vials;
6 placing it onboard is a matter of convenience.
7 Q. So you're pointing to two systems
8 with offboard test vials to demonstrate that
9 there were offboard test vials?
10 A. Klein already had a warning in his
11 system to replace it on a computer screen.
12 That's one. And Duchon says, You need to do --
13 to avoid the possibility of running out of fluid,
14 providing warnings with regard to fluid levels, I
15 believe that makes it obvious combine.
16 Q. Well, to be clear, you say in
17 Paragraph 747, Klein does not disclose that error
18 messages include a reminder to insert the eluate
19 reservoir in the shielded well.
20 Right?
21 A. He does not disclose that. He
22 discloses a large number of error messages. And
23 Duchon says you need to -- to supply messages
24 with regard to fluid levels.
25 Q. Is the eluate --

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 MR. WALKER: When you get wrapped
3 up with this line, I'd like to take a
4 break.
5 MS. BOOKBINDER: Okay.
6 BY MS. BOOKBINDER:
7 Q. -- is the eluate reservoir in the
8 shielded well a fluid level issue?
9 You're pointing to Duchon that it
10 tracks amount of fluid dispensed, right?
11 A. He -- Duchon tracks numerous process
12 parameters during promote -- operation and
13 presents alerts based on that information, so I
14 don't think it's a stretch at all to say
15 reminding a person to put a -- a vial -- a test
16 vial into a shielded well is not monitoring fluid
17 parameters and providing alerts with regard to
18 elution -- or sorry -- patient injection systems.
19 Q. Okay. So, again, to understand your
20 conclusion at 757, with the Klein cart, when
21 modified as taught by the prior art, meets the
22 subject matter, you are making modifications to
23 the Klein Thesis based on Duchon and the
24 knowledge of one of ordinary skill programming
25 equipment?

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 Is that the modification you're
3 proposing?
4 A. I'm making the modification as we
5 discussed here, knowing that you need to monitor
6 fluid levels, knowing that you need to provide
7 warnings with regard to fluid management systems,
8 that it would be obvious to a person of skill in
9 the art to make those a computerized warning,
10 whether it's on the cart or off the cart.
11 Q. But to be specific, it's the
12 Klein Thesis in view of Duchon, in view of a
13 POSITA's knowledge of programming; is that --
14 A. That's what I have here.
15 Q. -- is that the combination?
16 MS. BOOKBINDER: Okay. So we can
17 take a break.
18 THE VIDEOGRAPHER: We are going off
19 the record at 11:23 a.m.
20 - - -
21 (Whereupon, a recess was taken from
22 11:23 a.m. to 11:37 a.m.)
23 - - -
24 THE VIDEOGRAPHER: We are going
25 back on the record at 11:37 a.m.

<p style="text-align: right;">Page 138 Page 422</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 A. Sorry. Having automated maintenance</p> <p>3 quality -- daily quality control procedures</p> <p>4 and/or operation procedures to ensure the safety</p> <p>5 and efficacy.</p> <p>6 So Klein integrated those automated</p> <p>7 procedures into a single system. He had already</p> <p>8 met the need.</p> <p>9 Q. But Klein wasn't a fully integrated</p> <p>10 system on the cart, right? It still had</p> <p>11 components offboard the cart that resulted in</p> <p>12 limitations in what it could do, right?</p> <p>13 A. I think what we were just addressing</p> <p>14 was whether or not the FDA would trigger an unmet</p> <p>15 need for an automated procedure for doing</p> <p>16 the -- the breakthrough test, not that it had to</p> <p>17 be on the cart. So let's make that distinction.</p> <p>18 The distinction was automating the</p> <p>19 procedure so that it's accurate and doesn't</p> <p>20 miss -- end up with excessive radiation applied</p> <p>21 to the patient.</p> <p>22 Q. So looking at your Paragraph 442, you</p> <p>23 quote another section of your report describing a</p> <p>24 need for a, quote, fully integrated</p> <p>25 Strontium-Rubidium Infusion System.</p>	<p style="text-align: right;">Page 140 Page 424</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 A. I think I have to answer the</p> <p>3 questions to the best of my ability that you ask</p> <p>4 me. And in my report, I report that this in --</p> <p>5 unmet need that is alleged to have been generated</p> <p>6 by the FDA -- that unmet need had already been</p> <p>7 solved by the Klein Thesis. I think that's --</p> <p>8 and I have that in my report.</p> <p>9 Q. Right. So I'd like to talk about</p> <p>10 your report and not alleged FDA requests.</p> <p>11 Is that okay?</p> <p>12 A. That's fine.</p> <p>13 Q. Okay. So looking at Paragraph 442,</p> <p>14 you state, As explained herein, however, prior</p> <p>15 art references existed before the asserted</p> <p>16 patents' priority date that satisfied a need for,</p> <p>17 quote, a fully integrated Strontium-Rubidium</p> <p>18 Infusion System having automated maintenance,</p> <p>19 daily quality control procedures and/or operation</p> <p>20 procedures to ensure the safety and efficacy of</p> <p>21 each injected dose for the patient, end quote.</p> <p>22 A. I see that.</p> <p>23 Q. Okay. So is that long quote your</p> <p>24 understanding of the need at issue in these</p> <p>25 patents?</p>
<p style="text-align: right;">Page 139 Page 423</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Right?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. And is that your understanding</p> <p>5 of the unmet need at issue --</p> <p>6 MR. WALKER: Objection: vague.</p> <p>7 BY MS. BOOKBINDER:</p> <p>8 Q. -- for this technology?</p> <p>9 A. No. It is the automated maintenance</p> <p>10 that provides the daily quality control and/or</p> <p>11 operation procedures to ensure the safety and</p> <p>12 efficacy of each injected dose for the patient.</p> <p>13 Whether the breakthrough test is</p> <p>14 performed on cart or off cart, it was fully</p> <p>15 automated and had already solved the problem</p> <p>16 which was addressed by the FDA, which was cited</p> <p>17 as a reason for an unmet need previously.</p> <p>18 Q. You do not discuss the FDA in this</p> <p>19 paragraph, right?</p> <p>20 A. No. But you brought it up; I didn't</p> <p>21 bring it up.</p> <p>22 Q. Okay. All right.</p> <p>23 So sticking to what is in your</p> <p>24 report, and separate from any questions of the</p> <p>25 FDA --</p>	<p style="text-align: right;">Page 141 Page 425</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 A. That's what Klein described it.</p> <p>3 Q. This is a quote from Klein?</p> <p>4 A. Yes, I believe so.</p> <p>5 Q. Okay. Can we check that?</p> <p>6 A. XLC.</p> <p>7 MR. WALKER: I believe that's XI.</p> <p>8 THE WITNESS: XI? Sorry. Thank</p> <p>9 you.</p> <p>10 MR. WALKER: Yeah.</p> <p>11 (Whereupon, the witness reviews the</p> <p>12 material provided.)</p> <p>13 THE WITNESS: I do not see that</p> <p>14 quote referenced in here, but I will try</p> <p>15 to flash back and read it carefully.</p> <p>16 BY MS. BOOKBINDER:</p> <p>17 Q. Okay. Looking in this section on</p> <p>18 long-felt need in your report, you were focused</p> <p>19 on Paragraph 442.</p> <p>20 If we look to the preceding</p> <p>21 paragraphs, it looks like the quote actually came</p> <p>22 from the Bracco rebuttal contentions --</p> <p>23 A. I see --</p> <p>24 Q. -- that --</p> <p>25 A. -- okay.</p>

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2 And, again, I would allege that Klein

3 is fully integrated with all aspects here with

4 exception of placing the dose calibrator on the

5 cart. And he had solved the major issues, which

6 is automating that procedure and providing for

7 the safety and efficacy of each injected dose --

8 injected dose for the patient.

9 Q. So at the time of the Klein Thesis in

10 2005, was there a need for such a system?

11 A. He did an integrated system. If you

12 look at his block diagram of his system, even

13 though it's not on the cart, his block diagram

14 includes the dose calibrator. So it was a fully

15 integrated system whether it was physically on

16 the cart or not --

17 Q. So was --

18 A. -- so he saw the need for the system

19 when he did his thesis in 2005, and he solved the

20 problem.

21 Q. So it's your opinion that Dr. Klein

22 identified a problem and solution in 2005, but

23 when Bracco and Jubilant made their patent

24 filings or developed their systems, there was no

25 such need for that; there was -- that was only a

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 competitive opportunity?

3 A. He solved it competitive -- and

4 solved the long-felt needs. They did not choose

5 to put it in their product and, only later, chose

6 to put it in their patent application.

7 Q. Why is it that Dr. Klein -- strike

8 that.

9 Why -- what is the basis of your

10 opinion that Dr. Klein identified a need as

11 compared to the companies that identified an

12 opportunity? What is your distinction there?

13 A. Well, you said he -- he -- sorry.

14 Dr. Klein saw that the -- the system

15 needed to be fully integrated. He talks about

16 the things that were done by the system, what it

17 did. So, apparently, he identified a need and

18 other needs in it as well and solved that in his

19 system.

20 Whether he claimed he identified the

21 need or not, he certainly solved what other

22 people might perceive to be a need, because he

23 did come up with a fully integrated system that

24 provides for the safety and efficacy in the

25 system as it delivers, including the automated

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 breakthrough testing --

3 Q. And do you --

4 A. -- his block diagram shows that all

5 of those were integrated and computer-controlled.

6 Q. Do you agree that in 2005, there was

7 a need for this technical development?

8 A. There was, which he solved.

9 Q. Why do you believe that there was a

10 need in 2005?

11 A. Because breakthrough testing had to

12 be done. It was cumbersome. He recognized that.

13 Because there were other issues that needed to be

14 automated because the devices had not been, and

15 he solved those issues.

16 Q. There was no commercial device that

17 solved those issues until at least the late

18 2000-teens time, right?

19 A. I wouldn't comment on how long it

20 takes to put a commercial device that solves all

21 those together, but Dr. Klein had done so at that

22 point in time, and it's prior art.

23 Q. In your opinion?

24 A. Yes.

25 Q. Let's look at Paragraph 445.

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 Are you at 445?

3 A. I am.

4 Q. Okay. You note that The Klein design

5 was used extensively in real-world clinical

6 applications.

7 What are you referring to there?

8 A. A design that is ultimately quite

9 similar to Dr. Klein's system, the so-called

10 Version 1 and others. And if we have our rest --

11 our reference there, I believe we can show that

12 the product has been used in Canada in clinical

13 setting in over 22,000 patients without issues of

14 sterility or contamination reported to date.

15 So it was definitely being used in a

16 wide variety of places, though not as a U.S.

17 medical device.

18 Q. So let's look at the -- the

19 references that you cite here.

20 - - -

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 - - -

25

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 Q. I believe you testified earlier that
3 Version 1 was not publicly available in the
4 United States, right?

5 A. That's my understanding.

6 Q. And do you have an understanding of
7 whether Version 2 was publicly available in the
8 United States?

9 A. I don't know whether Version 2 was
10 publicly available in the United States. I don't
11 believe it was.

12 [REDACTED]

21 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 BY MS. BOOKBINDER:

3 Q. You give an opinion that The
4 materials cited by Bracco in their contentions
5 does not show a long-felt need existed for the
6 features of the asserted patents.

7 Right?

8 A. Because the need had already been
9 solved, as I said, in the Klein Thesis. So, no,
10 there was no long-felt need. The need had been
11 solved by Klein long before the -- these patents
12 were applied for, much less issued.

13 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

5 Q. Do you believe that the Version 2
6 device is prior art to the asserted patents?

7 A. I did not use that as a reference. I
8 do believe that the -- certainly, the
9 Klein Thesis is prior art. I don't believe I
10 looked at the Version 2 --

11 Q. Okay.

12 A. -- for that purpose.

13 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 Q. You understand if the Version 2
3 system did not predate the patents in the
4 United States that it cannot be prior art to the
5 patents, right?

6 A. I haven't made any comments with
7 regard to Version 2, other than what was --
8 you -- you reference and said, Do you know if
9 that was Version 1 or Version 2. The diagram
10 that's utilized is the Klein Thesis diagram.

11 So I have no way -- nothing to infer
12 other than that was the Klein Thesis, and it was
13 prior art.

14 MS. BOOKBINDER: I strike as
15 nonresponsive and ask my question again.

16 BY MS. BOOKBINDER:

17 Q. Do you understand that if the
18 Version 2 system itself was not publicly
19 available in the United States prior to the
20 asserted patents, it is not prior art to
21 those patents?

22 A. I don't fully understand that. I
23 would need a bit more discussion with regard to
24 it and when it was released, how publicly it was
25 released and sold, and whether the documents were

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 published and were only available to -- with
3 regard to it -- sorry. You're saying the system.

4 So if the system wasn't, then my
5 understanding would -- would be that it would not
6 be prior art.

7 Q. It's your opinion that there is not
8 evidence that Jubilant copied Bracco's designs in
9 creating the Version 3 system, right?

10 A. That's my belief; that's correct.

11 - - -
12 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 the patent, but if it's in my list of documents

3 reviewed, then I did.

4 Q. Okay. Just looking at the related

5 U.S. -- or strike that.

6 If you just look at the file date of

7 this publication, it's May 29, 2014, right?

8 A. I see that.

9 Q. So this patent application is not one

10 of the asserted patents which were filed later?

11 A. That's correct.

12 Q. And it's not one of the earliest

13 priority documents from 2008 and 2009, right?

14 A. That's correct.

15 Q. It's in the same family, though, as

16 you can tell from the related U.S. application

17 data; is that correct?

18 A. Yes.

19 Q. Okay. This is actually an example of

20 one of the related patent filings that was

21 omitted from the chart in your report, right?

22 A. I'll accept that.

23 Q. Okay. Because this is a continuation

24 application, this publication has the same

25 specification as the earlier filed patents and

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 that lunch is here. So we can take a

3 break.

4 MR. WALKER: Okay. Great.

5 THE VIDEOGRAPHER: We are going off

6 the record at 12:33 p.m.

7 (Whereupon, at 12:33 p.m., a

8 luncheon recess was taken.)

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1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 also the asserted patents which are, similarly,

3 continuations?

4 MR. WALKER: Is there a question?

5 THE WITNESS: Yes, is there a

6 question?

7 BY MS. BOOKBINDER:

8 Q. I want to confirm that you --

9 A. That's my understanding.

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 MS. BOOKBINDER: I've been told

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 A F T E R N O O N S E S S I O N

3 (1:13 p.m.)

4 - - -

5 ROBERT THOMAS STONE, PH.D.,

6 was called for continued examination and, after

7 having been previously duly sworn, was examined

8 and testified further as follows:

9 - - -

10 THE VIDEOGRAPHER: We are going

11 back on the record at 1:13 p.m.

12 - - -

13 EXAMINATION (CONTINUED) BY COUNSEL FOR COMPLAINANT

14 - - -

15 BY MS. BOOKBINDER:

16 Q. Dr. Stone, before the lunch break, we

17 had been discussing Exhibits 46 and 47.

18 You still have those?

19 A. I do.

20 Q. Okay.

21 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 [REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

[REDACTED]

17 Q. Are you familiar with a system called
18 Posijet, P-O-S-I-J-E-T?

19 A. Posijet, I believe, is how it's
20 stated. I've heard the name. I'd have to look
21 at the documents to see if I'm familiar with it.

22 - - -
23 (Stone Deposition Exhibit Number 55,
24 Lemer Pax Web page, Bates stamped
25 JDI-ITC-000123196, marked for

<p style="text-align: right;">Page 194 Page 478</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER 2 identification, as of this date.) 3 4 BY MS. BOOKBINDER: 5 Q. You've been handed a copy of 6 Exhibit 55, which is JDI-ITC-000123196. 7 A. Yes -- 8 Q. Is -- 9 A. -- I see it. 10 Q. -- is this the Posijet system that 11 you've heard of? 12 A. I don't know that I've ever seen 13 this. I'm not particularly familiar with it. 14 Q. Were you provided with a copy of 15 Jubilant's invalidity contentions prior to 16 preparing your report in this case? 17 A. I believe so. 18 (Whereupon, the witness reviews the 19 material provided.) 20 THE WITNESS: I don't know that I 21 reference it, but I -- and I don't recall 22 all the documents that I've seen at this 23 point, but I believe so. 24 BY MS. BOOKBINDER: 25 Q. Okay. Do you recall that Posijet was</p>	<p style="text-align: right;">Page 196 Page 480</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER 2 rounds, before preparing your report? 3 A. I don't recall specifically. 4 Q. And do you recall reviewing either 5 Exhibit 55 or any other materials about the 6 Posijet system in this case? 7 A. I do not recall off the top of my 8 head. 9 Q. How did you come to know how the name 10 Posijet is pronounced? 11 A. It's how I would pro -- pronounce it, 12 an inference because of how I know that names are 13 typically done. So I would have called it 14 Posijet, as opposed to Posijet. 15 Q. Okay. In the text of -- 16 A. I believe that's what I said earlier; 17 I would have called it Posijet. 18 Q. Okay. In the text of Exhibit 55, 19 there is a statement, The rapid development of 20 the Positron Emission Tomography currently with 21 the F-18 FDG but shortly with other 22 radioisotopes, such as Gallium-68 and 23 Rubidium-82. 24 Do you know whether the Posijet 25 system was ever built to use Rubidium-82?</p>
<p style="text-align: right;">Page 195 Page 479</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER 2 a reference included in Jubilant's invalidity 3 contentions? 4 A. I don't recall that at the point. 5 I think I state something with regard 6 to Posijet. 7 (Whereupon, the witness reviews the 8 material provided.) 9 THE WITNESS: I reviewed the 10 evidence that Bracco cited in the Bracco 11 rebuttal contentions, so I'm reasonably 12 sure I would have seen the -- 13 BY MS. BOOKBINDER: 14 Q. What paragraph are you at? 15 A. 251. 16 Q. 251? 17 A. Sorry. Page 251. Sorry. 18 Paragraph 508. 19 Q. Okay. So let me clarify my question, 20 which was about Jubilant's invalidity 21 contentions, rather than Bracco's rebuttal 22 contentions. 23 Did you have the opportunity to 24 review the invalidity contentions, which included 25 claim charts served by Jubilant in a couple of</p>	<p style="text-align: right;">Page 197 Page 481</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER 2 A. I do not. 3 Q. Okay. Did you consider the Posijet 4 system -- or lack of a system in your conclusion 5 that Bracco had not demonstrated a failure of 6 others in your report? 7 A. No. 8 Q. Seeing this document, does that 9 affect your opinion at all? 10 A. Well, again, the Posijet, as it 11 describes it, is an innovative process of 12 calibration injection of FDG but also of other 13 radioisotopes, such as Gallium-68 or Rubidium-82, 14 allowing a reduction of the doses received -- 15 THE COURT REPORTER: I'm sorry. 16 You just mumbled there something -- 17 THE WITNESS: I am sorry. 18 THE COURT REPORTER: -- after 19 Rubidium-82, you said something -- 20 THE WITNESS: -- allowing a 21 reduction of the doses received by the 22 exposed manipulators while carrying out a 23 traceability of the patient's manipulators 24 and kits. 25 So I don't know the full status as</p>

<p style="text-align: right;">Page 198 Page 482</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 to whether they have launched that</p> <p>3 product. What the basis of not launching</p> <p>4 that product may have been if they did not</p> <p>5 launch it or if they have launched it</p> <p>6 would not affect my opinion. It's not a</p> <p>7 failure to develop or a failure to produce</p> <p>8 if they didn't launch the product.</p> <p>9 I have no basis to form a</p> <p>10 conclusion based on that.</p> <p>11 BY MS. BOOKBINDER:</p> <p>12 Q. You said it's not a failure to</p> <p>13 develop if they didn't launch the product?</p> <p>14 A. Right --</p> <p>15 Q. Why --</p> <p>16 A. -- there's a lot that goes into</p> <p>17 deciding to launch a product: whether it's</p> <p>18 developed or not, whether the market has changed</p> <p>19 by the time it's developed, et cetera; it's not a</p> <p>20 proof of failure to develop.</p> <p>21 Q. Is this standard in considering</p> <p>22 obviousness a failure to develop or just a</p> <p>23 failure, period?</p> <p>24 A. I would want to carefully review that</p> <p>25 particular piece.</p>	<p style="text-align: right;">Page 200 Page 484</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 that they've developed. It could be a</p> <p>3 choice of -- of turning in a different</p> <p>4 direction. That's not a failure, to</p> <p>5 understand and develop. That -- that's</p> <p>6 not conclusive -- I wouldn't conclude</p> <p>7 anything from that.</p> <p>8 BY MS. BOOKBINDER:</p> <p>9 Q. So I -- I just want to make sure I</p> <p>10 understand your application of Paragraph 42 in</p> <p>11 your report.</p> <p>12 Because you -- you did assess</p> <p>13 objective considerations in your report, right,</p> <p>14 at least a few of them?</p> <p>15 A. Yes.</p> <p>16 Q. And in assessing failure of others --</p> <p>17 A. I would want to know why -- sorry.</p> <p>18 I'll let you ask the question.</p> <p>19 Q. Thanks.</p> <p>20 -- in assessing the failure of</p> <p>21 others, you were thinking from the perspective of</p> <p>22 whether a product was developed, not whether a</p> <p>23 product was commercialized; is that correct?</p> <p>24 MR. WALKER: I'm going to object to</p> <p>25 that as a compound question.</p>
<p style="text-align: right;">Page 199 Page 483</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 Q. Sure. So that's at Paragraph 42.</p> <p>3 A. Thank you.</p> <p>4 Paragraph 42?</p> <p>5 Q. Yep. So Paragraph 42 lists objective</p> <p>6 considerations in the fourth line after Unsolved</p> <p>7 need, Failure of others.</p> <p>8 A. I would have not concluded that a</p> <p>9 failure of others for business conditions other</p> <p>10 than -- I -- I would more consider that a failure</p> <p>11 of others to solve the same problem, as opposed</p> <p>12 to failure of others to have a commercial</p> <p>13 success.</p> <p>14 Q. If the product is not launched</p> <p>15 commercially, could the problem in the world</p> <p>16 actually be solved if people don't have access to</p> <p>17 the product?</p> <p>18 MR. WALKER: Objection --</p> <p>19 THE WITNESS: That --</p> <p>20 MR. WALKER: -- incomplete</p> <p>21 hypothetical.</p> <p>22 THE WITNESS: -- that's --</p> <p>23 hypothetical requires a lot of business</p> <p>24 considerations. There's lots of reasons</p> <p>25 why a person might not launch a product</p>	<p style="text-align: right;">Page 201 Page 485</p> <p>1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER</p> <p>2 THE WITNESS: Do you want to ask it</p> <p>3 in pieces?</p> <p>4 MS. BOOKBINDER: I don't actually</p> <p>5 think it's a compound question, because</p> <p>6 it's a compare-and-contrast. But I can</p> <p>7 try and rephrase it, anyway.</p> <p>8 MR. WALKER: It's not mutually</p> <p>9 exclusive to each other; that's the</p> <p>10 problem.</p> <p>11 If the answer isn't yes, what's</p> <p>12 your answer?</p> <p>13 BY MS. BOOKBINDER:</p> <p>14 Q. So in applying or assessing the</p> <p>15 objective consideration of failure of others, did</p> <p>16 you consider that from a perspective of failure</p> <p>17 to develop?</p> <p>18 A. No. As beginning in Paragraph 20</p> <p>19 [sic], what I have is that -- with respect to</p> <p>20 Lux Pax, which I believe -- it's actually</p> <p>21 Lemer Pax.</p> <p>22 Q. So you said you're in Paragraph 20?</p> <p>23 A. 520.</p> <p>24 So at that time, we were addressing</p> <p>25 what would be a Strontium Generator Infusion</p>

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 discussion going on with respect to -- if you
3 could turn to 420 -- Page 420 in your invalidity
4 report.

5 Is it 420? Yeah.

6 And do you recall some questions
7 yesterday with regard to these figures and
8 whether or not, I guess, there was a cap or a lid
9 and whether it was hinged in a door?

10 A. Yes, I recall that.

11 Q. Okay. I believe at the time, you
12 were taken back to the tape figure on top, and
13 there were some references in there that were
14 gone through. And it was somewhat
15 indeterminate.

16 And I believe, at the end, you
17 concluded, just in looking at Tate, that perhaps
18 you thought that there was -- you did not find
19 support in Tate for a hinge. But I was just
20 curious.

21 If you could turn to Page 171 of your
22 report. I realize this isn't the Tate, but it's
23 the -- according to your report, the [REDACTED]

25 Do you see the -- the figure there?

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 Q. -- JDI put out and marketed, is it
3 your understanding that that was approved by the
4 FDA in -- in 2016?

5 A. Yes.

6 Q. And is it your understanding that
7 those were approved before the patents-in-suit
8 were filed with the claims they have in them?

9 A. Yes.

10 Q. Okay. And is it your understanding
11 that those claims were actually copied or drafted
12 against the product itself?

13 A. Yes.

14 Q. Okay. And so do you think that the
15 Version 3 copied the claims, the scope of the
16 inventions in the asserted patents?

17 A. No.

18 Q. And I believe one of the -- the
19 things that you've discussed in your expert
20 report is motivation to combine.

21 In particular, I guess, this would be
22 in your Section VIII.B.1, Motivation to Combine
23 References?

24 A. Yes.

25 Q. And Subsection a., it states,

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 A. I do.

3 Q. [REDACTED]

[REDACTED]

13 Q. And there have been some allegations
14 here that JDI had copied the inventions that are
15 claimed in the -- in the asserted patents here.

16 Tell me -- the -- the Version 1 -- is
17 it your understanding that those products were on
18 the market before the patents-in-suit were filed
19 for?

20 MS. BOOKBINDER: Objection.

21 BY MR. WALKER:

22 Q. You can answer.

23 A. I'm sorry?

24 Q. The Version 3 cart that --

25 A. Yes.

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 Relocating Klein's dose calibrator, the dose
3 calibrator vial and its -- its shielding to an
4 on-cart location.

5 Do you see that?

6 A. I do.

7 Q. And just generally, is it -- is it
8 your opinion that you believe a person of skill
9 in the art would be motivated to relocate the
10 dose calibrator in the Klein Thesis onto the
11 cart?

12 A. Yes.

13 Q. And do you think that being able to
14 do that would be within the abilities of a person
15 of ordinary skill in the art back in -- in the
16 2008-2009 time frame?

17 A. Indeed.

18 Q. And one of the other things that you
19 reference here is relocating Klein's generator
20 and its shielding from the top shelf to the
21 bottom shelf of -- of -- of the cart.

22 Do you think -- is it your opinion
23 that a person of ordinary skill in the art would
24 be motivated to put the generator and the
25 shielding in the lower portion of the medical

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 cart?

3 A. Yes, as I have addressed, for a

4 couple of reasons.

5 Q. Okay. And do you believe that

6 relocating that to a lower area of a cart or

7 modifying the design to include it in the bottom

8 of the cart -- do you feel like that is something

9 that would have been within the abilities of a

10 person of ordinary skill in the art back in 2008

11 and 2009?

12 A. Yes.

13 Q. And the third thing that you talk

14 about is -- is tracking system parameters and

15 providing alerts and reminders to the operators.

16 Is that something that you think a

17 person of ordinary skill in the art would be

18 motivated to do back in 2008/2009?

19 A. Yes.

20 Q. And -- and do you feel like that

21 would have been something that was within the

22 abilities of a person of ordinary skill in the

23 art back in that time frame?

24 A. Yes.

25 Q. I believe at some point yesterday,

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 there was a question as to whether or not you

3 felt there was adequate written description or

4 whether you thought there was a lack of adequate

5 written description in the patents. My

6 recollection is that, at the time, you said no.

7 I'm not sure exactly what the context

8 was, but it's my understanding that you have an

9 opinion that -- that the priority date for

10 these patents could be no earlier than 2009; is

11 that correct?

12 A. That's correct.

13 Q. And what is that based on?

14 A. That's based on when the -- the

15 disclosure for -- if I recall which patent -- was

16 actually presented --

17 Q. Take a minute --

18 A. -- sorry. Let me go take a look at

19 --

20 Q. -- take a minute and look at your --

21 A. Yeah.

22 Q. -- priority analysis, if you like.

23 (Whereupon, the witness reviews the

24 material provided.)

25 THE WITNESS: Page -- Part --

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 Paragraph 194, I note further that the

3 '031 application that Bracco filed in

4 2009 -- June 2009 is the first patent

5 filing to which the asserted patents claim

6 priority that discloses a dose calibrator,

7 an eluate reservoir therefor or a shielded

8 well therefor onboard a cart. The patent

9 applications that Bracco filed in

10 June 2008 do not -- then I list those --

11 do not disclose an eluate reservoir

12 onboard a cart, and they do not disclose

13 performing any Strontium breakthrough test

14 on an eluate sample that is located in the

15 eluate reservoir onboard a cart. And

16 Thus, the priority date of the asserted

17 patents can be no earlier than June 11th,

18 2009, the date on which Bat -- Bracco

19 filed the '031 application, which

20 disclosed this subject matter.

21 MR. WALKER: Okay. No further

22 questions.

23 MS. BOOKBINDER: I have a few

24 follow-ups.

25

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER

2 - - -

3 EXAMINATION (CONTINUED) BY COUNSEL FOR COMPLAINANT

4 - - -

5 BY MS. BOOKBINDER:

6 Q. Dr. Stone, you're aware that the

7 specification of the patents-in-suit were

8 published much earlier than the time that

9 these patents issued, right?

10 A. The specifications were published

11 earlier than the patents issued; that is true.

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 Q. Is it your understanding that copying

18 as a secondary consideration of nonobviousness

19 must be of the patent claims?

20 A. It certainly has to fall under those,

21 yes.

22 Q. So do you understand that copying as

23 a secondary consideration of nonobviousness can

24 be based on the specification?

25 A. I have not drilled down into that

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Page 502

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 particular issue as to whether it's a
3 specification or copying the patented claims.
4 Q. So you don't know either way?
5 A. I cannot give an answer. I would
6 have to consult counsel for that.
7 Q. Okay. Mr. Walker just discussed very
8 quickly several features with you in regard to a
9 person of skill in the art, whether they would
10 understand/have the ability to work on those
11 features in the relevant time period, right?
12 A. Yes.
13 Q. Okay. You understand that to show
14 invalidity of the patent claims, you need to
15 point to specific prior art references, right?
16 A. And the -- and that in combination
17 with what a person of skill in the art would
18 know.
19 Q. And the specific prior art references
20 that you're relying on that you contend meet the
21 actual claim elements is contained in your
22 report?
23 A. That is correct.
24 Q. And you also just went through
25 Paragraph 194 of your report, right?


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Page 503

1 CONFIDENTIAL BUSINESS INFORMATION SUBJECT TO PROTECTIVE ORDER
2 A. That's correct.
3 Q. But you have not given an opinion
4 that the asserted patents are invalid due to lack
5 of written description, right?
6 A. I have not.
7 MS. BOOKBINDER: Okay. That's all.
8 Thanks.
9 MR. WALKER: Thank you.
10 Brian?
11 THE VIDEOGRAPHER: We are going off
12 the record at 2:23 p.m. This ends today's
13 deposition. Thank you.
14
15 - - -
16 (Witness excused.)
17 - - -
18
19 - - -
20 (Deposition concluded at 2:23 p.m.)
21
22
23
24
25

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Page 504

C E R T I F I C A T E

1
2 DISTRICT OF COLUMBIA:
3 I, Cindy L. Sebo, a Notary Public within and
4 for the Jurisdiction aforesaid, do hereby certify
5 that the foregoing deposition was taken before me,
6 pursuant to notice, at the time and place indicated;
7 that said deponent was by me duly sworn to tell the
8 truth, the whole truth, and nothing but the truth;
9 that the testimony of said deponent was correctly
10 recorded in machine shorthand by me and thereafter
11 transcribed under my supervision with computer-aided
12 transcription; that the deposition is a true record
13 of the testimony given by the witness; and that I am
14 neither of counsel nor kin to any party in said
15 action, nor interested in the outcome thereof.
16
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25



Cindy L. Sebo, RMR, CRR, RPR, CSR,
CCR, CLR, RSA, LiveDeposition
Authorized Reporter and Notary Public

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Page 505

I N S T R U C T I O N S T O W I T N E S S

1
2
3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the appropriate
6 space on the errata sheet for any corrections
7 that are made.
8 After doing so, please sign the
9 errata sheet and date it.
10 You are signing same subject to the
11 changes you have noted on the errata sheet, which
12 will be attached to your deposition.
13 It is imperative that you return the
14 original errata sheet to the deposing attorney
15 within thirty (30) days of receipt of the
16 deposition transcript by you. If you fail to do
17 so, the deposition transcript may be deemed to be
18 accurate and may be used in court.
19
20
21
22
23
24
25

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Page 506

1 E R R A T A

2 WITNESS: ROBERT THOMAS STONE, PH.D. (VOLUME II)

3 DATE: OCTOBER 10, 2018

4 CAPTION: IN THE MATTER OF CERTAIN
STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION
SYSTEMS

5

6 PAGE LINE REASON FOR CHANGE:
7 _____

8 PAGE LINE REASON FOR CHANGE:
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25 _____

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Page 508

1 ACKNOWLEDGMENT OF DEPONENT

2

3 I, _____, do

4 hereby certify that I have read the foregoing

5 pages, 285 to 503, and that the same is a correct

6 transcription of the answers given by me to the

7 questions therein propounded, except for the

8 corrections or changes in form or substance,

9 if any, noted in the attached errata sheet.

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25 Notary Public

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1 E R R A T A

2 WITNESS: ROBERT THOMAS STONE, PH.D. (VOLUME II)

3 DATE: OCTOBER 10, 2018

4 CAPTION: IN THE MATTER OF CERTAIN
STRONTIUM-RUBIDIUM RADIOISOTOPE INFUSION
SYSTEMS

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