

In the Matter of:

CURIUM US LLC

V.

UNIVERSITÄT HEIDELBERG, ET AL.

MICHAEL ROD ZALUTSKY, PH.D.

July 30, 2026



1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 CURIUM US LLC,)
4 Petitioner,))
5 V.))
6 UNIVERSITÄT HEIDELBERG AND THE))
7 EUROPEAN ATOMIC ENERGY)
8 COMMUNITY (EURATOM),)
9 REPRESENTED BY THE EUROPEAN)
10 COMMISSION,))
11 Patent Owner.))

12 Case No. IPR2025-01582

13 Patent No. 10,980,901 B2

CERTIFIED
TRANSCRIPT

14 Deposition of MICHAEL ROD ZALUTSKY, PH.D.

15 Held at the Law Offices of
16 Womble Bond Dickinson (US) LLP
17 Raleigh, North Carolina

18 Thursday, July 30, 2026

19 9:20 A.M.

20 Volume 1

21 Pages 1 through 173
22
23
24
25

Page 2				Page 4			
1	A P P E A R A N C E S			1	P R O C E E D I N G S 9:20 A.M.		
2	For the Petitioner Curriculum US, LLC:			2	(Whereupon,		
3	James P. Murphy, Esquire			3	Michael Rod Zalutsky, Ph.D.		
4	Polsinelli PC			4	was called as a witness, duly sworn, and testified as		
5	1000 Louisiana Street, Suite 6400			5	follows:)		
6	Houston, Texas 77002			6	Mr. Boetticher: All right, should we each		
7	(713) 374-1631			7	state our name for the record?		
8	jpmurphy@polsinelli.com			8	The Witness: Okay, you want me to go		
9	For the Patent Owner Universität Heidelberg and			9	first?		
10	the European Atomic Energy Community (Euratom),			10	Mr. Boetticher: Go ahead, please.		
11	Represented by the European Commission:			11	The Witness: My name is Michael		
12	Evan Boetticher, Esquire			12	Zalutsky.		
13	Womble Bond Dickinson (US) LLP			13	Mr. Boetticher: Could you spell it for		
14	50 California Street, Suite 2800			14	the record, please?		
15	San Francisco, California 94111			15	The Witness: Z-A-L-U-T-S-K-Y.		
16	(650) 687-8435			16	Mr. Boetticher: And you're the witness		
17	evan.boetticher@wbd-us.com			17	today, correct?		
18				18	The Witness: Uh-huh.		
19				19	Mr. Boetticher: My name is Evan		
20				20	Boetticher, representing University of Heidelberg and		
21				21	EURATOM.		
22				22	Mr. Murphy: This is James Murphy of		
23				23	Polsinelli, representing the Petitioner Curium.		
24				24	D I R E C T E X A M I N A T I O N 9:21 A.M.		
25				25	By Mr. Boetticher:		

Page 3				Page 5			
1	T A B L E O F C O N T E N T S			1	Q So first let me ask, have you ever been		
2				2	deposed before?		
3				3	A Uh-uh.		
4	Witness Direct Cross Redirect Recross			4	Q Okay, is this your first time as an expert on		
5	Michael Rod Zalutsky, Ph.D.			5	a case?		
6	by Mr. Boetticher: 4-171			6	A Yes.		
7				7	Q Okay; all right, so I'll lay out some ground		
8				8	rules. These are pretty standard ground rules, if your		
9				9	counsel hasn't already told you. So for starters,		
10				10	we'll be taking breaks throughout the day. Whenever		
11				11	you feel that you need a break, just let me know and we		
12				12	can do it. Usually they're about 15 minutes. We try		
13	E X H I B I T S			13	to keep them short, so we don't extend the day too		
14	Number	Description	Marked	14	much. The only exception is if we're in the middle of		
15	Exhibit 1	Article	13	15	a question or a series of questions, we can't leave		
16	Exhibit 2	Article	32	16	that hanging. So we'll finish up that question or the		
17	Exhibit 3	Article	41	17	line of questions before we take the break. One thing		
18	Exhibit 4	Article	53	18	that's very important is that we have a court reporter		
19	Exhibit 5	Article	140	19	here, and she has to be able to hear everything that		
20	Exhibit 6	Article	144	20	you're saying. She can't fill in for you, so no, you		
21	Exhibit 7	United States Patent	162	21	know, shaking of head or, you know, nodding up and		
22				22	down. Don't make her interpret that. Also, we'll try		
23				23	not to talk over each other. I mean, it happens.		
24				24	Sometimes I think you're done with your answer and I		
25				25	start talking, or you -- you think I'm done with the		

Page 6 1 question, and you start talking, but we'll try to avoid 2 talking over each other. Now during the process, your 3 counsel will object, I'm sure. That's his job, and 4 he'll say objection, but unless he actually tells you 5 not to answer, you still need to answer, regardless of 6 what the objection is, okay? Those objections, they go 7 on the record, and then at some point the judge may 8 rule on them, but not today. And you've just been 9 sworn in. That holds the same power as being sworn in 10 at a court, so it has the same, you know, force of law, 11 perjury, that sort of thing. Let's see here. At -- 12 during the course of the deposition, if there is 13 anything that you don't understand, please be sure to 14 let me know, okay? 15 A Uh-huh, yes. 16 Q And there are two questions I always ask. 17 I was taught to do this in law school. I hope they 18 don't offend you. But the first question is, do you 19 feel that there is anything today that would prevent 20 you from providing testimony properly and truthfully, 21 like if you're on any medication or you had any head 22 injuries or anything that would cause you to be dizzy 23 or unable to speak? 24 A There is nothing like that. 25 Q Okay, and the other question is, have you	Page 8 1 was part of a new program to have people in chemistry 2 gain experience in medical applications of chemistry. 3 So that involved spending time in nuclear medicine 4 departments at the University of Chicago and Rush 5 Presbyterian. Then I was offered a faculty position at 6 the University of Chicago. I stayed there for a few 7 years. It was at the medical school. Then I went to 8 Harvard for five years, and then I ended up at Duke. 9 So that's my background. 10 Q So when you went to Harvard, you were 11 teaching at Harvard? 12 A You know, it's funny. I was more research 13 than teaching. In fact, that was a characteristic of 14 most of the faculty there. 15 Q Okay, so throughout the day, I'm going to be 16 giving you exhibits to look at. 17 A Okay. 18 Q This is the first one. So this is Exhibit 19 1003, which was part of your declaration. 20 A Thank you. 21 Q Do you recognize this document? 22 A Yeah. 23 Q It's pretty lengthy, isn't it? 24 A Yes, it is. 25 Q What is this document?
Page 7 1 ever been convicted of or accused of a felony, which is 2 a crime that has a \$1,000.00 fine, or one-year jail 3 time? 4 A No, I have not. 5 Q Okay, so let me ask you, how did you prepare 6 for your deposition today? 7 A I read the patent, and I read associated 8 publications to the patent. I refreshed my memory on 9 the background information relevant to targeted 10 radiotherapy in general and targeted alpha particle 11 therapy in particular. 12 Q Did you review your declaration? 13 A Yes, I did. 14 Q Did you review the testimony even by the 15 previous expert, Rebecca Abergel? 16 A Yes, I did. 17 Q So let's start off with something easy. I'd 18 like to learn a little bit about your background. Can 19 you tell me about your education, where you went to 20 school? 21 A I went to a very small school in 22 Massachusetts as an undergraduate, Clark University. 23 And then I got my master's and my Ph.D. from Washington 24 University in St. Louis. Then I was a postdoctoral 25 research associate at the Argonne National Lab, which	Page 9 1 A This document is my curriculum vitae. 2 Q All right, I just want to go over a few 3 things with you on this document. So you -- you 4 mentioned before that you were involved in medicine, 5 teaching medicine. You were at the Harvard Medical 6 School, is that right? 7 A Correct. 8 Q So what is your role when you're involved in 9 nuclear medicine or teaching nuclear medicine? 10 A So as I mentioned before, I was doing mostly 11 research and not teaching. And so I was involved in 12 collaborative research projects with clinical faculty. 13 And all throughout my career, starting actually when I 14 was a postdoc, I was working with clinical faculty on 15 projects that involved taking scientific advances and 16 evaluating them as potential clinical diagnostic and 17 therapeutic interventions. 18 Q And so you say you mostly did research work. 19 Were you like -- you were in the lab or were you 20 working with patients? 21 A I was in the lab. 22 Q And so your job was to make the 23 radiotherapeutics? 24 A My job was to make the radiotherapeutics and 25 also provide a scientific perspective when we went

Page 10 1 forward into patients on evaluating the potential 2 effects of those agents in patients. And some of them 3 were diagnostics. Some were therapeutic. 4 Q Okay, and when you were evaluating the 5 effects, did you -- did you interact with the patients? 6 Did you perform the diagnostics on them? How would you 7 evaluate them? 8 A So my role was primarily to advise on the 9 appropriate times to -- to image the patients, to look 10 at the biodistribution of the radioactivity in the 11 patient, what would be appropriate times to sample 12 blood to look for how much radioactivity was in the 13 blood; to take whatever biokinetic information that was 14 available and be able to calculate how much radiation 15 dose was deposited in tumor and how much was deposited 16 in normal tissues. 17 Q Okay, and so when you were determining how 18 much was in the tumor and how much was in the normal 19 tissue, were you being given the tissues and you were 20 analyzing them? Were you performing diagnostics and 21 doing imaging like MRI or something? 22 A So in the early phase of my career, in one 23 particular study that we did in brain tumor patients, I 24 was given the tissue, and we were able to count the 25 tissue itself. In other situations, what one does is	Page 12 1 A I do not. 2 Q Okay, and so when you were at -- and so 3 you've got on your CV that there were some hospital 4 appointments. You were a radiochemist at the 5 University of Chicago, a radio analytic chemist at 6 Children's Hospital. What was your job at those times 7 when you were working in the hospitals? Is it the same 8 as what you just described? 9 A Basically the same as what I just described. 10 Q Okay, and again, you never worked in -- you 11 never worked in -- strike that. And, again, you never 12 worked directly with any of the patients when you were 13 at the hospital either? 14 A I did not. 15 Q And when you do your laboratory work, do you 16 work with animals, or do you work with cells, or do you 17 work with both? 18 A I work with animals and cells. 19 Q Okay, mostly mice? 20 A Mostly mice, but occasionally at one stage 21 worked with dogs that had cancer. 22 Q Okay; all right, you can put that aside. And 23 I'll tell you, the numbering is going to be a little 24 strange today because I'm not going to renumber the 25 documents that have already been filed with the USPTO,
Page 11 1 you can actually, with nuclear medicine techniques, 2 image the radioactivity itself. And so you have a 3 clear idea of where the radioactive molecule is by 4 doing standard nuclear medicine imaging. 5 Q Okay, and do you do that imaging? 6 A I don't do that myself, but what happens is 7 the nuclear medicine technologists will perform that, 8 and then what we'll do is put what's called regions of 9 interest and determine the amount of radioactivity in 10 those regions of interest. 11 Q Okay, so even though you are a professor of 12 nuclear medicine, you studied nuclear medicine, you're 13 not a clinician, correct? 14 A That is correct. 15 Q And you don't actually deal with any patients 16 day in and day out? 17 A That's correct. 18 Q And you don't do diagnostics on the patients 19 themselves? 20 A That's correct. 21 Q And you don't treat the patients or give them 22 the therapeutics? 23 A I don't do that. 24 Q Okay, so you don't think of yourself as a 25 clinician in any way, correct?	Page 13 1 but when I have new documents, they'll be numbers 1, 2, 2 3, 4 to your deposition, okay? And so I'm going to 3 give you Exhibit 1 to your deposition. 4 Mr. Murphy: So this is a -- a new 5 exhibit essentially? 6 Mr. Boetticher: Uh-huh. 7 Mr. Murphy: Okay. 8 The Witness: I've seen this before. 9 (Exhibit Number 1 marked for identification.) 10 By Mr. Boetticher: 11 Q So you recognize this document? 12 A I indeed do. 13 Q Okay, and what is this document? 14 A This document is a publication that describes 15 a radioactive molecule that was being evaluated in mice 16 for the treatment of PSMA-positive prostate cancer. 17 Q I think, and please correct me if I'm wrong; 18 I think that this is your first PSMA paper, is that 19 correct? 20 A I don't recall, but probably is. It seems 21 likely that it is. 22 Q This is around -- well, it was received by 23 the journal in February 17, 2016. Is that about when 24 you started working on PSMA? 25 A No, I started working a little bit before

Page 14 1 that; probably a year or two before that. 2 Q So around 2014 to 2015? 3 A Something like that, yeah. 4 Q And the work you did during that one or two 5 years, that's what led to this paper? 6 A Yes. 7 Q And what was your role in working on this 8 paper? 9 A My role in working on this paper was to 10 develop the methodologies for putting the radioactivity 11 onto the PSMA-targeted molecule. And my role was to 12 evaluate the effects of this molecule on cells that 13 express PSMA, to determine the tissue distribution of 14 this molecule in mice with PSMA-expressing tumors, and 15 to determine the therapeutic efficacy of this 16 particular molecule in mice with PSMA-positive tumors 17 in two different animal models, one a subcutaneous 18 model and the other a micrometastatic model. 19 Q What's a micrometastatic model? 20 A A micrometastatic model is a model that is 21 usually the second phase of investigation in animals, 22 and it involves creating animals where they have small 23 sites of disease spread throughout the body. 24 Q So it's sort of a model for a metastasis of a 25 tumor or cancer?	Page 16 1 adjunct faculty there, too. 2 Q And you were at Johns Hopkins when you did 3 this? 4 A No, no, no, so this project was -- and the 5 reason I said that it started a couple of years before 6 this paper, is Professor Pomper and I submitted a grant 7 to the National Institute of Health. They have a 8 program called Partnering Principal Investigator 9 Program. And so Dr. Pomper and I submitted an 10 application a year or two before this, got funded for a 11 joint project. So Dr. Pomper at that time was actually 12 the head of nuclear medicine at Johns Hopkins. I was 13 at Duke and so we collaborated on this NIH project. 14 And this is, I believe, the first paper that came out 15 of that collaboration. 16 Q So your career goes back to 1974, and now 17 here it is 2014; you're turning to PSMA. Why did you 18 turn to PSMA at this time? 19 A Why did I turn to PSMA at this time? I 20 turned to PSMA at this time because Dr. Pomper said it 21 would be really, potentially very fruitful to combine 22 the radiochemistry technologies that you have developed 23 at Duke with the PSMA technologies that I have 24 developed at Johns Hopkins. And as Marty is an 25 esteemed scientist, this seemed like a very good idea.
Page 15 1 A Yes. 2 Q All right, help me to understand this. I see 3 this phrase in here, the PSMA plus PC3 PIP cells. What 4 are those? 5 A So PC3 cells are a prostate line -- a 6 prostate cancer line that does not really express PSMA, 7 but what you can do is through genetic modification, 8 you can make that line express PSMA. 9 Q And what does the PIP stand for? 10 A I have no idea. 11 Q I was really hoping you'd tell me. That's 12 the thing that really confused me. 13 A That's a -- that's good question. I have no 14 idea. 15 Q Okay. 16 A Obviously that cell line came from my co-PI 17 on this, Martin Pomper. 18 Q So what was your title and where were you 19 when you did this work? 20 A My title -- my title was professor of 21 radiology. I think I had my distinguished chair at 22 that point, so I was also the Jonathan Spicehandler. I 23 could look at my CV and tell you that. So I had a 24 couple of joint appointments in other departments, for 25 example, Pathology, Radiation Oncology. I was an	Page 17 1 Q So with this project, you were looking at the 2 efficacy and you were designing the radiotherapeutics, 3 correct? 4 A Correct. 5 Q Okay, I want to draw your attention on the 6 first page about halfway down, that column on the 7 right. You'll see a sentence beginning with, however, 8 on the right-hand side there about halfway down. 9 A About halfway down? 10 Q Yeah; it says, however, and the next line 11 begins, survival benefit was only three months, and 12 therapeutic effect was limited to bone metastasis. Do 13 you see that? 14 A Where is that? It's on the right side, 15 right? 16 Q Well, let me -- let me take a -- let me -- 17 let me take -- maybe this will be easier to find. In 18 the middle of the paragraph, you see a citation to 19 three and four? 20 A Yeah, yeah. 21 Q Okay, so let's start from there. It says, 22 the recent phase three ALSYMPCA trial of Xofigo, 23 223-Ra-CL2, Bayer HealthCare Pharmaceuticals, 24 demonstrated the feasibility of alpha emitter RPT in 25 CRPC.

Page 18 1 A Uh-huh. 2 Q And then it continues, however, survival 3 benefit was only three months, and therapeutic effect 4 was limited to bone metastasis. So why was the radium 5 chloride limited to only bone metastasis? 6 Mr. Murphy: Objection; form. 7 Mr. Boetticher: You may answer. 8 The Witness: Because radium was 9 injected as radium chloride and metal ions that are not 10 attached to ligands localize in the bone. And so 11 therefore, there was no uptake in soft tissue 12 metastasis and therefore, because there was no uptake, 13 the treatment potential was limited to bone mets. 14 By Mr. Boetticher: 15 Q Do all radioactive metals -- strike that. Do 16 all radioactive metals collect in the bone? 17 A Most of them, most of them; they also, 18 depending on which radiometal you're talking about, 19 also can end up in the liver. 20 Q Okay, and so is -- is radium like a calcium 21 analog? 22 A Yeah, yeah, fair to say. 23 Q But not all metals are necessarily calcium 24 analogs? 25 A Correct.	Page 20 1 astatine, much like the Karlsruhe location at the time 2 of the actinium-225 research was just about the only 3 place that produced actinium-225. And I make this 4 point because availability of radionuclide is an 5 important parameter both in the past and in the 6 present in determining one's research direction and 7 feasibility. 8 Q And so you had access to the astatine. Is 9 that how you pronounce it? 10 A That's correct. 11 Q So you had access to the astatine, and that's 12 what led you to go this direction with it? 13 A Yes. 14 Q But you still believe that having a shorter 15 half-life is better for this particular ligand, 16 correct? 17 Mr. Murphy: Objection; form. 18 The Witness: It's certainly one 19 approach. Let me point out that another thing that one 20 can do with a properly designed ligand is to use a long 21 half-life radionuclide that internalizes rapidly into 22 the tumor cell, but is excreted very rapidly from the 23 body. And so in that case, you get a good tumor dose, 24 but most of the decays of the longer-lived radionuclide 25 happen outside the body. And for example, the radium-
Page 19 1 Q I'd like you to turn to the second page. And 2 at the top left -- sorry; probably in the middle of 3 this sentence, it says, <i>211At</i> has particularly 4 favorable characteristics for clinical development, 5 including a 7.2-hour half-life that is well matched to 6 small-molecule therapeutics. Do you see that? 7 A Yes, I do. 8 Q So why does the 7.2 half-life make it well 9 matched to small-molecule therapeutics? 10 A Because many small-molecule therapeutics 11 clear rapidly from the body and can be designed such 12 that they are taken up by the tumor rapidly. So that 13 means that you can deposit a significant amount of dose 14 to the tumor with clearance from normal tissues. 15 Q And so you prefer having a short half-life 16 when you're dealing with the small molecules as opposed 17 to a longer one? 18 Mr. Murphy: Objection; form. 19 The Witness: What I prefer to do is I 20 prefer to tailor-make the choice of radionuclide to the 21 nature of the radioligand. And frankly, I have 22 significant expertise in the chemistry of astatine-211. 23 And importantly, and this is a very important point, 24 the Duke University cyclotron is one of the only places 25 in the world that produces a significant quantity of	Page 21 1 223 that you mentioned earlier is a long-lived 2 radionuclide, but unbound radioactivity is excreted 3 rapidly from the body. So there are two ways of 4 playing it. 5 By Mr. Boetticher: 6 Q Okay, so are you saying that you want either 7 a short one or a long one and not something in between? 8 Mr. Murphy: Objection; form. 9 The Witness: I would say that it 10 depends on the nature of your labeling strategy and the 11 pharmacokinetics of the ligand in tandem with the 12 radioactive nuclide. 13 By Mr. Boetticher: 14 Q So I'd like to draw your attention to the 15 second column on the right, down there's a section 16 marked in italics, Toxicity and Maximum Tolerated Dose. 17 Do you see that? 18 A Right. 19 Q And you say the maximum tolerated dose was 20 defined as the highest dose at which no animal died or 21 lost more than 20 percent of its pretreatment weight? 22 A Correct. 23 Q And is that the typical definition for a 24 maximum tolerated dose? 25 Mr. Murphy: Objection; form.

Page 22 1 The Witness: That's the typical 2 definition in mice. 3 By Mr. Boetticher: 4 Q Is it different for people? 5 Mr. Murphy: Objection; form. 6 The Witness: That's a -- that's a very 7 complicated question. But yes, it is different in 8 people and that is something that is best determined by 9 a clinician. 10 By Mr. Boetticher: 11 Q All right, I'd like you to turn to page 1572 12 of the journal document. 13 A Yes. 14 Q And there's a section here entitled in 15 italics, Antitumor Efficacy in Micrometastatic Model. 16 Do you see that? 17 A Yes, I do. 18 Q So partway down it has a sentence that reads, 19 untreated animals died within 7 to 8 weeks after 20 receiving cells. 21 A Correct. 22 Q Median survival was 58, 59, 72, 97, and 110 23 days for those untreated and those receiving 37, 111, 24 185, and 370 -- 25 A Kilobecquerels.	Page 24 1 field. The -- the reason is there are humane endpoints 2 for size of tumor and degree of cancer burden. So the 3 difficulty is when you're trying to figure out what the 4 normal organ capacity for radiation is, if you've got 5 tumor growing at the same time, there are two problems. 6 Number one, the tumor could suck up radioactivity that 7 would normally go to the normal organs. And second of 8 all, if the humane endpoint, for example, is 1,000 9 cubic millimeters for a subcutaneous model, then the 10 animals would have to be euthanized because of tumor 11 growth while they might have survived otherwise, and 12 that way you would not be able to determine maximum 13 tolerated dose. 14 Q Okay, so you determined what the maximum 15 tolerated single dose was with mice that were -- that 16 had not been given tumors, correct? 17 A Correct. 18 Q Okay, but that -- that maximum tolerated 19 single dose still applies to ones that have tumors? 20 A It's fair, yes. I would say yes. 21 Q Okay, and so with the -- with the mice in 22 that first paragraph, the one entitled anti-tumor 23 efficacy in micrometastatic models, so those mice with 24 tumors were untreated or they received 37, 111, 185, or 25 370 kilobecquerels of radiation, correct?
Page 23 1 Q -- kilobecquerels, respectively. And then in 2 the next paragraph below you have a sentence that says, 3 the maximum tolerated single dose of 211At-6 in 4 immunocompetent CD1 mice was 37 kilobecquerels. Do you 5 see that? 6 A Uh-huh. 7 Q Okay, so if I'm reading this correctly, at 37 8 kilobecquerel treatment, the mice lived 59 days, which 9 wasn't a significant difference from the ones that 10 didn't get any treatment at all, right? 11 A So what I would like to point out is you're 12 talking about two different groups of mice. One group 13 has tumor, and we're talking about the survival of the 14 mice with tumor. The in vivo toxicity maximum 15 tolerated dose was done in mice with -- they were 16 immunocompetent CD1 mice, which was a different set of 17 mice. They were done in parallel. 18 Q I'm sorry. Could you explain that again? 19 A Yeah, I believe it was two separate 20 experiments. Yep, I'm right. 21 Q Okay, so could you explain it again to make 22 sure I understand it? 23 A Yeah, yeah, so I believe that you should do 24 your maximum tolerated dose measurements in mice 25 without tumors, and so do many other people in the	Page 25 1 A Correct. 2 Q And you found that at 37, which is the 3 maximum tolerated dose, there was really no effect on 4 their survival? 5 A Right. 6 Q And it wasn't until you went up to 111 that 7 these number of days increased to 72, correct? 8 A Yep, yes. 9 Q And then at 185 dose, you had 97 days, 10 correct? 11 A Yes. 12 Q And then at 370 kilobecquerels, they survived 13 for 110 days, correct? 14 A Correct. 15 Q Okay, so in order to get an efficacious 16 dosage, you had to go beyond the maximum tolerated 17 dose, correct? 18 Mr. Murphy: Objection, objection; 19 form. 20 The Witness: With this first 21 generation compound, yes; in subsequent research, 22 subsequent publications, we took what we learned from 23 this paper, modified chemical structures, and were able 24 to come up with compounds that were more efficacious 25 with less toxicity. They were PSMA compounds also

Page 26 1 labeled with astatine. This is first generation. 2 By Mr. Boetticher: 3 Q And that's the nature of research. 4 A That's the nature of research. In other 5 words, this did not progress towards clinical 6 investigation. 7 Q Right, and so we can agree that the maximum 8 tolerated single dose is not linked to the level of 9 dosage that would be efficacious? 10 Mr. Murphy: Objection. 11 By Mr. Boetticher: 12 Q Correct? 13 Mr. Murphy: Objection; form. 14 The Witness: So it really is going to 15 depend on the endpoints that one selects for maximum 16 tolerated dose and efficacy. It all depends on what 17 those endpoints are. 18 By Mr. Boetticher: 19 Q Well, how do you define efficacy? 20 A In mice? 21 Q In mice. 22 A In mice, generally you like to have a tumor 23 growth delay greater than 50 -- a tumor growth 24 inhibition greater than 50 percent in the majority of 25 animals.	Page 28 1 camera imaging, which is not very sensitive and allows 2 you to look at the regional distribution in the kidney. 3 And so the -- where's the picture? So you can actually 4 see, for example, the renal cortex. I'm pointing to 5 Figure 8, and this is Number 1, Exhibit 1. So you give 6 some -- you give a lot of radiation solely for the 7 purpose of being able to look at substructures both in 8 tumor and in kidney. And this work was done at Johns 9 Hopkins. 10 Q Okay, so a little further down in the 11 paragraph that's entitled dosimetry, in italics. A 12 couple of lines down, there's a sentence that begins, 13 considering only the alpha emissions and assuming local 14 deposition within the kidney and tumors, the mean 15 absorbed dose of 211-astatine-6 was 24.6, 10.0, and 16 0.44 Mgy kilobecquerels for the kidney. 17 A Uh-huh. 18 Q What does it mean by the absorbed dose? 19 A So radiation is a form of energy. An 20 absorbed dose is the amount of energy that is absorbed 21 by the tissue. So it is an indicator of potential 22 efficacy and potential toxicity. 23 Q And so when you give the radiation to a 24 mouse, what do you call that? Is that the 25 administrated dose?
Page 27 1 Q But in this case, in terms of efficacy, we're 2 looking at how long they had survived? 3 A That is the second thing you can look at. 4 Q And in this case, you had to exceed what you 5 determined to be the maximum tolerated dose in order to 6 get an effect? 7 A With this first generation compound, yes. 8 Q And so the level at which you can get an 9 effective dose is a separate question from what the 10 maximum tolerated dose is, correct? 11 Mr. Murphy: Objection; form. 12 The Witness: The level at which you 13 can get an effective dose; yes, it can be different. 14 By Mr. Boetticher: 15 Q Can I ask you, in the next column over, there 16 is a paragraph entitled, 211-astatine-6 tumor and 17 kidney biodistribution for dosimetry. You see that? 18 A Uh-huh. 19 Q And you give the -- it looks like you're 20 giving the mice 3.7, is that megabecquerels? 21 A Uh-huh. 22 Q That seems like a lot of radiation for a 23 mouse. Why -- why so much when you're giving 37 24 kilobecquerels before? 25 A So this is when we're going to do the alpha	Page 29 1 A So that is the administrated -- administrated 2 activity, radioactivity. So that is usually in 3 kilobecquerels; here, megabecquerels. And in the U.S., 4 the terms are things like microcuries and millicuries. 5 Q Okay, and what does the Mgy stand for? What 6 word is that? 7 A G-Y, that's gray. 8 Q Gray, so that's a milligray? 9 A A milligray. 10 Q Okay, and so the administered activity is 11 different from the absorbed dose? 12 A Absolutely. 13 Q And so you may give a certain amount for the 14 administered activity, and the absorbed dose could be 15 much, much lower or nothing, depending on where you're 16 looking? 17 A Yes; it's also different units, so. 18 Q Okay, and I think you mentioned that the -- 19 that the line from the administered activity to the 20 absorbed dose involves a lot of steps involving -- 21 strike that. So the absorbed dose is going to be a 22 portion of the administered activity, is that right? 23 A No. 24 Q Because they're different units of 25 measurement?

Page 30 1 A Well, that's one reason, yes. 2 Q Why else? 3 A Well, because the absorbed dose will be a 4 function of the fraction of the administered activity 5 that localizes, is taken up by the tissue or organ in 6 question, but what one has to do is to determine the 7 residence time, in other words, how long that 8 radioactivity is there. And so one determines 9 radioactivity times time. In other words, millicuries 10 kilogray times time determines the area under the curve 11 and then applies an energy factor that allows you to 12 calculate what the radiation dose in milligray or 13 kilogray or whatever is to that tissue. 14 Q And the ultimate radiation dose or the 15 absorbed dose that you get is based upon -- strike 16 that. The absorbed dose that you will get for a 17 particular tissue can be influenced by the delivery 18 system such as the molecule that the radiation is 19 attached to, correct? 20 Mr. Murphy: Objection to form. 21 The Witness: Correct. 22 By Mr. Boetticher: 23 Q And so you could give -- strike that. You 24 could administer the same activity with two different 25 molecules but get different absorbed doses at a	Page 32 1 kidneys, is that correct? 2 Mr. Murphy: Objection; form. 3 The Witness: That is correct, but I 4 will point out that, for example, with the findings of 5 this particular paper, Exhibit 1, the uptake in the 6 kidney motivated us to design second and third 7 generation compounds with less kidney uptake. 8 By Mr. Boetticher: 9 Q All right, but damage to the kidney from 10 PSMA-targeted RPTs was a real concern during that 11 period, correct? 12 Mr. Murphy: Objection; form. 13 The Witness: It was mentioned in order 14 to provide some context for the significant kidney 15 uptake that one can see in Figure 8. 16 Mr. Boetticher: All right, can you put 17 that aside? I'm going to give you Exhibit 2 to your 18 deposition and it should make you happy. 19 (Exhibit Number 2 marked for identification.) 20 The Witness: Oh, good. 21 By Mr. Boetticher: 22 Q Do you recognize this document? 23 A Oh, yes, I do. 24 Q What is this document? 25 A This document is a review article that
Page 31 1 particular tissue, correct? 2 Mr. Murphy: Objection; form. 3 The Witness: That's correct. 4 Mr. Boetticher: I'm learning so much. 5 That's why I like being a patent lawyer. 6 The Witness: I hope you're going to 7 look at our second and third generation compounds. 8 By Mr. Boetticher: 9 Q I'd like you to look at page 1573. That last 10 paragraph on the right-hand column, it says, the short 11 range of alpha particles may limit toxicity to off- 12 target tissues. But for PSMA-targeted RPT there is 13 concern regarding renal toxicity due to physiologic 14 PSMA expression in the proximal tubules. You see that? 15 A Uh-huh. 16 Q Did I read that correctly? 17 A That's correct. 18 Q And it goes on to say, PSMA expression has 19 been previously demonstrated in human proximal tubules 20 by immunohistochemistry, and PSMA imaging in humans 21 also demonstrates significant renal cortical uptake. 22 Did I read that correctly? 23 A Correct. 24 Q Okay, and so at this time, there was concern 25 that PSMA delivery systems could cause damage to the	Page 33 1 describes the state of the art with radiohalogenated 2 agents for imaging and treating prostate cancer. 3 Q Okay, now the first line of the first 4 paragraph says, radiohalogenated agents are often the 5 first line of pursuit in the development of new 6 radiopharmaceuticals, whether antibodies, peptides, or 7 small molecules, because of their ease of synthesis, 8 lack of substantial steric perturbation of the original 9 affinity agent, in some cases providing enhanced 10 affinity, and capacity to be transformed into 11 therapeutics, in some cases with a mere switch of an 12 isotope. Did I read that correctly? 13 A That's correct. 14 Q So you're saying that the radiohalogenated 15 agents are really the -- the -- the best selection for 16 this kind of work. Is that what you're saying? 17 Mr. Murphy: Objection; form. 18 The Witness: No; please recall that we 19 were talking both about imaging and therapy in this 20 study, and much of this work pertains to F-18, also a 21 radiohalogen, but really the most widely used 22 radionuclide for PET imaging. And so that is why that 23 was mentioned. 24 By Mr. Boetticher: 25 Q But in the sentence here, it says,

Page 34 1 radiohalogenated agents are often the first line of 2 pursuit in the development of new radiopharmaceuticals; 3 right? 4 A They are often. Often is the word we should 5 emphasize. 6 Q Okay, okay. 7 A If you happen to be a radiohalogen chemist, 8 then that's really where you look. If you are a 9 radiometal-focused chemist, you might prioritize other 10 radionuclides. 11 Q Okay, so you're saying that you wrote this 12 sentence because you were a radiohalogenist, 13 radiohalogen chemist? 14 A I wrote this sentence, because most of the 15 work in my lab, but not all, involves radiohalogens. 16 Q So turn to the second page, please. 17 A Yes. 18 Q And under the section entitled 19 Radiohalogenated Inhibitors of PSMA as Imaging Agents, 20 do you see that? 21 A Uh-huh. 22 Q So it says here, several scaffolds have been 23 used in the synthesis of small-molecule PSMA 24 inhibitors. These include thiols, carbamates, 25 phosphoramidates, phosphinic acids, and ureas, right?	Page 36 1 Q Okay, so I'd like you to look at page 94S -- 2 A 94S. 3 Q -- of the document. 4 A Yes. 5 Q There's a section entitled Radiohalogenated 6 PSMA-Targeted Small Molecules for Therapy. 7 A Uh-huh, yes. 8 Q And at the end of that first paragraph, it 9 says, however, as discussed elsewhere in this 10 supplement, most current work with beta emitters for 11 PSMA-targeted RPT is focused on radiometals such as 12 177-lutetium, because of perceived advantages in 13 emission spectra and convenience. 14 A Correct. 15 Q What were those perceived advantages in 16 emission spectra and convenience? 17 Mr. Murphy: Objection; form. 18 The Witness: For therapy, the 19 radiohalogen that was most available was iodine-131, 20 which is a beta emitter, like lutetium-177. However, 21 iodine-131 has a gamma emission of 362 keV, and the 22 difficulty is that that gamma emission could increase 23 nonspecific radiation of the patient. So that was a 24 negative to iodine-131. For that reason, that was 25 actually how people were motivated to start looking at
Page 35 1 A Uh-huh. 2 Q So at that time, a person of ordinary skill, 3 they were looking at a number of these different things 4 in order to synthesize small PSMA molecule inhibitors, 5 is that right? 6 A Some people were looking in this direction, 7 and others were looking in other directions. 8 Q Okay, but all of these were viable candidates 9 to be small-molecule PSMA inhibitors, correct? 10 A Figure 1 that is being discussed here, all 11 those are imaging agents, not therapeutics. 12 Q Okay, but that wasn't my question. 13 A What was your question? 14 Q So the question is, in this sentence, you say 15 several scaffolds have been used in the synthesis of 16 small-molecule PSMA inhibitors, and then you list a 17 number of different things? 18 A Right. 19 Q And so my question is, these different 20 things, the thiols, the carbamates, the 21 phosphoramidates, the phosphinic acids, and ureas were 22 all things that a person of ordinary skill in the art 23 was using at the time to make small-molecule PSMA 24 inhibitors, right? 25 A That's correct.	Page 37 1 lutetium-177, because it has a very similar beta 2 particle energy to iodine-131, but does not have that 3 gamma emission. And so that is really the primary 4 reason. The other is that lutetium-177 was widely 5 available in a format that could easily be incorporated 6 into many different types of targeting vectors, 7 including PSMA. 8 Q Okay, and in the next column over, in that 9 last paragraph, it begins, the radiohalogen 211At has 10 particularly favorable characteristics for clinical 11 development, including a 7.2-hour half-life, 100 12 percent alpha particle emission per decay, and the 13 absence of alpha particle-emitting daughters, which can 14 lead to excessive radiation doses to normal tissues 15 when released from the parent molecule. Do you see 16 that? 17 A Uh-huh. 18 Q Okay, so let's take this one by one. I think 19 we talked before about why you thought 7.2-hour half- 20 life was important for small molecules, but it seems 21 like you're making a broader statement here. 22 Mr. Murphy: Objection; form. 23 By Mr. Boetticher: 24 Q So do you mean that it's particularly 25 favorable characteristic for clinical development

Page 38 1 generally because of its 7.2-hour half-life? 2 Mr. Murphy: Objection to form. 3 The Witness: So the 7.2-hour half-life 4 comes with some advantages, which we've discussed, but 5 it also has practical disadvantages, and that is if 6 you're going to develop a drug for treating patients, 7 you have to produce it generally in one place and then 8 administer it in another place. And so you can get 9 significant decay during that transit, and because of 10 that, many people believe that longer half-life alpha 11 emitters are a better approach. 12 By Mr. Boetticher: 13 Q Okay, and the second part you have here is 14 100 percent alpha particle emission per decay. So what 15 do you mean by that? 16 A That means every decay of astatine-211 yields 17 one alpha particle. 18 Q And what -- what atom were you distinguishing 19 astatine from when you pointed out that particular 20 characteristic? 21 Mr. Murphy: Objection; form. 22 The Witness: I -- I was pointing to 23 long-lived alpha emitters, including thorium-229 or 24 227, radium-223, and actinium-225. 25 By Mr. Boetticher:	Page 40 1 Mr. Murphy: Objection; form. 2 The Witness: I am not a faculty member 3 at Johns Hopkins, but I will point out that this is for 4 an imaging drug called Pylarify, which is used in 5 thousands of patients throughout the world. And it's 6 not related to any work involving therapeutic intent. 7 By Mr. Boetticher: 8 Q So you said it is related to the drug 9 Pylarify, which is used with patients, correct? 10 A Correct. 11 Q But it's not related to therapeutic intent? 12 A Correct, it's an imaging agent. But this 13 article, this review article is about radiohalogens and 14 PSMA, including imaging agents. 15 Q And so this -- this comment about Martin G. 16 Pomper being entitled to royalties, is this because of 17 a -- a patent that he had? 18 A Yes. 19 Q And are you -- and do you also get royalties 20 on patents that you get through the work that you do at 21 Duke? 22 Mr. Murphy: Objection; form. 23 The Witness: Do I get royalties? I 24 will get royalties if things are successful. At this 25 point, I don't get royalties.
Page 39 1 Q And the next feature that you talk about is 2 the absence of alpha particle-emitting daughters, which 3 can lead to excessive radiation doses to normal 4 tissues. Were you also thinking of those three 5 nuclides when you mentioned this? 6 A Yes. 7 Mr. Murphy: Objection; form. 8 By Mr. Boetticher: 9 Q And so in this statement, you were setting 10 211At apart from those other alpha emitters as being 11 better in a number of ways, correct? 12 Mr. Murphy: Objection; form. 13 The Witness: Yes. 14 By Mr. Boetticher: 15 Q I'd like to ask you about the next page at 16 the very end of the article. There's a disclosure 17 section. Do you see that? 18 A Uh-huh. 19 Q In the second sentence it says, under a 20 licensing agreement between Progenics and Johns Hopkins 21 University, Martin G. Pomper is entitled to royalties 22 on an invention described in this article. 23 A Correct. 24 Q Could you explain to me how that policy works 25 at Johns Hopkins?	Page 41 1 By Mr. Boetticher: 2 Q Okay, all right, you can put that one aside. 3 Okay, I'm going to hand you what is Exhibit 3 to your 4 deposition. 5 (Exhibit Number 3 marked for identification.) 6 By Mr. Boetticher: 7 Q Do you recognize this document? 8 A Yes, I do. 9 Q What is this document? 10 A This document is a paper that describes the 11 third generation of PSMA-targeted agents labeled with 12 astatine that was developed by my group in 13 collaboration with Dr. Pomper's group. 14 Q Okay, and there are two different -- at least 15 two different compounds here. There's the [211At]L3-Lu 16 and the [211At]YF2, correct? 17 A Correct. 18 Q What's the difference between those two? 19 A So if we flip over the page, looking at the 20 graphical abstract, you can see the structures of the 21 two. And the L3-Lu has a DOTA for chelating, in this 22 case lutetium, and the YFT -- YF2 has a DOTAGA for 23 chelating the natural lutetium. 24 Q The lutetium that's in the DOTA and the 25 DOTAGA, you say it's natural, so it's not

Page 42 1 radioactive, -- 2 A Correct. 3 Q -- is that right? Why do you have it in 4 there? 5 A So we have found that with these particular 6 molecules that the biodistribution that results is more 7 favorable with natural lutetium in the macrocycle than 8 with it not in the macrocycle. 9 Q So the lutetium itself plays some role in 10 improving the distribution of the molecule? 11 A Correct. 12 Q So the DOTA's role as a chelator is -- strike 13 that. Why do you have the chelator as part of this 14 molecule? 15 A Because we have discovered that one way of 16 modulating charge and altering biodistribution is to 17 use a chelator as one of the components in the 18 molecular structure. 19 Q But does the chelator play a role as a 20 chelator which grabs onto a metal, or is it just its 21 general shape that seems to help? 22 Mr. Murphy: Objection; form. 23 The Witness: Well, as I just said, we 24 have shown that the biodistribution with the metal is 25 better than the biodistribution without the metal. So	Page 44 1 of the entire molecule, correct? 2 A Correct. 3 Q And that is in comparison to the DOTA that 4 was there before, correct? 5 A Correct. 6 Q And both of those had lutetium before? 7 A Right. 8 Q So when you add the DOTAGA, you change the 9 charge of the molecule because of the presence of the 10 DOTAGA? 11 A Yes, but all the action is happening in the 12 metal chelate part. 13 Q What do you mean all the action is 14 happening -- 15 A In other words, all the difference is in the 16 charge. 17 Q -- in the metal chelate part? 18 A It's the metal plus chelate, or macrocycle, 19 that governs the charge, not just the macrocycle. It's 20 the combination of the two. 21 Q Right, but its ability to hold lutetium isn't 22 as important as the fact that it's changing the charge 23 of the molecule? 24 Mr. Murphy: Objection; form. 25 The Witness: Well, if you lose the
Page 43 1 the fact that it grabs the metal and holds it in place 2 is certainly an important component. 3 By Mr. Boetticher: 4 Q Okay, and so you changed the DOTA to a 5 DOTAGA? 6 A Correct. 7 Q Why did you do that? 8 A Well, because it's one way of varying the 9 charge, and we know that trivalent metals like lutetium 10 are very well complexed by both DOTA and DOTAGA. 11 Q And when you say vary the charge, varying the 12 charge of what? 13 A The entire molecule. 14 Q And so the DOTAGA changes -- strike that. 15 The DOTAGA varies the charge of the entire molecule. 16 Is that what -- 17 A Correct. 18 Q -- you're saying? Sorry; and so in this 19 situation, that the DOTAGA is able to change the charge 20 of the entire molecule is a feature that is outside of 21 its role as a chelator grabbing lutetium, right? 22 Mr. Murphy: Objection; form. 23 The Witness: Incorrect. 24 By Mr. Boetticher: 25 Q Well, the DOTAGA is able to change the charge	Page 45 1 lutetium, you will change the charge, so its ability to 2 hold lutetium is indeed important. 3 By Mr. Boetticher: 4 Q So it's part of the DOTAGA molecule being 5 able to hold lutetium, right? 6 A Right. 7 Q But by switching from the DOTA to the DOTAGA, 8 they're both holding lutetium, but the charge changes? 9 A Correct. 10 Q Now at the time you did this, did you know 11 that the improvement was because of the charge? 12 Mr. Murphy: Objection; form. 13 The Witness: So we knew that that was 14 one potential factor. We don't know all the factors 15 that governed the change in properties between molecule 16 on the left and molecule on the right. 17 By Mr. Boetticher: 18 Q Because there's a certain level of 19 unpredictability when you start designing molecules 20 like this? 21 Mr. Murphy: Objection; form. 22 The Witness: Well, you have a pretty 23 good idea what could happen, but until you actually do 24 the study, you don't know the degree to which it's 25 going to happen, the time course over which it will

Page 46 1 happen. 2 By Mr. Boetticher: 3 Q And so when you switch from DOTA to DOTAGA, 4 you weren't doing it so that it could hold lutetium 5 better. You were doing it so that you could change the 6 charge of the molecule. Is that fair? 7 Mr. Murphy: Objection; objection to 8 form. 9 The Witness: It's -- it's a very 10 standard thing that people do, look at very similar 11 chelates. And sometimes, you know, that's the only 12 motivation. But I can tell you that we've done studies 13 with other molecules that provided some guidance to 14 this. 15 By Mr. Boetticher: 16 Q But again, my question was, when you switched 17 from DOTA to DOTAGA, you weren't doing it so that you 18 could hold lutetium better. You were doing it so that 19 you could modify the overall structure of the molecule, 20 correct? 21 Mr. Murphy: Objection; form. 22 The Witness: Well, the ability of 23 DOTAGA and DOTA to hold lutetium is very, very similar, 24 just like with all trivalent metals; the ability to 25 hold. In other words, what happens with DOTA and what	Page 48 1 A Uh-huh. 2 Q Okay, and if we look at citation seven, that 3 is a paper with Kratochwil as the first author, 4 published 2016. 5 A Correct. 6 Q Entitled, 225-Actinium Prostate -- sorry; 7 entitled, 225-Actinium-PSMA-617 for PSMA-targeted Alpha 8 Radiation Therapy of Metastatic Castration-Resistant 9 Prostate Cancer. And so you describe the results in 10 that paper as dramatic and significant? 11 Mr. Murphy: Objection; form. 12 The Witness: I describe them as 13 dramatic. The authors of reference number 7 describe 14 them as significant. 15 By Mr. Boetticher: 16 Q Well, you see here, a study using 225-Ac 17 labeled analog of PSMA-617 demonstrated significant 18 responses. You don't put that in quotation marks, do 19 you? 20 A Well, putting the reference at the end is 21 pretty much the same as putting it in quotation marks 22 because that's the origin of that information. 23 Q Well, it's -- it's the origin of the data, 24 but you don't put significant responses in quotation 25 marks. This sounds like what you're -- how you're
Page 47 1 happens with DOTAGA, it's -- it's fairly predictable 2 that if one works, the other will work. 3 By Mr. Boetticher: 4 Q But when you say, when one works, the other 5 will work, you're talking about binding lutetium? 6 A Right. 7 Q But in this case, you changed from DOTA to 8 DOTAGA, not about binding lutetium, but in order to 9 change the molecule so you have a different charge, 10 right? 11 Mr. Murphy: Objection; form. 12 The Witness: Right. 13 By Mr. Boetticher: 14 Q So let's go to the next page, the section 15 entitled Introduction. And you'll see about one, two, 16 three, eight lines down after the number 6 citation, 17 there's a sentence entitled -- or strike that. There's 18 a sentence entitled -- strike that. There's a 19 sentence that begins, targeted alpha particle therapy, 20 TAT, has shown even more dramatic results in some 21 studies. For instance, a study using 225-actinium 22 labeled analog of PSMA-617 demonstrated significant 23 responses even in individuals nonresponsive to prior 24 beta emitter therapy. And there's a citation 7. Do 25 you see that?	Page 49 1 describing the results. 2 Mr. Murphy: Objection; form. 3 The Witness: I would say these results 4 are more dramatic than significant, because if you look 5 at that reference, what you'll see is they show two 6 patients, only two patients. And what they do is they 7 take two patients who have been treated with the 8 lutetium compound and they have had recurrence, which 9 most patients treated with lutetium eventually have. 10 And then they treated these two patients with actinium- 11 225 and showed significant remission, according to 12 them. According to PSMA -- I mean PSA levels in these 13 patients; that was their indicator that there was a 14 therapeutic effect. There were images that were 15 dramatic. The images were dramatic. But do I think 16 they're significant; not at that point in time. Only 17 two patients; only one follow-up; we don't know if 18 these patients had toxicity. So, you know, I was just 19 referring to something out there that showed that the 20 alpha emitter, in general, was better than the beta 21 emitter. And you know, until you do more patients, 22 until you do significant follow-up, until you see if 23 there's long-term toxicity, you don't know what the 24 study really means. And you mentioned renal toxicity. 25 Renal toxicity is a late-stage event, okay? So if you

Page 50 1 look at the time frame of the images that they showed, 2 that was before renal toxicity would have occurred if 3 it were there. So yes, it's a nice, dramatic 4 representation of the potential of actinium-225. But 5 that study in itself, I don't view as significant. 6 By Mr. Boetticher: 7 Q You've reviewed the patent in this case, 8 correct? 9 A Correct. 10 Q And you've seen that there are additional 11 patients included in the patent, correct? 12 A Correct. 13 Q And you've seen they also have done studies 14 to see what the effect on nephrology is as well, 15 correct? 16 A Correct, and there have been many, many 17 studies since that time by multiple groups. 18 Q And do you find that significant now? 19 Mr. Murphy: Objection; form. 20 The Witness: The difficulty is that 21 with long-term follow-up, many of these patients do 22 have renal toxicity. Many of them, as noted with the 23 two patients in -- in reference number 7, have 24 xerostomia, which is dry mouth. And I will mention 25 that many of the patients currently being treated with	Page 52 1 So yeah, you can have your PSA drop, and then it can 2 shoot up again. 3 By Mr. Boetticher: 4 Q Okay, and so again, in this same paragraph 5 further down, you say our research in this area has 6 focused on the alpha particle limiter 211At in part 7 because its half-life 7.2 hours is a good match to the 8 biological half-life of LMW PSMA-targeted agents. You 9 see that? 10 A Yeah, LMW is low molecular weight. 11 Q Yeah. 12 A Yes. 13 Q And so are you thinking that this 211At is 14 specifically good for the low molecular weight PSMA- 15 targeted agents as opposed to antibodies? 16 Mr. Murphy: Objection; form. 17 The Witness: So that all depends. And 18 so the first clinical trials with this astatine-211 19 were done with antibodies. But they were antibodies 20 that were not given intravenously so that the potential 21 issues on matching an antibody with a 7.2-hour half- 22 life from a pharmacokinetic perspective would be 23 minimized. 24 Mr. Boetticher: You can put that one 25 away.
Page 51 1 PSMA-targeted agents drop out of their therapy studies 2 because the xerostomia is so problematic to quality of 3 life. So actinium-225-PSMA-617, like many of the 4 others, many of the patients do have these side 5 effects. 6 By Mr. Boetticher: 7 Q So in the study, both in the publication and 8 in the patent, the PSA levels decreased dramatically 9 from over 2000 to I think they went below measurable 10 amounts. You didn't -- you didn't think that was 11 significant? 12 Mr. Murphy: Objection; form. 13 The Witness: A one-time measurement 14 just a few months after treatment does not indicate a 15 response of duration greater than a few months, so 16 statistically significant at that point in time, highly 17 likely. But would that indicate that this is a durable 18 therapeutic response? We don't know. I will also 19 point out that many, many patients who are treated with 20 the lutetium beta emitter likewise undergo a similar 21 PSA drop. What we see with many of those patients, 22 they have recurrence. And I point out the lutetium 23 because that's an FDA-approved drug and there are 24 thousands of patients who have been treated. So 25 there's a -- a good set of patients one can look at.	Page 53 1 The Witness: I like that one. 2 Mr. Boetticher: All right, I'm going to 3 give you Exhibit 4 to your deposition. 4 (Exhibit Number 4 marked for identification.) 5 The Witness: Oh, yeah, this one. 6 By Mr. Boetticher: 7 Q So you recognize this one? 8 A Yes, I do. 9 Q And this is from 2025, correct? 10 A Uh-huh. 11 Q So this is one year after the one we were 12 just discussing? 13 A Right. 14 Q What is this document? 15 A This document is a publication that evaluated 16 the potential effect of adding the iodinated analog of 17 YF2 to reduce accumulation in the kidneys, salivary 18 glands and lacrimal glands. 19 Q I'd like you to turn to page 10. 20 A Page 10. 21 Q So right in the middle of the page there, 22 there's a paragraph that begins with, the differences 23 in the charge imparted. Do you see that? 24 A Uh-huh. 25 Q Could you read that to yourself and then let

Page 54 1 me know when you're finished? 2 A Just the first whole paragraph? 3 Q The paragraph, yeah. 4 A Okay. 5 Q I won't read it aloud this time. 6 A Okay. 7 Q So in this paragraph you're describing two 8 possible explanations for the improvements from adding 9 the DOTAGA to the molecule, correct? 10 A Correct. 11 Q And at this time you aren't sure which one is 12 correct, right? 13 A Correct. 14 Q But neither one of them really involved the 15 -- the binding of the lutetium by the DOTAGA; they 16 involve either the change in the charge or the steric 17 hindrance, correct? 18 Mr. Murphy: Objection; form. 19 The Witness: So the charge and the 20 steric hindrance relate to the lutetium macrocycle 21 portion of the molecule, whether it be DOTA or DOTAGA. 22 By Mr. Boetticher: 23 Q But the difference between DOTA and DOTAGA, 24 you're -- you're -- you're trying -- strike that. 25 You're trying to account for the difference between	Page 56 1 So there's a drone up there? I just want to -- 2 Q Okay, so I understand that the molecule is 3 different with and without lutetium. But the point is 4 that the difference between the DOTA and DOTAGA is not 5 the presence of lutetium, correct? 6 A Correct. 7 Q The difference between DOTA and DOTAGA is in 8 their shapes and structure? 9 A Correct. 10 Q And their different shapes and structure 11 cause a different charge and a different steric 12 hindrance? 13 Mr. Murphy: Objection; form. 14 The Witness: But the molecule has both 15 the macrocycle and the metal. So I'm only interested 16 in what happens with my molecule, not what happens to 17 the molecule I have thrown away because its 18 biodistribution wasn't as good as with the lutetium 19 present. 20 By Mr. Boetticher: 21 Q I understand that, but that wasn't my 22 question. Both DOTA and DOTAGA have lutetium in them, 23 right? 24 A Right. 25 Q And the difference between the DOTA and the
Page 55 1 DOTA and DOTAGA through either the change in the charge 2 or the steric hindrance, correct? 3 A Uh-huh. 4 Q So while lutetium is part of the DOTAGA or 5 the DOTA, the difference here that may have caused the 6 improvement is not due to lutetium, which was a -- 7 which was a consistent part of both of them, but due to 8 the change in the charge or the steric hindrance, 9 correct? 10 Mr. Murphy: Objection; form. 11 The Witness: Except for the fact that 12 both the charge and the steric hindrance are created by 13 the interaction between the lutetium and the 14 macrocycle. So if you didn't have the lutetium, you'd 15 have a different charge and different steric hindrance. 16 By Mr. Boetticher: 17 Q But you had lutetium with both the DOTA and 18 the DOTAGA, right? 19 A That's true. 20 Q But the DOTAGA is different in that it has a 21 different shape and a different charge? 22 A But that's irrelevant because we only care -- 23 I only care, about the shape and the charge of the 24 DOTAGA and the DOTA when they have lutetium there, 25 which is different than when the lutetium isn't there.	Page 57 1 DOTAGA was not the lutetium. It was in the shape of 2 the chelator and the charge of the chelator. 3 Mr. Murphy: Objection; form. 4 The Witness: Well, let's just say if 5 you have a generic molecule with a generic trivalent 6 metal and you're comparing DOTA and DOTAGA, the 7 difference will be between -- will be the presence of 8 DOTA versus DOTAGA. 9 By Mr. Boetticher: 10 Q And so it was that difference between the 11 DOTA and DOTAGA that changed the distribution of your 12 new molecule, the [211At]YF2, correct? 13 A Correct. 14 Q And so in this case, the difference between 15 the previous molecule and the new molecule, [211At]YF2, 16 was not a change in its ability to bind lutetium, but a 17 change in the -- the structure of the chelator? 18 A Well, one has to consider what happens in 19 vivo. And one can speculate the potential for having 20 differences in the ability for the lutetium to be 21 retained in vivo between the DOTA and DOTAGA, which 22 could influence biodistribution. So their ability to 23 hang on to the metal could be important. 24 Q But earlier, you said the differences between 25 them are very small. So they're able to hold on to the

Page 58 1 metal equally well, right? 2 A So when you're -- I -- I would have to go 3 back and look at, you know, the complexation constants 4 for lutetium with those two. But there could be 5 differences, and there could be differences in 6 enzymatic attack in vivo based on differences in 7 charge. Again, I am totally speculating here. But, 8 you know, these are complex systems, even though 9 they're small molecules. So what one does in a 10 discussion of an academic paper is speculate. That's 11 what it is. It's all speculation. And so that's what 12 we're doing in that paragraph, and that's what I've 13 just done about the in vivo stability. 14 Q So when you added the DOTAGA, you weren't 15 sure what the effect would be, right? 16 Mr. Murphy: Objection; form. 17 The Witness: Well, one cannot be 18 certain. But based on the fact that charge can be 19 important in terms of uptake and retention in cells, I 20 believe that there was a high likelihood or a 21 reasonable likelihood that we would get an improvement. 22 By Mr. Boetticher: 23 Q But you didn't know for sure that you would, 24 right? 25 A I don't know for sure anything.	Page 60 1 Q How does he determine the gold standard? 2 A How does he determine the gold standard? My 3 guess is that, based on the consensus of inorganic 4 chemists working in the field, what are the best 5 combinations of chelate and radiometal? 6 Q And when you say best combination, what makes 7 it best? 8 A Well, holds the radiometal with the highest 9 tightness. In other words, the complexation constant 10 is very, very high. So the metal doesn't escape. 11 Q Okay, so his standard for what is the -- 12 strike that. So you think he defines gold standard by 13 its ability to hold a metal and not let it escape? 14 Mr. Murphy: Objection; form. 15 The Witness: So hold the metal and not 16 let it escape. That is certainly the primary property, 17 but another property that is important is the ease to 18 which you can complex the radiometal with that chelate, 19 so in other words, the amount of time, the temperature, 20 the pH. 21 By Mr. Boetticher: 22 Q Okay, now in the paper of yours that we were 23 just discussing, when you switched from DOTA to DOTAGA, 24 it wasn't in order to make the chelator bind lutetium 25 better, right?
Page 59 1 Q But in this case, you didn't switch from DOTA 2 to DOTAGA in order to prove the binding of lutetium, 3 correct? 4 A No. 5 Q And you don't think that the effect that you 6 saw between the DOTA and DOTAGA was due to any change 7 in the binding of lutetium, correct? 8 A Unlikely. 9 Q All right, I am going to give you what is 10 Exhibit 1041 in this case. 11 A Thank you. 12 Mr. Boetticher: Sorry; it's not one of 13 yours. 14 The Witness: That's okay. I know 15 Chris. 16 By Mr. Boetticher: 17 Q So you're familiar with this? 18 A Indeed I am. 19 Q So what is this document? 20 A So this is a review article written by Eric 21 Price and Chris Orbig on matching chelators to 22 radiometals. 23 Q Now in this document, he uses a phrase, gold 24 standard. 25 A Uh-huh.	Page 61 1 A Right, but what I want to see is if he 2 actually has numbers for lutetium, and in other words, 3 we can actually see 23, 21. One of these has both DOTA 4 and DOTAGA in the same picture, not TETO. So instead 5 of speculating, we'll have the real numbers. 6 Q Are you thinking of Table 2? 7 A I believe so. Let me just check. Where is 8 Table 2? 9 Q Page 8. 10 A Yeah, so here they give the DOTA value for 11 lutetium, which is quite reasonable, quite good. 12 Q Okay, so back to my question; when -- in the 13 previous paper of yours that we were just discussing, 14 you do not change from DOTA to DOTAGA to improve the 15 binding of lutetium, correct? 16 A That was not the primary motivation. 17 Q You switched from one to the other to improve 18 the distribution of the molecule, correct? 19 A The distribution and the ability of tumor 20 cells to take up the molecule and retain the 21 radioactivity. 22 Q Okay, so there are reasons other than what he 23 defines as the gold standard to choose a chelator and 24 add it to a molecule, correct? 25 A Correct.

Page 62 1 Mr. Boetticher: It's been about two 2 hours. Do you want to take a break? 3 The Witness: I'm fine, but if you want 4 to take a break, that's fine. 5 Mr. Boetticher: Yeah, let's go ahead and 6 take a break. 7 (A short break was taken at 10:58 A.M.) 8 (Direct Examination resumed at 11:08 A.M.) 9 By Mr. Boetticher: 10 Q All right, I'm going to give you Exhibit 11 1028. 12 A Thank you. 13 Q Do you recognize this document? 14 A Indeed I do. 15 Q What is this document? 16 A This document is a publication in the Journal 17 of Nuclear Medicine with Martina Weisen as first 18 author and Hans-Jürgen Wester as senior author, and it 19 discusses -- or it describes gallium-68 and lutetium- 20 177 labeled PSMA I&T. 21 Q It doesn't discuss actinium, right? 22 A No, it does not. 23 Q Okay, and so this is the first time that the 24 PSMA I&T has been introduced, correct? 25 Mr. Murphy: Objection; form.	Page 64 1 everything until you get to the first carboxyl group is 2 the same. 3 Q And the DOTAGA itself is the same? 4 A Yes. 5 Q So they were able to change this -- we'll 6 call it the linker portion -- 7 A Correct. 8 Q -- in between, and that resulted in increased 9 binding and increased uptake? 10 Mr. Murphy: Objection; form. 11 The Witness: Yes. 12 By Mr. Boetticher: 13 Q I'm going to ask, do you have any idea as to 14 why that would have increased either binding or uptake? 15 A Probably differences in lipophilicity of the 16 linker, a little bit difference in the orientation as I 17 mentioned. So you could have differences in the, you 18 know, potential steric hindrance and potential 19 secondary interactions with PSMA binding pocket, which 20 as you know is deep in the funnel. 21 Q Nobody's ever done any X-ray crystallography 22 on this, right? 23 Mr. Murphy: Objection; form. 24 The Witness: I'm thinking. People 25 have done X-ray crystallography on the binding of some
Page 63 1 The Witness: I believe so, yes. My 2 hesitation is whether someone had used a different name 3 other than I&T, which is for imaging and therapy, in 4 some previous publication, but I doubt it. 5 By Mr. Boetticher: 6 Q Well, let me draw your attention to Figure 1. 7 A Yes, Figure 1. 8 Q So in Figure 1, they are describing the 9 changes that they made to DOTAGA-FFK to create PSMA 10 I&T, is that correct? 11 A Correct. 12 Q So can you describe to me the changes that 13 they made between these two molecules? 14 A The primary one is that instead of having a 15 benzyl substituent, they have a benzene ring with both 16 a hydroxyl group and an iodine substituent. Hydroxyl 17 is para to the site of attachment to the rest of the 18 scaffold, and the iodine is meta. The other difference 19 is if you look at those little wedges, if you will, 20 those little very incredible small triangles, -- 21 Q Yeah. 22 A -- those govern like stereochemistry. So it 23 suggests a little bit different configuration in space. 24 Those are the primary two things that I notice. The 25 PSMA binding element off to the left is the same, and	Page 65 1 ligands to PSMA, but I don't believe it has been done 2 for these compounds, although I can't be certain. 3 By Mr. Boetticher: 4 Q All right, I'd like you to look at Table 2. 5 A Yes, oh, Table 2? 6 Q Yeah. 7 A I like Table 1 better. 8 Q That's on page 1172. 9 A Right. 10 Q So what is Table 2 doing here? 11 A So Table 2 is comparing the biodistribution 12 of the gallium-68 analog and the lutetium-177-PSMA I&T 13 analog in mice with PSMA expressing LNCaP tumors. 14 Q And if we look at the results for kidney, we 15 see that with the gallium and the PSMA I&T, they have a 16 percentage IDG of 53.26, plus or minus 9.02. And for 17 the 177-lutetium-PSMA I&T, it has 107.24, plus or minus 18 15.61. You see that? 19 A Uh-huh. 20 Q That's a very large difference between those 21 two nearly identical molecules. 22 Mr. Murphy: Objection. 23 By Mr. Boetticher: 24 Q Correct? 25 Mr. Murphy: Objection; form.

Page 66 1 The Witness: There is a critical 2 difference, however. And the critical difference is 3 that gallium is a very small radiometal compared with 4 lutetium-177 and also actinium-225. People who work 5 with gallium as their endpoint -- in other words, 6 that's really what they want to do, don't use DOTA, 7 don't use DOTAGA, but they use NOTA. And I believe you 8 will also see that in -- 9 Mr. Boetticher: Price's work. 10 The Witness: -- Price's work. So the 11 ability for the two radiometals to remain in the 12 macrocycle would not be expected to be the same. 13 By Mr. Boetticher: 14 Q Would you be able to predict which one would 15 have the higher percentage IDG? 16 Mr. Murphy: Objection; form. 17 The Witness: Probably, yes. 18 By Mr. Boetticher: 19 Q How? 20 A Because what I would do is I would make the 21 assumption that a certain amount of the gallium escaped 22 the compound, and there are several things that could 23 happen. The gallium could just distribute as small ion 24 or -- and remember, it might go wherever gallium goes. 25 But the other thing is that gallium being a trivalent	Page 68 1 know, steric hindrance and all these other factors have 2 to be considered. 3 Q So you're saying that less of the gallium- 4 PSMA I&T is in the kidney because -- because the 5 gallium leaked from the PSMA I&T? 6 A That would be my speculation, and if you look 7 at the tumor uptake, you will see the tumor uptake is 8 considerably lower than the lutetium. 9 Q Which -- which is the tumor uptake; oh, at 10 the bottom there? 11 A Yeah, which is consistent with what I just 12 said. 13 Q But doesn't that assume that the presence of 14 gallium is important for it to be taken up by the 15 kidney and the tumor? 16 A We are only counting gallium here. We're not 17 counting the molecule. It's only the -- so when you 18 put these tissues in the automated gamma counter, the 19 automated gamma counter can't tell if it's gallium-PSMA 20 I&T, gallium transferrin, whatever. You're only 21 counting the gallium activity. 22 Q So you're saying that it's less about its 23 ability to be taken up by these different tissues, it's 24 more about the inability to measure the gallium? 25 A No, it's about the inability for the DOTA or
Page 67 1 could bind to the metal-binding proteins like 2 transferrin, lactoferrin, and all of those which don't 3 go to the kidney. So, you know, you could predict this 4 based on what is presumably known about the 5 biodistribution of -- of gallium without the PSMA I&T. 6 Q Are you really predicting it or are you 7 explaining the results afterwards? 8 Mr. Murphy: Objection; form. 9 The Witness: You know, if you ask me 10 to speculate, I would say that I would predict it based 11 on the known differences in stability. 12 By Mr. Boetticher: 13 Q So changes in the nuclide that the chelator 14 is holding can have effects on its -- the placement of 15 the molecule in tissue, correct? Am I saying that 16 correctly? 17 A You're saying it correctly, but it's 18 incorrect. So the story is that we are only interested 19 in a way in the radioactive part of the molecule 20 because that is what is used for imaging and what is 21 used for therapy. So, you know, to interpret the 22 biodistribution, you have to know what has happened to 23 the gallium-68. You know, if gallium-68 were bound to 24 another molecule with -- with a DOTA instead of a NOTA, 25 you would predict a similar problem, although, you	Page 69 1 DOTAGA macrocycle to contain the gallium within the 2 macrocycle. 3 Q And then you won't be able to measure the 4 gallium because it's not there, even if the molecule 5 has been taken up? 6 A No, you're only looking at -- gallium is the 7 only thing you're looking at when you're counting. 8 Q I understand that, but what I'm getting at is 9 that because you're only measuring the gallium, the 10 PSMA I&T could still be taken up into the kidney, but 11 there's no gallium to measure? 12 A Absolutely, yes, sorry. 13 Q So take a look at Figure 3 for me. Oh, wait; 14 before we do that, I'm sorry; Table 2. So the high 15 amount of PSMA I&T, either lutetium or gallium, that we 16 see in the kidney, this reflects people's concern about 17 PSMA-targeting molecules ending up in the kidney and 18 damaging them, correct? 19 Mr. Murphy: Objection; form. 20 The Witness: It could be mediated by 21 binding to PSMA in the kidney, certainly. It also 22 could be a radiolabeled catabolite in the kidney. But 23 clearly, whatever the reason, you would like to 24 minimize the amount of radioactivity in the kidney. 25 By Mr. Boetticher:

Page 70 1 Q So now looking at Figure 3, what is Figure 3? 2 A Figure 3 is a compilation of tumor-to-organ 3 ratios at one hour after injection. 4 Q So by doing a comparison of tumor to organ, 5 are they controlling for the loss of gallium from the 6 DOTA? 7 A No. 8 Q Why not? 9 A They're just counting radioactivity, and they 10 don't know whether the gallium is on the DOTA or not. 11 Q But if the gallium is being lost from the 12 DOTA equally throughout, and you're doing a ratio of 13 your tumor to other organs or tissues, then this 14 becomes just a comparison of how much ends up in the 15 tumor versus how much ends up in the other tissue? 16 A Right, but please notice that the tumor-to- 17 organ ratios for the gallium are lower than the ratio 18 for the lutetium. 19 Q But not for all of them; it's higher for the 20 intestines, correct? 21 A Yeah. 22 Q And it's equal for the muscles, correct? 23 A Right. 24 Q So why would that be? 25 A Well, first I would have to refresh my memory	Page 72 1 A No, because when you work with radioactivity, 2 the only thing you care about is where the 3 radioactivity is, so it's not an artifact. 4 Q Okay, but what they're measuring here, when 5 they talk about binding, for example, or where the 6 location is, it says here dual-tracer biodistribution 7 percentage, IDG, and LNCaP tumor-bearing CD-1 nu/nu 8 mice at one hour after injection, correct? 9 A That's correct. 10 Q And then it says gallium-PSMA I&T, and it has 11 a series of numbers under it, correct? 12 A Correct. 13 Q And the next column is lutetium-PSMA I&T. It 14 has a series of numbers on it, correct? 15 A Right. 16 Q So it is trying to indicate where the 17 gallium-PSMA I&T is, right? 18 A It's trying to indicate where the gallium is 19 after injection of gallium-PSMA I&T. For example, if 20 you look at Table 3, total absorbed doses after 21 application of lutetium, it says what was injected. 22 That doesn't necessarily indicate what the chemical 23 form is that has resulted in these radiation doses. 24 There are some people who will say tumor-to-organ 25 ratios of gallium-68 and lutetium-177 after injection
Page 71 1 on where the gallium distributes all by itself without 2 the ligands, and I can't recall that, so I can't answer 3 that. However, I will say that, you know, intestinal 4 uptake sometimes is a reflection of a relatively 5 lipophilic molecule. 6 Q So do you think the gallium is simply going 7 to those places on its own? 8 A I don't know whether it's going there on its 9 own, or whether it's going there based on binding to 10 some component in vivo. 11 Q So your conclusion is that the differences we 12 see in the uptake and binding in these numbers is not 13 due necessarily to an actual difference between the 14 gallium-PSMA I&T and the 177-lutetium-PSMA I&T, to 15 those features, but merely because of an artifact of 16 gallium not being held by the DOTA? 17 A It's not an artifact. 18 Mr. Murphy: Objection; form. 19 The Witness: Why is it an artifact? 20 It's not an artifact. 21 By Mr. Boetticher: 22 Q Well, because you end up not measuring 23 something you were trying to measure, and it's throwing 24 off your numbers, and you think you're measuring one 25 thing, but you're not.	Page 73 1 of gallium and lutetium-PSMA I&T, which is more 2 correct, because you don't know what's happening. I 3 hope I was smart enough to do that. But yeah, I mean, 4 that's -- that's really the correct statement. Oh, for 5 example, Figure 3 -- 6 Q Which exhibit? 7 A -- of Exhibit 1; the -- the caption is uptake 8 of iodine-131 and astatine-211 in whatever xenografts 9 after administration of I-131-5 and astatine-211-6 in 10 mice. That's really the correct way to write it, so 11 because you're only looking at the radioactivity. 12 Q Okay, so you think that this -- that 13 Weineisen was in error to list it this way? 14 A It's -- I mean, it's not an error, but the 15 phraseology is not perfect. But it gets the point 16 across, because all you care about is the 17 radioactivity. But I would have worded it the way I 18 worded it, because it creates confusion. 19 Q So Figure 6, can you explain what Figure 6 20 is? 21 A Figure 6 shows a positron emission 22 tomographic image, PET, of a clinically used, but not 23 FDA approved at the time, gallium-68 compound. And 24 they're comparing it with the uptake at 47 hours of 25 lutetium-PSMA I&T.

Page 74 1 Q Okay. 2 A So A is at 60 minutes, and B is at 47 hours. 3 Q So in the text on the left-hand side, they 4 discuss administered activity of 5.7 and 8.0 5 gigabecquerel, correct? 6 A Uh-huh. 7 Q And so they ascribe that in patient two had a 8 PSA level of 54.2 nanograms per mil. 9 A Uh-huh. 10 Q In the next paragraph, they say that patient 11 three had a PSA level of 40.2, correct? 12 A Correct. 13 Q Let's see here. And then they say the 14 patient, which I guess they're referring to patient 15 three, underwent one therapy cycle with the 8.0 16 gigabecquerel of 177-lutetium-PSMA I&T. And they see 17 further on the paragraph at the top of the next column 18 that it was accompanied by a significant drop to the 19 PSA to 0.7 nanograms per mil. Am I interpreting that 20 correctly? 21 A Yep. 22 Q So do you think that the drop from the 40.2 23 nanograms per mil to the 0.7 nanograms per mil is 24 significant? 25 Mr. Murphy: Objection; form.	Page 76 1 measurements were done? 2 A Yes. 3 Q So look at page 7, the column on the left- 4 hand side. The third line begins with, interestingly, 5 although the PSMA affinity of natural lutetium-PSMA I&T 6 is only marginally increased compared with natural 7 gallium-PSMA I&T, internalization of 177-lutetium-PSMA 8 I&T into LNCaP cells is significantly enhanced. 9 A Uh-huh. 10 Q So could you explain to me what they're 11 discussing there? 12 A So affinity is how tightly the molecules bind 13 to PSMA. And I don't remember the exact assay they 14 used, but, you know, that is often done just with PSMA 15 on a plate. The internalization, which they mentioned, 16 is a very important parameter because it governs 17 retention inside the cell. And what this indicates is 18 that the internalization with lutetium is much higher. 19 Q So even though the affinity didn't increase 20 that much, at least compared to the gallium, the -- its 21 ability to be taken up did? 22 A Right. 23 Q And so these are really -- strike that. So 24 while presumably increased binding could help with 25 internalization, these are actually two separate
Page 75 1 The Witness: It is significant for the 2 status at that point in time, yes. 3 By Mr. Boetticher: 4 Q So you think that this result is significant, 5 but the result in the Kratochwil 2016 paper is not? 6 Mr. Murphy: Objection; form. 7 The Witness: That's why I added that 8 point in time. All you know is what happens at that 9 point in time. We don't know whether the patient here 10 or the patient with the other study progressed after 11 three months. We don't know that. So it's likely 12 statistically significant at that one point in time. 13 By Mr. Boetticher: 14 Q Okay, but before you said the other one, 15 Kratochwil 2016, was not significant. You said it was 16 dramatic, but not significant, correct? 17 A We don't have enough information to know if 18 it's clinically significant, namely that the patient 19 had a durable response. 20 Q But you think that this one in Weineisen is 21 significant? 22 A As I said, it is significant at the point in 23 time when that measurement was done. 24 Q And do you think that Kratochwil 2016's 25 results were significant at that point in time that the	Page 77 1 parameters? 2 Mr. Murphy: Objection; form. 3 The Witness: So -- so binding 4 affinity, if you don't bind to the target cell, you 5 clearly can't internalize. It's not necessarily 6 affinity that is the important factor. It is the -- 7 what's called the forward binding rate constant. So 8 what you've got, binding and then dissociation, 9 association, dissociation. So the two important 10 parameters really are the association constant, the 11 forward binding constant, and the internalization 12 constant, and those two are the parameters that will 13 govern uptake into the cell. 14 Q The association constant and the 15 internalization constant? 16 A Right, the forward binding constant. 17 Q And -- but what they're explaining here is 18 that one can be improved without necessarily improving 19 the other? 20 A Right, however -- sorry; obviously the 21 forward binding constant is part of the affinity 22 constant. But it's not the only thing. See what I 23 mean, because there's also the dissociation. 24 Q Right, but as far as the internalization 25 constant, that's going to be something else?

Page 78 1 A Right. 2 Q And so this one, this Weinstein (sic) paper 3 from 2015, this is what you rely on for your 4 obviousness argument, correct? 5 A Correct. 6 Q And no place in this document do they discuss 7 using actinium, correct? 8 A Not in this document. 9 Q Okay, let's move on to Exhibit 1031. You 10 recognize this document? 11 A Yes, I do. 12 Q So you're familiar with this, correct? 13 A I am familiar. 14 Q There isn't much of it, is there? 15 A That's because it's an abstract. 16 Q And so this is also a document you're relying 17 on for your obviousness argument, correct? 18 A Correct. 19 Q Now you're familiar with this DOTATOC 20 molecule that's in the title of this document? 21 A Correct. 22 Q Okay, now in this abstract, this isn't -- 23 they aren't looking at the same disease that they were 24 looking at in Weineisen, correct? 25 A Correct.	Page 80 1 A No. 2 Q And this article doesn't cite back to 3 Weineisen? 4 A Correct. 5 Q So there is no common line to draw from the 6 Weineisen article to this article, is there? 7 Mr. Murphy: Objection; form. 8 The Witness: So -- 9 By Mr. Boetticher: 10 Q Is that a yes or a no? 11 Mr. Murphy: Objection; form. 12 The Witness: Yes. 13 By Mr. Boetticher: 14 Q Okay, what is that line? 15 A What is what line, sorry? 16 Q My question was, there's no line to be drawn 17 between Weineisen and this article, right? 18 A Uh-huh. 19 Q Okay, so a person of ordinary skill in the 20 art would not necessarily move from Weineisen to this 21 article. They could have moved on to any article, 22 correct? 23 Mr. Murphy: Objection; form. 24 The Witness: So this article, 25 abstract, discusses dose ranges. That's the focus of
Page 79 1 Q And they're not binding the molecule to the 2 same binding target as they were in Weineisen, correct? 3 A Correct. 4 Q And they're not using the same targeting 5 molecule as they were in Weineisen, correct? 6 A Correct. 7 Q And they're not using the same chelator 8 subclass as they were in Weineisen? 9 Mr. Murphy: Objection; form. 10 The Witness: It is -- yeah, they're 11 using DOTA instead of DOTAGA. 12 By Mr. Boetticher: 13 Q And in fact, Weineisen taught away from using 14 DOTA because she switched over to DOTAGA, right? 15 Mr. Murphy: Objection; form. 16 The Witness: That's correct. 17 By Mr. Boetticher: 18 Q And this doesn't use the same nucleotide, 19 right? 20 A That's correct. 21 Q And this paper, the nucleotide is a different 22 -- it emits a different particle, correct? 23 A Yes, it only describes what happens with 24 Actinium-225. 25 Q And Weineisen doesn't cite to this article?	Page 81 1 this article, is dose ranges. And clearly, if one were 2 planning a new targeted radiotherapeutic that one 3 wanted to advance into patients, understanding dose 4 ranges that have been used before would be important, 5 okay? This article -- 6 By Mr. Boetticher: 7 Q Which article? 8 A The Weineisen article discusses lutetium- 9 labeled PSMA I&T and in a previous article of theirs, 10 they discuss the possibility of using actinium. Now 11 there have been many, many, many publications where 12 what people do is they look at what happened with the 13 beta emitter and then they move to the chemically 14 similar alpha. And so if one wanted to do that with 15 radiometals, you would look at lutetium and then you 16 would look at actinium and say, hey, there are doses 17 that are tolerated with actinium with a small molecule 18 with a similar type of chelate. To me, it would be 19 obvious that you could just replace the lutetium in 20 PSMA I&T with actinium-225. 21 Q Okay, but your analysis is assuming that 22 they're already -- that they already want to add the 23 actinium and they looked at this article for the 24 dosing, isn't it? 25 Mr. Murphy: Objection; form.

Page 82 1 The Witness: So that's certainly a 2 possibility. The difficulty is what one does is you 3 look at what's out there in the literature, what you've 4 heard at meetings, and you try to come up with 5 something that has a high probability of success. 6 By Mr. Boetticher: 7 Q Would using bismuth have a high probability 8 of success? 9 Mr. Murphy: Objection; form. 10 The Witness: You know, if you had 11 bismuth, you would probably want to try it. But, you 12 know, actinium -- all of the studies that I know where 13 people have used bismuth-213, they switched to 14 actinium-225 for practical reasons. It's what you 15 have. 16 By Mr. Boetticher: 17 Q But using bismuth would also have a high 18 level of success, correct? 19 Mr. Murphy: Objection; form. 20 The Witness: Not necessarily, because 21 first of all, bismuth is chemically different than 22 lutetium and actinium-225, which are chemically 23 similar. And the half-life of lutetium and the half- 24 life of actinium-225 are similar; whereas, the half- 25 life of bismuth-213 is less than an hour. And that	Page 84 1 the time, there were three sources of actinium-225 in 2 the world. One was in Russia. One was in Oak Ridge, 3 Tennessee. And the vast majority of the actinium-225 4 came from a German national lab located in Karlsruhe, 5 and some of the people on that patent worked at 6 Karlsruhe. So they had ready access to actinium-225. 7 Q That's very interesting, but it doesn't 8 answer my question. What you just described was 9 availability being important, and then you explained 10 how people didn't have availability to actinium. So 11 you're describing a POSA who would choose to use 12 actinium when they didn't have availability to it; what 13 about bismuth; what about lead; what about thorium? 14 A The -- 15 Mr. Murphy: Objection; form. 16 The Witness: The availability at that 17 point in time for all of those was not great. 18 By Mr. Boetticher: 19 Q Was it better than actinium? 20 A I don't recall. 21 Q And, in fact, a POSA wouldn't even have to go 22 to an alpha emitter. They could try other beta 23 emitters, couldn't they? 24 A If they were trying to develop an alpha- 25 emitting targeted radiotherapeutic to take advantage of
Page 83 1 means that your radiation dose is going to be deposited 2 very rapidly, and it's going to be incredibly 3 impractical to actually use. So, you know, bismuth is 4 off here; actinium and lutetium are here. 5 By Mr. Boetticher: 6 Q But your -- 7 A Sorry for that; I'm sorry. 8 Q But your explanation begins with wanting to 9 put in actinium and then coming to this article in 10 order to find out the dosage, right? 11 Mr. Murphy: Objection; form. 12 The Witness: Yeah, I mean, you'd have 13 to want to use actinium-225. 14 By Mr. Boetticher: 15 Q Now you'd want to use actinium instead of 16 lead or thorium or bismuth, right? 17 Mr. Murphy: Objection; form. 18 The Witness: Right. 19 By Mr. Boetticher: 20 Q But POSA could have tried one of those other 21 ones, right? 22 A It again gets to availability, and 23 availability in a chemically tractable form and with 24 sufficient radionuclidic purity that one could 25 potentially advance it to patients. And, you know, at	Page 85 1 its radiobiological advantages, they would not do 2 another beta emitter. 3 Q And so you're starting your assumption, your 4 analysis, from the idea that that's exactly what 5 they're trying to do. They're trying to develop an 6 alpha emitter, correct? 7 A They were interested in developing an alpha 8 emitter, but my guess is they didn't have availability 9 of the alpha emitter. 10 Q They who? 11 A The Weineisen group. 12 Q Oh, I didn't realize we were talking about 13 the Weineisen group. 14 A Well, you wanted me to connect these two 15 documents. 16 Q I was talking in terms of a person of 17 ordinary skill in the art looking at the two documents. 18 A Which could include the Weineisen group. 19 Q Okay, all right, so -- so this Kratochwil 20 paper, it describes itself as an empiric dose 21 escalation to find the maximum tolerable dose, correct? 22 A Correct. 23 Q Now we discussed earlier about how in your 24 first paper, when you were first starting out with your 25 series of molecules, how the maximum tolerable dose is

Page 86 1 different from what would be an effective or 2 efficacious dose, correct? 3 Mr. Murphy: Objection to form. 4 The Witness: Correct. 5 By Mr. Boetticher: 6 Q And so the maximum tolerable dose doesn't 7 really provide any guidance on what the efficacious 8 dose would be, correct; correct? 9 A Well, it sets boundaries. 10 Q Well, the efficacious dose can be higher than 11 the maximum tolerable dose, can't it? 12 A Right. 13 Q Okay. 14 A May I read you one sentence from the 15 conclusion? 16 Q No. 17 Mr. Murphy: You have to let the 18 witness answer the question. 19 Mr. Boetticher: Well, I let him answer 20 the question. He wants to now speak up and -- and read 21 a section that I didn't ask about. 22 The Witness: Well, it is exactly 23 related to the question. 24 By Mr. Boetticher: 25 Q Well, let me -- let me finish my line of	Page 88 1 or equivalent to the maximum tolerated dose. 2 By Mr. Boetticher: 3 Q So you want one that's lower, but it could be 4 higher, right? 5 A It couldn't be higher. 6 Q So what happened with your first paper, 7 Exhibit 1, you had a maximum tolerable dose, but you 8 didn't get an effect until you went beyond that point, 9 right? 10 A Right. 11 Q So the effective dose could be higher than 12 the maximum tolerable dose? 13 A Presumably you want to administer a dose that 14 will not harm the patient. 15 Q I understand that. But that dose that would 16 be effective could be beyond the point where you would 17 be harming the patient, and so you can't really use it? 18 Mr. Murphy: Objection; form. 19 The Witness: The -- there are 20 compounds where the first dose or the lowest dose which 21 is effective is above the maximum tolerated dose. 22 By Mr. Boetticher: 23 Q Right, and there are compounds where it's 24 below the maximum tolerated dose, right? 25 A Right.
Page 87 1 questions, okay? 2 A Okay, cool. 3 Q And if your counsel wants to follow up with 4 it when I'm done, then he can do that, okay? If it's a 5 response to one of my questions, okay, but this isn't a 6 chance for you to speak, to like make a speech, okay? 7 Mr. Murphy: I believe Dr. Zalutsky 8 was responding to your question, and you cut him off. 9 Mr. Boetticher: No, he said, let me read 10 a different part of the document. 11 Mr. Murphy: To respond to the 12 question. 13 By Mr. Boetticher: 14 Q So let me -- let me finish my line of 15 questioning, okay? 16 A Sure. 17 Q So you still haven't answered my question, 18 which is that the maximum tolerable dose is different 19 from the efficacious dose, right? 20 Mr. Murphy: Objection; form. 21 The Witness: So it can be different, 22 and it's interesting because the FDA now is more 23 interested in the minimum effective dose rather than 24 the maximum tolerated dose. But, you know, you 25 obviously want to have an effective dose that is below	Page 89 1 Q Because the two are really independent of 2 each other? 3 A Generally so, yes. 4 Q And so the efficacious dose could be far 5 below the maximum tolerable dose, right? 6 A Right. 7 Q And so if I were to say that my maximum 8 tolerable dose is at a certain level, and I say that I 9 do have some efficacious effect, that doesn't mean it's 10 at the maximum tolerable dose, right? 11 A Right. 12 Q And so while the maximum tolerable dose could 13 create boundaries, it's not going to define where that 14 efficacious dose is? 15 A It will say that the efficacious dose is at 16 or below the MTD. But let me qualify that. The -- the 17 efficacious dose in patients, okay, that one could 18 actually administer to patients, not animals -- the 19 efficacious dose has to be equal to or below the MTD. 20 Q Right, so you're talking about a 21 pharmaceutical that's going to be released to the 22 public, right? 23 Mr. Murphy: Objection; form. 24 The Witness: I'm talking about a 25 pharmaceutical that has potential for clinical

Page 90 1 investigation. 2 By Mr. Boetticher: 3 Q So the efficacious dose, when you're doing a 4 study, could be above the maximum tolerable dose and so 5 you never reach it, right? 6 A It could be, yes. 7 Q And if we set a boundary for the efficacious 8 dose at the maximum tolerable dose, then it could be 9 significantly below it, correct? 10 A One of the complicating parameters for this, 11 answering this question, is the time frame for efficacy 12 and the time frame for MTD. By that, I will go back to 13 animals, if that's okay. And, you know, there are a 14 lot of these PSMA compounds, including actinium ones, 15 that were efficacious and then in a parallel study 16 where they were looking at maximum tolerated dose, the 17 side effects did not happen until much later. So the 18 time window for looking at efficacy and the time window 19 for looking at MTD are different. 20 Q So on the second page, at the top of the 21 second page where you have it there, that first 22 sentence says, the MTD, the maximum tolerable dose, of 23 a single cycle actinium-225 DOTATOC was considered to 24 be 40 megabecqs. 25 A Megabecqs, yeah.	Page 92 1 Q Right? 2 A Well, we know that one of those three gave 3 promising treatment efficacy. And it is standard in 4 the field to look at both single doses and fractionated 5 doses. So if one were interested in, let's say, a 6 compound labeled with actinium, generally what one does 7 clinically is you start with a single dose and then you 8 fractionate. So it's all part of normal progression of 9 clinical investigation to do this. 10 Q But that's not in this paper? 11 A Yes, it is. Well, it's not a paper. It's an 12 abstract. 13 Q It's an abstract. 14 A So they start by describing 40 as a single, 15 and then they talk about dividing it into 25 16 megabecquerel increments and then 18.5. And they tell 17 you that you could give up to 75 megabecquerels with it 18 being tolerated. So that must be a multiple-dose 19 protocol because the MTD for single dose is 40, so it's 20 got to be MTD. It's got to be a multiple-dose 21 protocol. 22 Q It does not have to be a multiple-dose 23 protocol, does it? They have a unitary at 40 24 megabecquerels. And it also says multiple fractions 25 were tolerated with 25 megabecquerels every four months
Page 91 1 Q Okay, so that doesn't tell you where the 2 efficacious dose would actually be for that compound, 3 correct? 4 A All I know is that they described 5 radioactivity administered under different formats, 6 single cycle, multiple fraction, that said it was well 7 tolerated. So every four months, 25 megabecqs or else 8 -- or 18 every two. So they've got three different 9 dosing regimens. And then later on they say it also 10 demonstrated promising treatment efficacy in various 11 patients. So that tells me that one of those doses was 12 efficacious. 13 Q Good, but we don't know where that is, do we? 14 A If I had been present in that presentation, I 15 probably would have, because one writes an abstract 16 that is -- I guess it's 250, 300 words, in order to get 17 it accepted for oral presentation. So this thing was 18 presented orally sometime in 2015. And I can only 19 presume that the author elaborated on the relationship 20 between the various treatment protocols that are 21 described and which ones demonstrated promising 22 treatment efficacy. 23 Q But that's pure speculation, right? 24 Mr. Murphy: Objection; form. 25 By Mr. Boetticher:	Page 93 1 or 18.5 megabecquerels every two months. Do you see 2 that? 3 A Yes, I do. 4 Q So they were trying different treatment 5 types, correct? 6 A This is basically the standard approach for 7 targeted radiotherapy. 8 Q They were trying different treatment types, 9 correct? 10 A So what they did is they determined single- 11 dose MTD and then they determined multiple-dose MTD. 12 Q And those are different treatment types, 13 right? 14 A Different regimens. 15 Q Okay, so they tried different regimens? 16 A Correct. 17 Q We don't know which of those regimens 18 produced the promising treatment efficacy, correct? 19 A Not from reading this abstract. 20 Q And it also says cumulative activities of 75 21 megabecquerels were found tolerable in regard to 22 delayed toxicity. Do you see that? 23 A Correct. 24 Q So it could be up to 75 megabecquerels? 25 A Right.

Page 94 1 Q So we don't know where that line is drawn, 2 correct? 3 A We do not, from the abstract, know that. 4 Q And just to be clear, you weren't in the room 5 when they were presenting this abstract, correct? 6 A I very well may have been. No, seriously;;, 7 but I don't remember, because it was like 10 years ago. 8 Q Yeah. 9 A No, I probably was, actually. 10 Q Okay, so we don't really know where that 11 promising treatment efficacy line is, right? We can 12 agree to that? 13 Mr. Murphy: Objection; form. 14 The Witness: We don't know a specific, 15 but we know kind of a range. 16 By Mr. Boetticher: 17 Q All right, I'm going to give you what is 18 Exhibit 1011. Do you recognize this document? 19 A Yes, I do. 20 Q What is this document? 21 A This document is -- it's actually a poster. 22 So it's like an abstract of a Phase I trial using 23 actinium, and that's an antibody, lintuzumab, and low- 24 dose cytarabine in older patients with AML. 25 Q And what is cytarabine?	Page 96 1 correct? 2 A That's correct. 3 Q And the chelator here is not identified, but 4 it must differ from at least one of them, right? 5 A I'm trying to remember what it is. It's not 6 in this paper. You're right. But it's probably -- 7 it's probably either -- probably DOTA. 8 Q But it could be some other form of DOTA? 9 A It's either DOTA or an acyclic version like 10 CHX-DTPA. 11 Q So it could be different from either one of 12 the chelators that was used in Weineisen and 13 Kratochwil? 14 A Correct. 15 Q And the nucleotide here is definitely 16 different from the one being used in Weineisen, right? 17 A Right. 18 Q And again, Weineisen doesn't make reference 19 to this paper, right? 20 A That's correct. 21 Q And this paper doesn't make reference to 22 Weineisen, does it? 23 A It's not. Nor does it make reference to 24 anybody, because it's a poster. 25 Q And so again, there's no common line that
Page 95 1 A It's a chemotherapeutic. 2 Q For what? 3 A My guess is leukemia. 4 Q Your guess, you don't know for sure? 5 A I do know for sure. It's used for leukemia 6 and other things, but yes, leukemia, certainly. 7 Q And what is lintuzumab? 8 A That is -- that is a humanized antibody 9 called HU195. 10 Q And what is its antigen? 11 A CD -- I'm trying to remember. I've got all 12 these CDs, but CD33, right. 13 Q So this poster isn't treating either of the 14 diseases that Weineisen or Kratochwil were treating, 15 correct? 16 A Correct. 17 Q And it doesn't use the same binding target as 18 either Kratochwil or Weineisen were using, correct? 19 A That's correct. 20 Q And it isn't even using the same kind of 21 molecule that Weineisen and Kratochwil were using? 22 A That's correct. 23 Q And usually an antibody doesn't have the same 24 kind of pharmacokinetics that you see with the 25 molecules that Weineisen and Kratochwil were using,	Page 97 1 could be drawn from Weineisen to this paper where they 2 overlap that would cause a person of ordinary skill to 3 follow along the field to it? 4 Mr. Murphy: Objection; form. 5 The Witness: I think that a person of 6 ordinary skill who wanted to develop a, for example, 7 actinium PSMA-targeted compound would read everything 8 they can get their hands on about actinium and 9 everything they can get their hands on about PSMA and 10 look for the best way of combining all of that 11 information. 12 By Mr. Boetticher: 13 Q So you think a person of ordinary skill would 14 gather up all of the information and combine it into 15 the best possible structure that they could? 16 Mr. Murphy: Objection; form. 17 The Witness: I think that many people 18 of ordinary skill would do that. 19 By Mr. Boetticher: 20 Q And so you think that the person of ordinary 21 skill would pick actinium out of all of the other 22 possible nuclides that they could use? 23 A I think that many people would. 24 Q And so they wouldn't use, for example, 25 bismuth that we mentioned before?

Page 98 1 Mr. Murphy: Objection; form. 2 The Witness: Interestingly, the first 3 stage of this investigation was with bismuth. And they 4 said, hey, actinium is more convenient. So they moved 5 forward from bismuth to actinium with that lintuzumab. 6 But by this point in time, they had already moved to 7 actinium from bismuth, and I don't think very many 8 other people were focusing on bismuth. It was mostly, 9 if I could get my hands on actinium, I would use it. 10 By Mr. Boetticher: 11 Q So your thinking is that a person of ordinary 12 skill would have gravitated to actinium because they 13 could? 14 Mr. Murphy: Objection; form. 15 The Witness: I think a person of 16 ordinary skill, if their goal was to develop an alpha- 17 emitting targeted radiotherapeutic, would gravitate 18 towards actinium, not all, but a significant number of 19 them would. 20 By Mr. Boetticher: 21 Q And again, you're beginning your process by 22 assuming that they want to make an alpha-emitting PSMA- 23 targeted molecule, right? 24 Mr. Murphy: Objection; form. 25 The Witness: Based on the limited	Page 100 1 and N is 3. And I can't guarantee you that that's why 2 he did it, but that is the most likely reason based on 3 traditional Phase 1 trial design. 4 Q So you don't know for sure that that's what 5 he did, but you're basing it on your experience as to 6 how trials might work? 7 A And how trials do work. 8 Q So was -- was cytarabine already a well- 9 established drug at that point? 10 A Yeah. 11 Q And so what he's doing here is trying to 12 figure out the effects of the 225-Ac on the lintuzumab; 13 in combination with a low dose of cytarabine, right? 14 A Right. 15 Q But he doesn't have a negative control, 16 right? 17 Mr. Murphy: Objection; form. 18 The Witness: So my guess is this was 19 done this way because cytarabine is standard of care. 20 And when you're doing a Phase 1 study, you cannot 21 deprive a patient of standard of care, so this is what 22 you have to do. 23 By Mr. Boetticher: 24 Q I think you misunderstood my question. I 25 understand cytarabine is the standard of care. There's
Page 99 1 advantage of using the beta emitters in the context of 2 PSMA-targeted radiotherapy, I think they would be 3 motivated to look for an alpha emitter. 4 By Mr. Boetticher: 5 Q So in this poster presentation by Jurcic, 6 what are they doing? 7 A So first of all, what they're doing is a 8 Phase I trial, which is a dose escalation trial, where 9 you start at the lowest dose -- well, actually, it's 10 the highest dose you can get away with with the FDA, 11 and then you incrementally increase it. And your 12 starting dose is generally determined by what one knows 13 about the likely maximum tolerated dose. And it's just 14 usually a 3 plus 3 design. If you get any toxicity, 15 you back down one dose level and do another three 16 patients, which is why at dose level 1, it's like it 17 goes back and forth, back and forth. 18 Q I'm sorry. You say it's going back and 19 forth, back and forth? 20 A In other words, let's say you go to dose 21 level 2, and you get a toxicity in one out of three 22 patients, then you would go back and do three extra 23 patients at dose level 1. 24 Q Okay, and where does it say that he did this? 25 A Look at the Ns there, and you can see N is 6	Page 101 1 no zero control for what he's testing, which is the 2 lintuzumab. 3 A Uh-huh, so you have to consider that this is 4 not a scientific experiment. This format is governed 5 by the regulatory authorities in the United States, the 6 FDA, and for Phase 1 studies, you cannot keep patients 7 from receiving standard of care. 8 Q And what is the standard of care in this 9 case? 10 A Cytarabine. 11 Q So they could have given cytarabine without 12 the lintuzumab, right? 13 A And I'm sure there are many, many patients 14 who have received that and -- 15 Q But not here? 16 A Not here. 17 Q And so without the negative control for 18 lintuzumab, you can't really say what its effects are 19 in this study, can you? 20 Mr. Murphy: Objection to form. 21 The Witness: Well, you have to 22 understand that the purpose of a Phase 1 study is not 23 efficacy. It's tolerability. And so this is all about 24 tolerability and determining the maximum tolerated 25 dose. It doesn't really have any -- I mean, yeah, they

Page 102 1 may make a statement or two about efficacy, but Phase 1 2 studies are all about tolerability. 3 By Mr. Boetticher: 4 Q In Table 1, -- 5 A Yeah. 6 Q -- you see a section that says response on 7 the far left side -- 8 A Uh-huh. 9 Q -- and it says CR. What does that stand for? 10 A Complete remission. 11 Q So is that a tolerability question or an 12 efficacy question? 13 A So this study is designed to address 14 tolerability. What one can do as a secondary motive is 15 discuss any potential efficacy that you might see. So 16 it's all about tolerability for Phase 1. 17 Q So in other words, we don't need to rely -- 18 strike that. In other words, we should just ignore 19 their efficacy data? 20 Mr. Murphy: Objection; form. 21 The Witness: You know, I mean, if you 22 get efficacy in a Phase 1 study, it's like a big plus. 23 But the study is not designed to obtain efficacy. It 24 is designed to determine tolerability. 25 By Mr. Boetticher:	Page 104 1 can conclude. You can also see preliminarily that 2 there are some complete responses at the 1 and the 1.5 3 microcurie per kilogram per fraction dose levels. 4 By Mr. Boetticher: 5 Q Well, you say that we can see some complete 6 responses here, but we don't have a zero control to 7 compare it to, do we? 8 A This was not designed to determine efficacy, 9 so you could do historical comparisons. You could 10 certainly do historical comparisons. 11 Q What do you mean by historical comparisons? 12 A Patients that received only the cytarabine, 13 and were followed had similar levels of disease, all 14 that. And I don't know if they discussed historical 15 controls, but clearly that's not ideal. You -- you 16 would like to have a parallel arm, but again, you can't 17 do that. 18 Q Well, I mean, you can. 19 A You can in a Phase 2, but not in a Phase 1. 20 Q Why can't you do it in a Phase 1? 21 A Because the FDA will not let you. 22 Q The standard of care is not the Lintuzumab? 23 A No, no, no, I'm taking -- I'm saying that it 24 just gets very complicated, but you're right. It would 25 be nice to have a parallel analysis of the cytarabine
Page 103 1 Q So we shouldn't rely on the efficacy results, 2 then? 3 Mr. Murphy: Objection; form. 4 The Witness: It's difficult because 5 it's a dose escalation trial. And the whole purpose is 6 to determine the maximum tolerated dose. So I don't 7 know if they actually got the MTD. I'll have to read 8 it again, but what you see is as you go up, you do see 9 some more complete responses. So I would look at the 10 efficacy stratified and really only focus on the 11 efficacy at the higher doses, which presumably are 12 approaching maximum tolerated dose. In other words, 13 you know your first dose level ain't going to work. 14 It's just to make the FDA happy. So you're not going 15 to get efficacy. I mean, you might get incredibly 16 lucky, but. 17 By Mr. Boetticher: 18 Q So from this -- so you're saying that -- 19 let's strike that. You're saying that this study is a 20 maximum tolerated dose study, correct? 21 A Absolutely. 22 Q So all we can conclude from this is what the 23 maximum tolerated dose is? 24 Mr. Murphy: Objection; form. 25 The Witness: No, that's not all you	Page 105 1 alone, -- 2 Q Okay. 3 A -- but there are hundreds, if not thousands, 4 of patients treated that way. 5 Q You said I could rely on historical studies, 6 so if I look at historical studies and at the same 7 doses of -- 8 A Cytarabine. 9 Q -- cytarabine. 10 A Yeah. 11 Q Okay, strike that. You said that I could 12 look at historical studies. So if I looked at other 13 studies that used low-dose cytarabine, and I found that 14 they were more efficacious, I would conclude that the 15 lintuzumab didn't do anything. 16 Mr. Murphy: Objection; form. 17 By Mr. Boetticher: 18 Q Correct? 19 A You could make that conclusion. 20 Mr. Boetticher: Okay, so let's take 21 a break. Let me see what else I've got. 22 (A short break was taken at 12:23 P.M.) 23 (Direct Examination resumed at 12:30 P.M.) 24 By Mr. Boetticher: 25 Q All right, I'm going to give you Exhibit

Page 106 1 1002. Here we go. So you recognize this exhibit? 2 A Yes, I do. 3 Q What is this exhibit? 4 A This is the declaration that I put together. 5 Q Okay, now this is based on -- to some degree, 6 on the previous expert, Rebecca Abergel's declaration, 7 isn't it? 8 A That's correct. 9 Q And so you read this and the thing that you 10 left in, you agreed with? 11 A Uh-huh. 12 Q Okay, let's go to paragraph 16 on page 10. 13 A Paragraph 16 on page 10, okay. 14 Q So in this paragraph, you talk about your 15 opinion as to what a POSA would consist of. Do you see 16 that? 17 A Yes, I do. 18 Q So you say a scientist or clinician with a 19 Ph.D. or M.D. or a team of such individuals? 20 A Right. 21 Q What do you mean by a team of such 22 individuals? How does that create a POSA? 23 A Well, these days, in fact for a long time, 24 most research, particularly translational work, is 25 often a collaboration of people with different types of	Page 108 1 person. I think that is the definition that is usually 2 used, but from a practical perspective, most -- most 3 advancements and most research is really done by a 4 team. But if that does not qualify as POSA according 5 to the legal perspective, of which I know not, then 6 that should be removed. 7 By Mr. Boetticher: 8 Q Let me ask you about element three. 9 A Element three. 10 Q The design, synthesis, and use of chelators 11 that form kinetically and thermodynamically stable 12 complexes with the radiometals. The patent doesn't 13 claim synthesis of chelators, correct? 14 A Right; in fact, it has nothing -- no 15 information about synthesis, purity; none of that, 16 totally lacking. 17 Q Of the chelator? 18 A Of the chelator or the compound, totally 19 lacking. 20 Q It doesn't claim the purity, right? 21 A Nope. 22 Q It doesn't claim synthesis? 23 A No, it does not. 24 Q So synthesis probably wouldn't be appropriate 25 for a person of ordinary skill as a quality here,
Page 107 1 expertise. For example, if you look at the patent in 2 question, you will see Ph.D.s and M.D.s both as 3 inventors, and that is commonly the case. So when 4 advancing or trying to advance technology, oftentimes 5 you need expertise that comes from different 6 directions. 7 Q And so if a person of ordinary skill in the 8 art didn't have all of these qualities, then they could 9 just combine with somebody else, and that would make 10 them a person of ordinary skill in the art? 11 A Is that a legal question? 12 Q I'm trying to figure out what you've decided 13 is a person of ordinary skill in the art. 14 Mr. Murphy: Objection; form. 15 The Witness: I said, or, not that the 16 team is exclusively a team. It could be an individual. 17 It could be a group of people. 18 By Mr. Boetticher: 19 Q Okay, but if -- if one person doesn't have a 20 Ph.D. or M.D., and then they team up with somebody who 21 does have an M.D., does that make that person a person 22 of ordinary skill in the art under your definition? 23 Mr. Murphy: Objection; form. 24 The Witness: It makes them a team. So 25 it's my interpretation that POSA is an individual, one	Page 109 1 right? 2 A Well, if you were considering using a 3 chelate, you would need to know how to make it. 4 Q Would you? 5 Mr. Murphy: Objection; form. 6 The Witness: If you're considering 7 using a novel chelate, you would either have to be able 8 to synthesize it or you would have to find some custom 9 synthesis house to make it. 10 By Mr. Boetticher: 11 Q And is that what is happening in these 12 claims? 13 A No, there is no explicit synthesis in the 14 claims. 15 Q Okay, at the end of part three, you have an 16 and slash or. So does that mean that a person of 17 ordinary skill could have just one of these four 18 attributes? 19 A Yes. 20 Q And that would make them a person of ordinary 21 skill in the art? 22 A Yes. 23 Q And then for part four, you have the 24 evaluation or clinical use of radiotherapeutic agents. 25 So if somebody is just skilled in the evaluation of

Page 110 1 radiotherapeutic agents, that would make them a person 2 of ordinary skill in the art? 3 A Yes. 4 Q Okay, all right, I'd like you to look at 5 paragraph 27 on page 17. 6 A Right. 7 Q The last line, selection of each of the 8 radionuclide chelator, linker, and targeting moiety is 9 key to ensure the radiopharmaceutical is effective in 10 the treatment of the particular cancer a patient may 11 have. You see that? 12 A Uh-huh. 13 Q So what did you mean by that? 14 A That the design of a successful targeted 15 radiotherapeutic agent has to consider all the 16 components of that agent. And these include the 17 radionuclide and the chelator, which is used to attach 18 it to the molecule, the linker, which is the spacer 19 between the chelator, and then the targeting vector. 20 Q And so the modification of any one of these 21 four things could change the functioning of the -- of 22 the radiopharmaceutical? 23 A That's correct. 24 Q I'd like you to look at paragraph 28. You 25 say, in some -- in some radionuclides that undergo	Page 112 1 (A short break was taken at 12:40 P.M.) 2 (Direct Examination resumed at 12:41 P.M.) 3 By Mr. Boetticher: 4 Q You say, the recoil effect of 225-Ac was 5 known at the time of the invention. Kruijff notes 6 several studies that showed a range of outcomes due to 7 toxicity caused by the recoil effect, but largely 8 indicates that safe and effective treatments may be 9 reasonably achieved. You see that? 10 A Uh-huh. 11 Q So when you say largely indicates, are you 12 saying that the majority of his paper, he says that 13 treatments may be reasonably safe, and effective 14 treatments may be reasonably achieved? 15 A I think the point is this recoil effect is 16 out there. It's a problem, but several studies both in 17 patients and in animal models have shown that despite 18 this recoil effect, it is possible to safely administer 19 effective treatments with actinium-225. 20 Q But you say that Kruijff is saying it 21 largely indicates, as though the majority of them are 22 safe and effective. Is that what you're trying to 23 indicate? 24 A Largely indicates that safe and effective 25 treatments may be reasonably achieved. Well, I don't
Page 111 1 alpha decay, including 225-Ac, the radionuclide has 2 multiple alpha-emitting daughters, which, due to recoil 3 effect, separate the daughter radionuclide from the 4 chelator. The recoil effect can potentially lead to 5 toxicity because the daughter radionuclides produced 6 from the initial alpha decay are no longer bound to the 7 targeting compound, and therefore may travel to other 8 areas of the body and cause damage to healthy tissues. 9 See that? 10 A Yep. 11 Q So were you thinking specifically about 12 actinium there? 13 A Not specifically, but it does include 14 actinium. 15 Q Okay, and so you've expressed about -- you've 16 expressed this concern about the daughter nuclides from 17 actinium causing damage in your writings, correct? 18 A Correct. 19 Q And you expressed those concerns both before 20 and after the patent ensued, correct? 21 A Correct. 22 Mr. Boetticher: All right, I think we 23 should take a break, coming up on a big section. 24 The Witness: Big section. 25 Mr. Boetticher: Big section.	Page 113 1 know that it -- I think that there are sufficient 2 numbers -- number of examples that indicate that 3 actinium can be safely administered both in patients 4 and -- and in animals. So I think I'm trying to say 5 that the bulk of that paper indicates, not that the 6 majority. I'm just saying largely indicates. 7 Q All right. 8 A I'm talking about the paper, not the -- 9 Q Let me give you Exhibit 1043, which is the 10 Kruijff paper. 11 A Okay. 12 Q So you recognize this is the one we were 13 discussing before? 14 A Yeah, yes. 15 Q So in your declaration, you say, for example, 16 225-Ac labeled humanized anti-CD33 monoclonal antibody 17 HUM193 was shown to be safe in humans at doses of less 18 than 0.1 megabecquerel per kilogram, -- 19 A Right. 20 Q -- right? And that's at 1043 at 3, so if we 21 go to Kruijff at page 3. 22 A Oh, I get it, okay. 23 Q This would be in the second complete 24 paragraph beginning with, the third radionuclide with 25 alpha-emitting daughters. Do you see that?

Page 114 1 A Uh-huh. 2 Q So this is the one where they discuss a Phase 3 I trial has demonstrated it is safe to use at doses of 4 less than 0.1 megabecquerel per kilogram. Am I saying 5 that right? 6 A Megabecquerel. 7 Q Becquerel, you mean the actress, I guess? 8 A No, no, the physicist. 9 Q Oh. 10 A His name is Henri Becquerel from France. 11 Q Okay, but later on in that paragraph, it 12 says, in -- in a subsequent Phase I trial, elderly 13 patients with a total administered activity between 2.5 14 and 7.4 megabecquerel have been treated. Bone marrow 15 blast reductions have been seen in four out of six 16 patients. But unfortunately, no complete remissions 17 have been reported. DLT has occurred in one patient 18 with grade 4 thrombocytopenia. And other toxicities 19 include grade 3 febrile neutropenia and pneumonia. So 20 it provides a number of issues, even after it discusses 21 using the -- the 0.1 level of -- of treatment, doesn't 22 it? 23 A Yes, there were some toxicities. 24 Q Okay, and then later on in your declaration, 25 in another in vivo study in animal models utilizing	Page 116 1 These toxic effects are believed to be caused by the 2 released daughters from the unbound antibody, 221-Fr 3 and 213-bismuth, which are expected to accumulate in 4 the kidneys. 5 A Right. 6 Q Now this is an example of what you talked 7 before about how it takes time for the negative effects 8 to appear, right? 9 A Right. 10 Q So when you say that -- when they say that 11 there were initially no negative effects, in fact, 12 there were long term, weren't there? 13 A At the higher doses, yes. 14 Q Well, those were the cumulative doses. So 15 that was over time? 16 A No, no, no, cumulative doses is because they 17 gave the radioactivity more than once. In other words, 18 just like with that abstract, it was a multiple dose 19 protocol. 20 Q Right, so it wasn't a high dose at once; it 21 was cumulative doses over time, -- 22 A Correct. 23 Q -- right? And if you look at the last page, 24 page 11 of Kruijff, or last page of text, he says, 25 this paper has presented a review on alpha radionuclide
Page 115 1 antibodies J591 and B4 conjugated to DOTA to treat 2 prostate carcinoma and disseminated lymphoma, 3 respectively, indicated a clear benefit of alpha 4 radiation at low administered activities with no toxic 5 effects. You see that? 6 A Uh-huh. 7 Q And that's on page 9. So we have to go all 8 the way from page 3 to page 9 to find another positive 9 thing about actinium. Let's see if I can find it here. 10 Right, so it's in the last paragraph on page 9. The 11 results of these studies indicated a clear benefit of 12 alpha radiation at low administration activities with 13 no toxic effects. You see that? 14 A Uh-huh. 15 Q Further, in this investigation, the in vitro 16 stability of Ac DOTA bound to lintuzumab has been 17 determined, revealing little disassociation with Ac. 18 The same antibody coupled to 225-Ac has also been 19 applied in experiments concerning non-human primates. 20 The half-life blood circulation time of the antibody 21 has been found to be 12 days with a 45 percent blood 22 clearance of 213-bismuth. In addition to this, at low 23 activities, no toxics have been observed within six 24 months, but at cumulative doses of 215 to 370 25 kilobecquerel, severe toxic effects became apparent.	Page 117 1 therapy. During the past few years, some progress has 2 been made in getting a few alpha radionuclide therapy 3 concepts to the clinic. However, by and large, we find 4 that in most studies concerning long-lived alpha 5 emitters, recoiling daughter atoms pose a serious 6 problem. If the distribution of recoiled atoms is not 7 controlled, toxic effects due to the recoiling 8 daughters will be present. Do you see that? 9 A Uh-huh. 10 Q So that is his conclusion? 11 A Uh-huh. 12 Q So by and large, he doesn't indicate that 13 it's safe and effective. His conclusion is that the 14 daughters need to be controlled, isn't it? 15 Mr. Murphy: Objection; form. 16 The Witness: In the ideal world, we 17 would be able to control the daughters. However, he 18 does point out examples where actinium-labeled compound 19 can be given at a safe and effective dose. Now that's 20 not always the case. But if you want to increase the 21 utility of long-lived alpha emitters like actinium and 22 thorium and -- and radium, then you would need to 23 control the daughters. But that's not to say there 24 aren't examples where you can -- can't have a safe and 25 effective dose without controlling the daughters. Part

Page 118 1 of it relates to how much internalization you get. So 2 if you get internalization into the cell, then the 3 daughters are trapped inside the cell. Now the whole 4 point of some of the work that people have been doing 5 is to develop analogs of, for example, PSMA-targeting 6 vectors where internalization is increased. And, you 7 know, we discussed some of this, why with PSMA I&T, 8 lutetium seemed like a good match because they measured 9 the internalization and they showed that they had good 10 retention and that the internalization was more than 11 the previous generation. So if you can trap the 12 radioactivity inside the tumor cell, then the daughters 13 remain in place. That's one strategy for doing. And 14 in fact, I believe -- I don't remember this 15 individual's gender. He or she may have mentioned that 16 here somewhere. But certainly, that's why 17 internalization is -- is very, very important. 18 By Mr. Boetticher: 19 Q Well, my question wasn't about 20 internalization and why it was important. My question 21 was, isn't Kruijff's conclusion that the daughter 22 nuclides being released from actinium are dangerous and 23 not, by and large, safe and effective? 24 Mr. Murphy: Objection; form. 25 The Witness: So he tempers -- he, she,	Page 120 1 Q Now are you actually suggesting that the 223- 2 radium is comparable to the 225-actinium and its 3 daughters? 4 A It's comparable in that both have recoiling 5 alpha-emitting daughters that are likely released from 6 their point of origin. 7 Q But as we discussed earlier, the radium is a 8 calcium analog, right? 9 A Right. 10 Q And so it goes directly into the bone and 11 remains there, right? 12 A Not all of it. 13 Q Eventually it finds its way to the bone, 14 doesn't it? 15 A Not all of it. 16 Q How much of it finds its way into the bone? 17 A Well, the -- the primary other location for 18 radium, I believe, is the liver. 19 Q Okay, so the radium that goes into the bone, 20 though, like, for example, with the Xofigo that you 21 mention here, when it releases its daughters, do you 22 know what the half-lives of those daughters are? 23 A Yeah, they're short. 24 Q So it releases the daughters, and they 25 immediately release their particles?
Page 119 1 I don't know which Robin is, she, tempers the -- the -- 2 the concerns, and they are valid concerns, about the 3 daughters by supplying some counterexamples. And 4 that's fine, but by and large, the daughters are a 5 concern. 6 By Mr. Boetticher: 7 Q Okay, look at paragraph 30 for me. 8 A My 35? 9 Q No, it's just the next paragraph. 10 A Oh. 11 Q Paragraph 30. 12 A Okay. 13 Q Right after what we were just talking about; 14 could you read this paragraph to yourself and let me 15 know when you're done? 16 A Yep. 17 Q So you say towards the end, since 223-radium 18 exhibits a daughter recoil effect similar to 225- 19 actinium, one of skill in the art at the time the '901 20 patent was filed would have readily appreciated that 21 the therapeutic benefit of alpha emitter therapy, 22 including 225-actinium, may outweigh any potential 23 negatives associated with a daughter recoil effect. 24 You see that? 25 A Uh-huh.	Page 121 1 A Not that short; sorry, not that short; in 2 other words, short enough that they can diffuse away, 3 just like the actinium-225 can diffuse away. So 4 there's four or five for radium. There's four 5 daughters for actinium-225, but each one of those alpha 6 Ks, the recoil nucleus has probably about 100 times the 7 energy, the kinetic energy as bond strength. So 8 they're like maybe 80 to -- I don't know, they'll 9 travel like 0.08 microns. And they have, as I said, 10 about 100 times bond strength. 11 Q But to get the radium into the bone, which is 12 the target, there's no additional molecule that's 13 attached to the radium, correct? 14 A That's correct. 15 Q But with the actinium, you'd have to have it 16 on a chelator of some kind to target it to, in this 17 case, PSMA, correct? 18 A Correct. 19 Q Okay, so there's -- so they have very 20 different targeting systems, correct? 21 A Right, but they are both subject to release. 22 Q So I'd like you to look at paragraph 81. 23 A Okay. 24 Q So in paragraph 81, the second paragraph, you 25 say, due to ethical and safety concerns, human studies

Page 122 1 are reserved for only the safest and most promising 2 therapies. See that? 3 A Uh-huh. 4 Q You don't have a citation for that. Is that 5 just based on your opinion? 6 A It is probably also the guidelines for 7 regulatory agencies. 8 Q Which regulatory agencies? 9 A Like FDA, like DKMA. 10 Q What's DKMA? 11 A Oh, sorry; that's the Danish regulatory 12 agency. I'm doing something there. I just don't know. 13 So yeah, I mean, I don't know. There is no reference 14 that I know of that says that ethical and safety 15 concerns are, you know, a critical issue before human 16 studies are done. On the other hand, given the expense 17 of human studies and the fact that whether or not you 18 have ethical or safety concerns, you have to get 19 regulatory approval, the effort involved and the cost 20 involved would motivate one to only evaluate the safest 21 and most promising therapies. 22 Q Well, I mean, you're talking in terms of the 23 cost; what about for academics? 24 A What about for academics; it's also very 25 expensive for academics.	Page 124 1 coupled set of criteria. 2 Q So it has to be both? 3 A It should be safe and promising, yes. It 4 should have the -- you -- you have no -- let me back 5 up. One can only speculate on what's the safest and 6 most promising based on preclinical data. 7 But basically that's all anyone has, preclinical data. 8 And so if a drug based on preclinical data appears to 9 be safe and appears to be promising, then it is more 10 likely to be investigated clinically than a drug with 11 preclinical data that suggests or indicates it is not 12 safe or promising. 13 Q And yet none of that is what you say here. 14 What you say is due to ethical and safety concerns, 15 human studies are reserved for only the safest and most 16 promising therapies, not just safe, not just promising, 17 but only the safest and most promising. 18 Mr. Murphy: Objection; form. 19 The Witness: Fortunately, you've 20 provided me with an example. This was our first 21 generation astatine PSMA compound, and we could have 22 investigated that in patients. We had funding for 23 that. But we decided to wait until we had something 24 that was the safest and most promising approach that we 25 could develop, based on that scaffold, based at the
Page 123 1 Q So are you familiar with the Declaration of 2 Helsinki's Unproven Interventions in Clinical Practice? 3 Mr. Murphy: Objection; form. 4 The Witness: Yes. 5 Mr. Boetticher: Okay, -- 6 The Witness: I'm sorry. 7 By Mr. Boetticher: 8 Q Do you know what compassionate care is? 9 A I understand how it's used in Germany, yes. 10 Q Okay, and so when you say the safest and most 11 promising, the standards are a little different when 12 we're talking about compassionate care, aren't they? 13 A The standards are different when you're 14 talking about studies in Germany. 15 Q Okay, and even in America, when we talk about 16 Phase I studies, usually the point is to establish 17 whether or not they're safe. 18 A Correct. 19 Q Isn't that right? 20 A Absolutely. 21 Q So it's a little inappropriate to say that 22 the human studies are only done if they're already safe 23 when the whole point of a Phase I is to determine if 24 it's safe? 25 A The safest and most promising, that's a	Page 125 1 nuclei and all of that. So that -- this -- this is my 2 opinion. 3 Mr. Boetticher: Okay. 4 The Witness: That's why there's no 5 quote. That's why there's no reference. 6 By Mr. Boetticher: 7 Q So but this doesn't take into account things 8 like compassionate care, right? 9 A Again, this goes to how you define 10 compassionate care. 11 Q Okay, and isn't the -- isn't the statement 12 itself rather circular? 13 Mr. Murphy: Objection; form. 14 By Mr. Boetticher: 15 Q I mean, you're saying that the study was done 16 because it was the safest and most promising therapy, 17 and I know this because the study was done? 18 Mr. Murphy: Objection; form. 19 The Witness: It only said it was of 20 particular interest. It was shown that the lutetium in 21 patients had some efficacy and did decrease PSA at that 22 particular point in time. And the gallium-68 showed 23 that you could image it and localize it, even though 24 the gallium-68 was not in the best of chelates. So 25 based on that information and alternative approaches

Page 126 1 that were known at that time, this would be a molecule 2 that would seem most promising or highly promising for 3 pursuit. 4 By Mr. Boetticher: 5 Q Which molecule? 6 A PSMA I&T. 7 Q No; which molecule? 8 Mr. Murphy: Objection; form. 9 By Mr. Boetticher: 10 Q Isn't this, in fact, lutetium-PSMA I&T? 11 A The data from human studies was with lutetium 12 and gallium. 13 Q And so when they say that even if you want to 14 say it was the safest and most promising therapy, 15 you're referring to the study that Weineisen did, and 16 that's lutetium -- 17 A Correct. 18 Q -- PSMA I&T? 19 A Correct. 20 Q It does not reflect necessarily on actinium- 21 PSMA I&T; is that fair? 22 A If you view this as a standalone paper and do 23 not consider the previous paper where they explicitly 24 mention actinium-225, and if you do not consider the 25 fact that the complexation chemistry of lutetium and	Page 128 1 studies show that PSMA I&T, not lutetium. It's the 2 scaffold. 3 By Mr. Boetticher: 4 Q Which data from PSMA I&T did not involve 5 lutetium? 6 A The gallium. 7 Q But it didn't involve actinium, did it? 8 A It did not. 9 Q Okay, we can stop there. 10 (A lunch break was taken at 1:07 P.M.) 11 (Direct Examination resumed at 1:37 P.M.) 12 By Mr. Boetticher: 13 Q All right, I'd like you to pull out what 14 we've marked as Exhibit 3 again. 15 A 3. 16 Q Yep, one of your papers. 17 A 3. 18 Mr. Murphy: Okay, I don't have the 19 numbers on mine. Is that the same article? 20 Mr. Boetticher: It's the third generation 21 PSMA targeted. 22 Mr. Murphy: Okay, is that 3? 23 The Witness: Yep, got it. 24 Mr. Murphy: Do you know what YF2 25 stands for?
Page 127 1 actinium-225 with DOTAGA are quite similar, then yeah. 2 Q Move to strike as nonresponsive; the question 3 was, when you talk about the safest and most promising 4 therapy, you're talking about lutetium-PSMA I&T, not 5 actinium-PSMA I&T. 6 A No, I'm talking about -- 7 Mr. Murphy: Objection; form. 8 The Witness: Sorry; I'm talking about 9 the scaffold, PSMA I&T, the scaffold. 10 By Mr. Boetticher: 11 Q Paragraph 81 says, additionally, Weineisen 12 2015 used lutetium-PSMA I&T in human studies. Due to 13 ethical and safety concerns, human studies are reserved 14 for only the safest and most promising therapies. 15 A Uh-huh. 16 Q So using the lutetium-PSMA I&T, maybe you can 17 say it's the safest and most promising therapy, but you 18 can't apply that to actinium because they didn't use 19 it, did they? 20 Mr. Murphy: Objection; form. 21 The Witness: So it's about, as we 22 pointed out before, getting the best targeted 23 radiotherapeutic involves many factors, and I said by 24 selecting PSMA I&T -- I didn't say selecting lutetium. 25 I said selecting that scaffold. The data from human	Page 129 1 Mr. Boetticher: What's that? 2 Mr. Murphy: YF2, what it is. 3 The Witness: Yutian Feng Compound 2; 4 the first author, YF2. 5 Mr. Boetticher: What? 6 The Witness: Those are his initials, 7 so. 8 Mr. Boetticher: Oh, oh, I see, okay. 9 That's pretty good. 10 The Witness: Yeah. 11 Mr. Boetticher: I'm going to tell you 12 another story I know about something like that. 13 The Witness: Okay. 14 Mr. Boetticher: I won't take the time on 15 it. 16 By Mr. Boetticher: 17 Q Okay, I'd like you to go first to page 14. 18 A Okay. 19 Q So in that first paragraph -- 20 A Uh-huh. 21 Q -- five lines down, partway across the line, 22 it begins, for example. Do you see that? 23 A The first complete paragraph? 24 Q Yeah, well, the first, starting at the top of 25 the page.

Page 130 1 A Okay. 2 Q And then five lines down. 3 A Oh, I see. 4 Q Across the line; for example, the total 5 production time for [225-Ac]Ac-PSMA I&T, was about 1.5 6 days, and the final production formulation consisted of 7 and 1 mole ascorbate and 100 micrograms of PSMA I&T 8 mass to stabilize the active ingredient [225Ac]Ac-PSMA 9 I&T. The required -- that required dilution of the 10 product with saline just before administration to avoid 11 excessive osmolality, and the shelf life of the final 12 formulation was only about three hours. What are you 13 explaining here? 14 A What am I explaining here? So this is the 15 process that, at that point in time, was used to make 16 PSMA I&T, and I think it was in the Netherlands 17 somewhere. The idea is that they were worried about 18 the radiolytic stability of the product. In other 19 words, does the radiation destroy the product? And the 20 way to prevent that is to put in a compound like 21 ascorbate, which prevents that from happening. The 22 problem is they -- they put in so much ascorbate that 23 the ionicity was so high that the osmolality, when they 24 finished with that preparation, was too high for safe 25 human injection, and so they diluted it just before it	Page 132 1 Q So does this undermine the idea of using mice 2 as models for humans? 3 Mr. Murphy: Objection; form. 4 The Witness: It points to the 5 complexity of doing that. It's certainly a problem, 6 but at this point in time and in the past, just about 7 every, if not every, radioactive molecule was evaluated 8 in -- in mice. But if you're going to compare 9 molecules, this is, I believe, the critical point. If 10 you're going to compare molecules of different types, 11 you should make sure that the molecules being compared 12 were done in the same strain of mice. 13 By Mr. Boetticher: 14 Q Okay, could you turn to the next page, page 15 16? And go down to that last paragraph. 16 A Because? 17 Q Yeah, and you say, because of differences in 18 PSMA expression in humans and mice, it is not certain 19 that the high renal levels observed in mice for 20 [221At]YF2 is a valid harbinger of a high potential for 21 renal toxicity in patients. Do you see that? 22 A Yep. 23 Q And so I believe this is where you determined 24 that there was a difference in the PSMA between mice 25 and humans?
Page 131 1 was injected. Now this is not the only way to make 2 PSMA I&T, but what we would call, for my purpose, a 3 useful straw dog because it was very long, very 4 complicated, but not the only way to make it. 5 Q So beyond the idea that there's other ways to 6 make it, there was a -- a -- a problem with the alpha 7 emitters damaging their own carriers, is that right? 8 A Yes. 9 Q And that's what you were trying to solve with 10 the ascorbate, right? 11 A They were trying to solve. 12 Q Okay, and this would be a problem with all 13 alpha emitters? 14 A Correct. 15 Q Okay, I'd like you to go to page 15. 16 A Okay. 17 Q Go down to the -- the third paragraph, the 18 one that begins many different scaffolds. Could you 19 read that to yourself and then let me know when you're 20 done? 21 A Okay; okay. 22 Q So in this paragraph, you explain that 23 different mice strains can give different results, is 24 that right? 25 A Correct.	Page 133 1 A There's a difference. Well, certainly 2 there's a subtle difference in the sequence of the two 3 PSMA's. But there can be, with some molecules, a 4 difference in the binding to murine PSMA and human 5 PSMA. 6 Q So you found -- or you explained that another 7 researcher had showed an approximately 40-fold higher 8 peak in kidney uptake than that of 177-lutetium-PSMA 9 617? 10 A Uh-huh. 11 Q Resulting in an approximately 30-fold higher 12 cumulative kidney activity for the 177-lutetium-PSMA 13 I&T? 14 A Right. 15 Q So is this where you were -- excuse me. So 16 in this case, they were -- they had predicted -- strike 17 that. In this case, the other researcher had predicted 18 that there would be a much higher kidney uptake than 19 there was, is that right? 20 A So if you looked at the mouse data, the 21 lutetium-PSMA I&T has much, much higher kidney uptake 22 than the lutetium-PSMA 617. However, if you do the 23 same comparison in patients of those same two 24 molecules, the two molecules are quite similar. So 25 what that says is the relative ranking that you would

Page 134 1 get in mice is not the same as the relative ranking, if 2 you will, that you would get in humans. 3 Q And so again, this undermines the idea that 4 mice can be a reliable model for what goes on in 5 humans, right? 6 Mr. Murphy: Objection; form. 7 The Witness: That's true. 8 By Mr. Boetticher: 9 Q Let's look at Exhibit 4. 10 A 4. 11 Q That is the Enhancing the Therapeutic Index 12 paper. 13 A I was wondering when you'd get to this point. 14 I'll even go there before you go there. 15 Q Could you go to page 10? 16 A I went to page 19, but you can go to -- you 17 can start at 10, yes. 18 Q So in that last paragraph at the bottom, in 19 this work we clearly demonstrated the addition of iodo 20 YF2 can reduce non-target tissue uptake, especially in 21 the kidneys. However, results obtained from murine 22 models may prove to be misleading due to differences in 23 PSMA expression in mice and humans. In fact, a paper 24 recently published by Medvedeva, et al, investigating 25 TCB00413 reported no mass effect in humans despite such	Page 136 1 see any similar effect of improving the ratio to normal 2 organs by adding mass to that molecule. 3 By Mr. Boetticher: 4 Q Okay, and so this was an effect that they saw 5 in mice, but they didn't see it in humans? 6 A Correct. 7 Q And so sometimes you can see a positive 8 effect in mice, and it doesn't play out in human 9 studies? 10 A That's correct. 11 Q Okay, and that's a fairly common problem, 12 isn't it? 13 A It's a very common problem. 14 Q Now in the next page, page 11, at the top, 15 you explain that the human PSMA possesses a unique 16 dileucine motif comprising two consecutive leucines, or 17 sometimes a leucine-isoleucine pair in the 18 intercellular domain, which has been found to mediate 19 internalization and targeting to endosomes and 20 lysosomes. I read that correctly? 21 A Uh-huh. 22 Q And so in fact, the PSMA with human and mice 23 are completely different? 24 A They have 83 percent homology. 25 Q Okay, but that's still 17 percent off?
Page 135 1 an effect being observed in murine prostate cancer 2 model. Did I read that correctly? 3 A Uh-huh. 4 Q And so what you're explaining here is that, 5 again, the mouse model is not reliable to describe 6 what's going on -- what could happen in humans, 7 correct? 8 Mr. Murphy: Objection; form. 9 The Witness: The mouse model certainly 10 has limitations. I don't know about reliability, but 11 it's really the only way people have available to 12 preclinically test. But it is -- it does have 13 limitations, certainly. 14 By Mr. Boetticher: 15 Q So it should be followed with caution; is 16 that fair? 17 A Yep. 18 Q And this case by Medvedeva, can you tell me 19 about this? There was an effect in mice, but it didn't 20 appear in humans? 21 Mr. Murphy: Objection; form. 22 The Witness: In other words, what they 23 did is looked at whether adding carrier, in other 24 words, cold molecule to the technetium radioactive 25 molecule affected the biodistribution, and they did not	Page 137 1 A That's correct. 2 Q And I think further down you explain that 3 part of the confounder is that you've been using 4 xenografts that have PSMA transduced into them, and the 5 PSMA is human PSMA? 6 A Correct. 7 Q But then when we see the PSMA-targeting 8 proteins in mice kidney, they're responding to mice 9 kidney -- sorry; they're responding to mouse PSMA? 10 A PSMA, yeah. 11 Q So was the conclusion that the belief that 12 there would be kidney damage from PSMA-targeting 13 radionuclides just not true? 14 Mr. Murphy: Objection; form. 15 The Witness: That's incorrect. 16 Mr. Boetticher: Okay. 17 The Witness: So the difficulty is when 18 you're doing the murine studies, the levels of PSMA 19 expression, the levels -- the concentration of PSMA in 20 -- in murine kidneys and human kidneys is different. 21 And this is not just because of the organ size, it's 22 just the concentration, so that is the difference. But 23 the other thing is that different radiolabeled PSMA 24 compounds each have their own relative binding to human 25 PSMA versus murine PSMA. It's a characteristic of that

Page 138 1 molecule that allows you -- or facilitates you 2 extrapolating from murine to human. 3 By Mr. Boetticher: 4 Q It facilitates -- 5 A Facilitates. 6 Q -- extrapolating from murine to human. 7 A Uh-huh. 8 Q And what way does it do that? 9 A Because if, for example, you have a PSMA 10 radioligand that binds to both murine PSMA and human 11 PSMA identically, then the mouse data is helpful given 12 the aforementioned limitations of murine data. But if 13 they're totally different, then it's going to be even 14 more difficult to interpret based on what you see in 15 the mouse. 16 Q And this paper that explains this, this is 17 from 2025, isn't it? 18 A Uh-huh. 19 Q So in 2016, at the time of the patent, we 20 didn't know about this? 21 Mr. Murphy: Objection; form. 22 The Witness: I don't know what other 23 people knew at that point in time. 24 By Mr. Boetticher: 25 Q But there was no evidence that you know of	Page 140 1 Q Okay, and so it's fair to say that mouse data 2 needs to be looked at carefully and should not be fully 3 relied on on its own, correct? 4 Mr. Murphy: Objection; form. 5 The Witness: Correct. 6 Mr. Boetticher: Okay, I'm going to hand 7 you Exhibit 5 to your deposition. 8 (Exhibit Number 5 marked for identification.) 9 The Witness: Oh, man, it's like that 10 old TV show, This is Your Life. 11 Mr. Boetticher: Yeah, exactly; exactly, 12 I'm walking through your whole career. So take a look 13 at page 11 for me. 14 The Witness: Okay. 15 By Mr. Boetticher: 16 Q And there's a section here at the top, that 17 first paragraph, beginning at the top of the page, 18 where you discuss radium chloride uptake. Could you 19 read through that, please, and let me know when you're 20 finished? 21 A Uh-huh; okay. 22 Q So what are you discussing here in this 23 paragraph concerning the 223-radium chloride? 24 A So what we are doing is comparing the 25 properties of the alpha emitter, radium-223, to
Page 139 1 showing that the PSMA differed between human and mice? 2 A Well, we do know about the homology. That's 3 the 83 percent. But to the best of my knowledge, I 4 don't know that anyone related that to differential 5 binding of a particular -- of any -- any radioligand 6 targeting PSMA to murine versus human. 7 Q And so this kind of issue can arise in other 8 studies as well, right? 9 A It can. 10 Q And so again, mouse data should be taken 11 carefully? 12 A Always; for example, if I'm allowed a little 13 digression. 14 Q Go ahead. 15 A Trastuzumab, which everybody uses for 16 treating breast cancer; all the preclinical studies 17 that were done with trastuzumab, which targets HER2, 18 all done in mice. Well, guess what? Trastuzumab does 19 not bind to murine HER2, only human HER2. So all that 20 data has similar limitation to what we're discussing 21 right now. So this is a very common problem. 22 Q And so in that case, it wasn't binding to the 23 mouse HER2, but there are also situations like this one 24 where it does bind to something in the mouse? 25 A That's correct.	Page 141 1 strontium-89, which was a beta emitter commonly in use 2 at that time for treating bone pain, and talking about 3 its distribution. And, again, most of this discussion 4 is about the radium-223 itself, not its daughters. 5 Q Uh-huh. 6 A And I believe there was one mention of the 7 daughters. 8 Q It does say only very little if any of the 9 daughter radionuclides of 223-Ra are redistributed from 10 the site of radium decay in the bone to soft tissue. 11 A To soft tissues. 12 Q You see that? 13 A Uh-huh. 14 Q And so in this case, you're saying that the 15 radium, even after it emits its daughters, it still 16 stays in the bone rather than moving on to the soft 17 tissue, right? 18 A Uh-huh. 19 Q So a comparison of the radium to, say, 20 actinium would be inappropriate, partly because even 21 when the radium is emitting its daughters, it still 22 stays in the bone? 23 Mr. Murphy: Objection; form. 24 By Mr. Boetticher: 25 Q Isn't that right?

Page 142 1 A Well, it's not localizing to soft tissues, 2 which means it could be excreted. And I can't recall, 3 reference 61, what methods they were using to look at 4 daughters because they're usually pretty complex. And, 5 oh, yeah, it's the same group that initially developed 6 the radium-223. But I don't know exactly how they 7 looked at the daughters, which, as I said, is 8 complicated. Some of them could be radioactive gases. 9 Q But it says here, so only very little if any 10 of the daughter radionuclides of 223-radium 11 redistributed from the site of radium decay in the bone 12 to soft tissue. So that makes it sound as though they 13 are staying in the bone, right? 14 A Or just not going to soft tissues. 15 Q Okay, so this paper is from 2011. I'd like 16 you to look on page 13. 17 A Okay. 18 Q In that middle section, chelating agents for 19 complexing 223-radium, that last sentence is, however, 20 the authors predicted that this chelating agent may not 21 be suitable for in vivo use due to the rapid 22 disassociation of 223-radium from the complex. You see 23 that? 24 A Right. 25 Q And so what are you saying there?	Page 144 1 center which is stable and inert from attack from like 2 water molecules and everything like that. So there's 3 lots of access for exchange, and then the radium can 4 just fall right out. 5 Q Okay, all right, you can put that aside. All 6 right, I'm going to hand you what will be Exhibit 6 of 7 your deposition. 8 (Exhibit Number 6 marked for identification.) 9 By Mr. Boetticher: 10 Q You recognize this document? 11 A Yes, this is generation 2 in our search for 12 an astatine-labeled PSMA-targeted alpha therapeutic. 13 And it is again a collaboration between Martin Pomper's 14 group at Johns Hopkins and my group at Duke. 15 Q I'd like you to look at the front page, the 16 right-hand column. You see that there is a paragraph 17 -- the second paragraph begins with, a possible issue. 18 Do you see that? 19 A Uh-huh. 20 Q It says a possible issue with alpha emitters 21 such as 223-Ac is the multiple alpha-emitting daughters 22 are generated from alpha-emitting parents. And in each 23 case, the energy imparted by the nuclear recoil effect 24 is orders of magnitude greater than chemical bonds. So 25 what you're describing there is how the actinium breaks
Page 143 1 A That the -- the coordination chemistry of 2 radium-223 is incredibly difficult. And it doesn't, 3 with that generation of chelates, form very stable 4 complexes. And so developing classical chelate 5 macrocycle-based radiotherapeutics with radium-223 is 6 going to be a very difficult task. 7 Q And so basically it sounds like you're saying 8 that radium is not a viable candidate to be used with a 9 -- a chelator system or a -- a -- a targeting system. 10 A Well, we go on to mention liposomes as a 11 potential way of doing it. It's a different sort of 12 targeting system. And the idea is that the liposome 13 could trap all the radium daughters in there, which of 14 course is critical. And so what you would do is you 15 put your targeting vector on the surface of the 16 liposome. So you could do it where you could take like 17 a nanoparticle, a liposome, as a carrier system for the 18 radium. And then you would, for example, put your 19 PSMA-targeting vector on the surface of that, and then 20 you could use radium. 21 Q Okay, going back to the previous paragraph, 22 though. So you blamed it on the rapid disassociation 23 of 223-radium from the complex. How does it rapidly 24 disassociate from the complex? 25 A It doesn't form a -- like a coordination	Page 145 1 out of a -- a -- a chelator, correct? 2 A Correct. 3 Q And then you go on to say, that energy makes 4 the release of the radioactive daughters from the 5 targeting vector extremely likely, which can lead to 6 unintended irradiation of non-target tissues. Did I 7 read that correctly? 8 A Correct. 9 Q So you are concerned about the -- the 10 daughters of the actinium being released and causing 11 further damage to the body, correct? 12 A Correct. 13 Q Okay, so let me ask you, if we were to put 14 aside the issue of availability between At and Ac, 15 which one would you prefer, just putting aside the one 16 issue of availability? 17 Mr. Murphy: Objection; form. 18 The Witness: Which would I prefer? 19 By Mr. Boetticher: 20 Q Which one do you think is a better candidate? 21 Mr. Murphy: Objection; form. 22 The Witness: Putting aside the issue 23 of availability, but how are people going to explore it 24 if it's not available? So no, I won't put it aside. 25 Mr. Boetticher: All right.

Page 146 1 The Witness: There are many choices 2 that one can make in science, and it depends in part on 3 your inclination. It depends on your training, and it 4 depends upon what sort of problems you find appealing. 5 For my personal set of characteristics, mine, I would 6 pick astatine, because its covalent chemistry appeals 7 to me, and I like the idea of having to do syntheses in 8 short periods of time. But there are some very big 9 problems with astatine, and the main one is that the 10 carbon-astatine bond is not very stable. So actinium 11 has its recoiling daughters problems, astatine has its 12 bond strength problems. So it depends upon which devil 13 you want to deal with, and because of my training, my 14 background, and my inclinations, I am working with 15 astatine. 16 By Mr. Boetticher: 17 Q So I want to draw your attention to the first 18 page again. In that first paragraph, you say, halfway 19 down, PSMA-targeted alpha particle emitters may be even 20 more promising as evidenced by treatment with a 225- 21 actinium-labeled agent producing a significant tumor 22 response in patients who were unresponsive to prior 23 beta-emitter therapy. Do you see that? 24 A Uh-huh. 25 Q Now do you remember which article you were	Page 148 1 Mr. Murphy: Objection; form. 2 The Witness: Yes. 3 By Mr. Boetticher: 4 Q Okay, and if you look at Figure 2, so this is 5 a study in which they treated with lutetium-PSMA and 6 then followed up with actinium-PSMA, correct? 7 A Uh-huh. 8 Q What is the -- the BSC at the end? 9 A Best Supported Care. 10 Q Okay, and so these results that we see in 11 Figure 2, at least for the first four, are similar to 12 what we saw in the 2016 Kratochwil paper, correct? 13 Mr. Murphy: Objection; form. 14 The Witness: They're similar, yes. 15 By Mr. Boetticher: 16 Q And then we look at Figure 1 with PSA 17 reductions. Could you explain to me how to read these 18 plots? Are you familiar with these? 19 A Yeah, they're waterfall plots. 20 Q Okay. 21 A What you do is you line up your best to your 22 worst response for individual patients, and so what 23 happens is you would like to see a decline in PSMA 24 after treatment. So if you start from the left of A, 25 what one sees is not very much decline, but then you
Page 147 1 referring to there? 2 A I thought it was one of the Kratochwil 3 articles, 12 and 13. There's also other papers that 4 have appeared since. No, it's actually a different 5 group. That's the I&T group. 6 Q Okay, I'm going to hand you Exhibit 2056. 7 A Okay, thank you. 8 Q There you go. This is the document you're 9 referring to, one of them? 10 A Uh-huh. 11 Q So do you remember what you found significant 12 here, or promising? 13 Mr. Murphy: Objection; form. 14 The Witness: That they did see 15 promising anti-tumor effects in metastatic prostate 16 cancer patients, and that these effects were comparable 17 to PSMA-617. 18 By Mr. Boetticher: 19 Q Okay, and so this molecule that they're 20 working with, this is the actinium form of the -- 21 strike that. So the molecule they're working with here 22 is actinium-PSMA I&T, correct? 23 A Correct. 24 Q And this is the same molecule that you are 25 saying renders the '901 patent obvious?	Page 149 1 keep going and keep going, and then instead of seeing 2 an increase in PSMA, you actually see a decrease. And 3 A is at eight weeks, but then B is the best over the 4 course of the study. And so you can see they're 5 different. 6 Q Okay. 7 A Okay? 8 Q And to the best of your recollection, do 9 these line up with what you saw in Kratochwil and/or 10 the '901 patent? 11 Mr. Murphy: Objection; form. 12 The Witness: Well, if you were to 13 title B only PSMA response, because they only did it 14 once. 15 By Mr. Boetticher: 16 Q Okay, all right, you can put that one away. 17 I'm going to give you Exhibit 1006. 18 A Okay. 19 Q Do you recognize this document? 20 A Yes, I do. 21 Q What is this document? 22 A This is another abstract, and it is comparing 23 two different bismuth-213-labeled PSMA-targeting 24 agents. One, a small molecule, in particular PSMA I&T, 25 and then a PSMA-labeled nanobody, which is a small

Page 150 1 protein. 2 Q Okay, and so they're comparing these two. If 3 you look on the second page under Results, on that 4 third line, it shows the data, 5.75 plus or minus 2.7 5 percent IDG and 2.68 plus or minus 0.56 percent IDG. 6 Given the large standard deviation on the 5.75 number, 7 would you consider these differences to be significant? 8 Mr. Murphy: Objection; form. 9 The Witness: No. 10 By Mr. Boetticher: 11 Q Okay, and then later on in the next sentence, 12 it says the two tracers showed similar tumor-to-kidney 13 ratios. Do you see that? 14 A Uh-huh. 15 Q So between these two, the conclusion of the 16 researcher is that they're basically equivalent, right? 17 Mr. Murphy: Objection; form. 18 The Witness: They just said they're 19 both good. They didn't say they were equivalent. 20 By Mr. Boetticher: 21 Q Okay, and so somebody approaching this 22 wouldn't have any reason to choose between one or the 23 other if they were just approaching this paper tabula 24 rasa? 25 Mr. Murphy: Objection; form.	Page 152 1 I&T as well, don't you? 2 A It's just chemical. 3 Q Okay, all right, I'm going to give you 4 Exhibit 1015. You recognize this document? 5 A Yes, I do. 6 Q What is this document? 7 A This -- what they -- what they do, and some 8 people do this, is describe actinium-225 as actually a 9 generator for its end product, namely bismuth-213. 10 That's where that generator concept comes from, but 11 it's basically DOTATOC labeled with actinium-225. 12 Q Okay, so using DOTATOC, this is different 13 from either the 617 or the PSMA I&T, right? 14 A That's correct. 15 Q And so these researchers found that they 16 could avoid toxic effects as long as they kept the 17 administered dose below 20 kilobecquerel, correct? 18 A Correct. 19 Q In fact, later on in the results section in 20 the front page, they say activities were shown to be 21 nontoxic, and they say 12 to 20 kilobecquerel. You see 22 that? 23 A Uh-huh. 24 Q That's a very narrow window in which they 25 could avoid toxicity, correct?
Page 151 1 The Witness: Well, from a commercial 2 development perspective, nanobodies, you have to have 3 an immortalized cell line. In other words, it's going 4 to be much more expensive to develop the nanobody drug 5 than the PSMA I&T drug. So if two things are 6 approximately the same, I'm going to go with the small- 7 molecule drug because it's going to be easier to do the 8 production of it for clinical use and it's going to be 9 a lot less expensive. So I would choose the PSMA I&T 10 based even on equivalence. 11 By Mr. Boetticher: 12 Q So you're saying that for the PSMA nanobody, 13 you have to have a cell culture? 14 A No, no, no, see, what happens is you have to 15 -- so if you develop a protein therapeutic, you have to 16 have a cell line that will produce it. And you have to 17 have it immortalized so you have this great source of 18 it in the future. And establishing that cell line, 19 perpetuating it and doing all that costs a lot of 20 money. 21 Q Wouldn't they presumably already have the 22 cell line if they have the nanobody? 23 A No, because they probably just made it in 24 like baculovirus or something like that. 25 Q But you have to constantly construct the PSMA	Page 153 1 Mr. Murphy: Objection; form. 2 The Witness: I don't know if it's 3 narrow, but certainly not the largest window. 4 By Mr. Boetticher: 5 Q And they also say, in contrast, activities 6 higher than 30 kilobecquerel induced tubular necrosis. 7 Do you see that? 8 A Yes, I do. 9 Q So they created a fairly narrow range in 10 which they can still use the actinium with the DOTATOC 11 and avoid toxicity? 12 A Right. 13 Q So let me take you to the second page, left- 14 hand side. And so once again, this researcher is 15 showing concern over the daughter molecules of 16 actinium. Halfway down the paragraph it reads, 17 however, after disintegration of the retention of 18 daughter isotopes within the chelate is highly 19 unlikely, either due to the physical recoil energy of 20 the different chemical properties of the first daughter 21 nuclide, 221-Fr. 22 A Francium. 23 Q Francium, thank you; despite their relatively 24 short half-lives, the alpha-emitting daughter nuclide, 25 221-francium, and its subsequent daughters, 212-As and

Page 154 1 213-bismuth. 2 A That's a typo. It's actually At. 3 Q Are capable of relocating within the 4 organism; an accumulation of 213-bismuth originating 5 from the bloodstream into the kidneys with subsequent 6 radiation damage has been shown in nonhuman primates. 7 You see that? 8 A Uh-huh. 9 Q So it's still an ongoing issue. This is -- 10 what year is this; 2008. As far back as 2008, they -- 11 they were concerned about it, and it was limiting their 12 use, correct? 13 A What do you mean by limiting their use? 14 Q It forced them to use smaller administrative 15 doses. 16 A Yes, they were small doses. 17 Q And -- and the bismuth is known to accumulate 18 in the renal cortex, correct? 19 A Correct. 20 Q So even after -- so even -- strike that. So 21 even after the actinium daughters are released from the 22 chelator, it would still end up in the kidneys because 23 bismuth gathers there? 24 Mr. Murphy: Objection. 25 By Mr. Boetticher:	Page 156 1 Q So how did you become the founder of Z-Alpha 2 Therapeutics? 3 A How did I become the founder? Well, I talked 4 to some people with experience in business. I 5 convinced them that targeted radiotherapy was a useful 6 pursuit. I convinced them to license a bunch of IP 7 from Duke, and Marty and I convinced them to license 8 some IP from Johns Hopkins, and we raised some money, 9 and that's what we did. 10 Q So how much of Z-Alpha Therapeutics do you 11 own? 12 Mr. Murphy: Let me just object to the 13 extent it asks for anything confidential. You can 14 answer the question, but don't reveal anything 15 confidential. 16 The Witness: Not a major amount. 17 By Mr. Boetticher: 18 Q Can you give me a percentage? 19 A No. 20 Q Okay, I'd like you to look at -- which 21 exhibit was this, Exhibit 5, an improved 211-At-labeled 22 agent. 23 Mr. Murphy: Which -- Number 5 -- 24 sorry. 25 Mr. Boetticher: I think it's Number 5,
Page 155 1 Q Is that right? 2 Mr. Murphy: Objection; form. 3 The Witness: Quite possibly; it really 4 depends where they're released in the body, because, 5 for example, if they were released in the GI system, 6 even though bismuth localized in the kidney, it would 7 probably go out another way, so yeah, but generally, 8 generally. 9 By Mr. Boetticher: 10 Q Okay, well, it says that in particular, on 11 page 5, it says, in particular it's known that free 12 bismuth is accumulated by the renal cortex. 13 A That's correct. 14 Q So the danger here is not just that the PSMA 15 may target the actinium there, but even if it escapes, 16 it could end up in the renal cortex as well? 17 A Right. 18 Q Okay; all right, going back to your 19 declaration, Exhibit 1002, I'd like to go to paragraph 20 6. 21 A Paragraph 6, oh, yes. 22 Q I am the founder and chief technology 23 officer, CTO, of a company called Z-Alpha Therapeutics, 24 which focuses on targeted radiotherapy. 25 A Right.	Page 157 1 yeah. 2 The Witness: No, 5 is the -- 3 Mr. Boetticher: Okay, it must be Number 4 4 then. 5 The Witness: Which one is it; the 6 improved YF2. 7 Mr. Boetticher: Yes, this one. 8 The Witness: Oh, that's the one, this 9 one. 10 Mr. Boetticher: Yeah. 11 The Witness: All right, we'll find it. 12 Don't worry, third generation; all right, here, 6. 13 Mr. Boetticher: Okay, Number 6. 14 Mr. Murphy: Okay, hold on one second. 15 Okay, I'm ready. 16 By Mr. Boetticher: 17 Q All right, I'd like you to go to the back, 18 page 266. It says financial support was received from, 19 gives a number of sources. And the next sentence says, 20 under a license agreement between D&D Pharmatech and 21 Johns Hopkins and Duke Universities, the universities' 22 Ronnie Mease, Martin Pomper, Sangeeta Banerjee, Ganesan 23 Vaidyanathan, and Michael Zalutsky are entitled to 24 royalty distribution relating to the technology 25 described in the study discussed in this publication.

Page 158 1 You see that? 2 A Uh-huh. 3 Q And it says here that Michael Zalutsky owns 4 equity in D&D Pharmatech. You see that? 5 A Uh-huh. 6 Q And it says that they and Michael Zalutsky 7 are also paid consultants to the company. You see 8 that? 9 A Right. 10 Q Okay, so is D&D Pharmatech a different 11 company or is it part of Z-Alpha? 12 A Good question; so what happened was D&D 13 Pharmatech was like an umbrella company for two or 14 three different Johns Hopkins startups. 15 A Uh-huh. 16 A Okay, and one of them was called Precision 17 Molecular. Precision Molecular is the part of D&D that 18 dealt with radioactive technologies. I was a 19 consultant to PMI and thus the parent company, D&D. 20 And D&D had licensed the PSMA technology from Duke and 21 Johns Hopkins. However -- however, D&D joined forces 22 with another company and merged with Zentera, which was 23 primarily based in China at the time, and that merger 24 created Z-Alpha Therapeutics. So the technology went 25 from Hopkins, Duke to PMI within D&D and then PMI and	Page 160 1 A Correct. 2 Q And so the technology that we see here in 3 Exhibit 6, is this the kind of technology that they 4 licensed from you? 5 Mr. Murphy: Objection; form. 6 The Witness: It's part of it, yes. 7 By Mr. Boetticher: 8 Q And so what we're looking at then, the 9 technology that they're licensing is PSMA that's been 10 labeled with radioactive astatine? 11 Mr. Murphy: Objection; form. 12 Mr. Boetticher: I'm sorry. I'm sorry. 13 Let me withdraw that. 14 By Mr. Boetticher: 15 Q The kind of technology we're looking at are 16 molecules that target PSMA and have been labeled with 17 radioactive astatine? 18 Mr. Murphy: Object to form and object 19 to the extent it calls for anything confidential; you 20 can answer it to the extent you have to reveal any 21 confidential information. 22 The Witness: We do a lot of stuff with 23 astatine, period. 24 By Mr. Boetticher: 25 Q Okay, so if they do work with the kind of
Page 159 1 Zentera joined forces to create Z-Alpha Therapeutics. 2 That's it. 3 Q So the Z is for Zentera and not Zalutsky? 4 A I can't answer that question. No, it 5 actually is. It's a joke. I mean, it's like they 6 always refer to it as my name, but it actually is 7 because Zentera, the Chinese company, was a spin-out 8 from Zentalis, a U.S. company based in San Diego, and 9 it's also traded on NASDAQ, not radioactive drugs. So 10 there's been a perpetuation of Zs in the name. 11 Q Okay, so the -- the royalties that they 12 mentioned at the end of this paper for technology, was 13 that -- was that technology ultimately licensed to 14 Z-Alpha? 15 A Yes. 16 Q And so Z-Alpha specializes in astatine, 17 doesn't it? 18 A Correct. 19 Q Okay, and you own a portion of Z-Alpha, 20 correct? 21 A Correct. 22 Q Okay, let me ask you this. And so if Z-Alpha 23 is successful, you would stand to profit from the 24 royalties on the technology that they licensed from 25 you?	Page 161 1 technology that's in this paper, and they license it 2 from you, and you get royalties, wouldn't you say that 3 this technology is competing with the technology that's 4 in the '901 patent? 5 Mr. Murphy: Objection; form. 6 The Witness: Hypothetically, it's 7 competing, but the reality is no, because it depends 8 upon where the PSMA technology is in our pipeline. 9 By Mr. Boetticher: 10 Q But if you are working on PSMA technology, 11 then it would be competing with the technology that's 12 in the '901 patent? 13 Mr. Murphy: Objection; form. 14 The Witness: You know, I can't tell 15 you what we are actually working on. 16 Mr. Boetticher: I understand that. 17 The Witness: I can tell you we've 18 licensed more than we can work on in the next 50 years. 19 By Mr. Boetticher: 20 Q I understand that. But if the '901 patent is 21 invalidated and you have licensed this technology 22 involving PSMA-targeting molecules labeled with 23 astatine, doesn't it benefit you because Z-Alpha will 24 do better? 25 Mr. Murphy: Objection; form.

Page 162 1 The Witness: So maybe I don't 2 understand this a little bit. So you have a company 3 called Curium that is challenging the patent. Curium 4 is a pharmaceutical company that is well placed to 5 develop this molecule. If you follow your logic, 6 wouldn't it be advisable for me to make it difficult 7 for a company with billions of dollars in the pot to be 8 able to pursue this? I mean, you know, I mean, I -- if 9 more companies can do this, that's going to be more 10 competition for me. 11 By Mr. Boetticher: 12 Q But you'll be the company that has the 13 patent? 14 A I won't -- 15 Mr. Murphy: Objection; form. 16 By Mr. Boetticher: 17 Q Z-Alpha would be the company that has the 18 patent? 19 A What patent; oh, that patent. 20 Q I'm going to give you what is Number 7, 21 Exhibit Number 7. 22 A Thank you. 23 (Exhibit Number 7 marked for identification.) 24 By Mr. Boetticher: 25 Q So do you recognize this document?	Page 164 1 question. 2 A Okay. 3 Q If the '901 patent is invalidated, you will 4 hold a patent for an alpha emitter attached to a PSMA- 5 targeting molecule? 6 A True. 7 Mr. Murphy: Objection; form. 8 By Mr. Boetticher: 9 Q And removing the '901 patent removes part of 10 your competition in the marketplace, doesn't it? 11 Mr. Murphy: Objection; form. 12 The Witness: I can't answer that 13 question. 14 Mr. Boetticher: Okay, I think I may 15 actually be reaching the end. Let's go on break and 16 I'll take a look and see what I've got left, okay? 17 The Witness: Okay. 18 (A short break was taken at 2:37 P.M.) 19 (Direct Examination resumed at 2:46 P.M.) 20 By Mr. Boetticher: 21 Q I'd like you to look at your declaration. 22 A Okay. 23 Q Paragraph 42. 24 A Okay. 25 Q You say the specification acknowledges some
Page 163 1 A Yes, I do. 2 Q This is entitled PSMA-targeted 3 Radiohalogenated Urea Polyamide Carboxylates for Cancer 4 Radiotherapy. 5 A Right. 6 Q And this is a patent that has your name on it 7 as an inventor, correct? 8 A Absolutely, yes. 9 Q Is this the same technology or related to 10 what was in Exhibit 6? 11 A Yes. 12 Q And so you would receive royalties from this 13 patent if somebody licensed it, correct? 14 Mr. Murphy: Objection; form and 15 objection to the extent it calls for any confidential 16 information; you can answer as long as you don't reveal 17 any confidential information. 18 The Witness: If you look carefully at 19 this patent, you will see that it only relates to 20 radiohalogens. It does not relate to radiometals, 21 including actinium-225. So if somebody does work with 22 actinium-225 on the very same scaffolds, we don't have 23 coverage. 24 By Mr. Boetticher: 25 Q I understand that, but that wasn't my	Page 165 1 of the known benefits of using alpha emitters like 2 225-Ac in radiopharmaceuticals. For example, the 3 specification discloses that the very efficient and 4 specific targeting of the Ac-225 radiopharmaceuticals 5 to PSMA combined with short range, less than 100 6 micrometer, action of the Ac-225 alpha emitter allows 7 for very good results of destruction of cancer cells 8 without notable damage to non-target tissues. And then 9 you say despite these known benefits, the inventors 10 claimed radiopharmaceuticals comprising 225-Ac have 11 been surprisingly found to provide considerably and 12 significantly better therapeutic results than 13 corresponding radiopharmaceuticals. You see that? 14 A Uh-huh. 15 Q So this section that you're quoting, where is 16 that from in the patent? Do you know offhand? 17 A No, I don't know offhand. 18 Q Okay, I'm going to give you Exhibit 1001. 19 A Page 11, 3632; page 11. 20 Q It would be column 11. 21 A Column 11, sorry, 3632; yeah, I see it. It 22 has been surprisingly found. 23 Q Right, so do you know which section of the 24 patent you're looking at right now? 25 A Not the claims; it's kind of like the

Page 166 1 background. 2 Q It is not? 3 A It is not. 4 Q So if you go back to column 2. 5 A General description of the invention. 6 Q Right, so this is not the background section. 7 This is the general description of the invention? 8 A Right. 9 Q So what they're describing here is their 10 invention, not what was in the prior art before. This 11 is what they have found out? 12 Mr. Murphy: Objection; form. 13 By Mr. Boetticher: 14 Q So I'd like you to look at column 16. It's 15 the last paragraph, I believe it's line 61. 16 A Column -- can you -- 61? 17 Q Yeah, so it begins, clinical course of 18 patient A. 19 A Right. 20 Q Presented with diffuse red marrow 21 infiltration, right; and if you pop down to the bottom, 22 so do you understand what they're describing here? 23 This is part of their experiments, correct? 24 A Yeah, their clinical experiment. 25 Q Right, and so you look at the bottom portion	Page 168 1 something else to target the tumor that they're 2 imaging. The actinium-225 is not being imaged. 3 Q But if they can confirm that the tumor has 4 been destroyed by the actinium-225, then they can show 5 that it has been properly targeted, can't they? 6 Mr. Murphy: Objection; form. 7 The Witness: The radiation has been 8 targeted, and I don't know -- and it is sufficient for 9 causing an effect, but I can't say anything beyond 10 that. 11 By Mr. Boetticher: 12 Q So once they are able to confirm that the 13 tumor has been properly targeted, they're able to say 14 that in a particularly preferred aspect, the invention 15 relates to a treatment of disseminated cancer or cancer 16 cells, and that it was a very efficient and specific 17 targeting of the Ac-225 radiopharmaceuticals to PSMA 18 combined to the short-range, less than 100 micrometers, 19 action of the Ac-225. 20 Mr. Murphy: Objection; form. 21 The Witness: They -- they confirmed 22 that the tumor shrank. They confirmed -- they 23 confirmed that they injected actinium-225-PSMA-617, but 24 they did not confirm that the actinium-225 actually 25 targeted the tumor; no evidence for that except
Page 167 1 of that. The sentence begins, post-therapeutic 2 emission scans validated sufficient tumor targeting. 3 Do you see that? 4 A Yeah. 5 Q And so they confirmed on their own that the 6 tumors had been properly targeted, correct? 7 Mr. Murphy: Objection; form. 8 The Witness: Post-therapeutic emission 9 scans; scans of what; with what; you can't scan 10 actinium-225, so it's not clear what they're talking 11 about here. See, they're talking about the targeting 12 -- I see. They're talking about the targeting of the 13 imaging agent, not about the actinium-225, because you 14 can't image actinium-225. 15 By Mr. Boetticher: 16 Q All right, say that again? 17 A The post-therapeutic emission scans were not 18 done with the actinium-225. They were done with 19 something else. 20 Q Right, but they -- 21 A They -- 22 Q They were done to confirm that the actinium 23 had properly targeted the tumor. 24 A And how would they -- I -- I -- I don't 25 understand how that happens, because they're using	Page 169 1 indirect -- indirect evidence the tumor PSA dropped. 2 By Mr. Boetticher: 3 Q Isn't indirect evidence evidence? 4 A It is indirect evidence. 5 Q But it's evidence, nonetheless? 6 A It is one of the classes of evidence, 7 certainly. 8 Q Well, if you're saying that actinium can't be 9 imaged, then there's no level of evidence that you 10 would accept, is there? 11 Mr. Murphy: Objection; form. 12 The Witness: There would be ways of 13 doing it. 14 Mr. Boetticher: If I -- 15 The Witness: May I? 16 Mr. Boetticher: Okay. 17 The Witness: One thing you could do is 18 if these were patients that were going to go to the 19 operating room, you could remove their tumor and count 20 the actinium. 21 By Mr. Boetticher: 22 Q I think the point of this invention is to 23 avoid the operating room, and many of them are 24 metastasized anyway. 25 A Yes, but if you want to prove that your

Page 170 1 actinium actually gets there, you probably need to do 2 that, because, and I'll just put in a plug, because 3 unlike astatine-211, actinium can't be imaged. 4 Q But in the experiment, they treat the patient 5 with 225-actinium on a PSMA-targeting molecule. The 6 tumor is gone, and they confirm it using another marker 7 to confirm that the tumor is gone. Are you saying that 8 you wouldn't be convinced that the actinium is what got 9 rid of the tumor? 10 A Probably not. 11 Q Okay. 12 A Again, I would suggest doing a small set of 13 patients with biopsies. Then I'd be convinced. 14 Q So you're not convinced unless we cut 15 somebody open? 16 A Well, sometimes you have to do that in order 17 to save lives. 18 Q All right, I'm going to give you Exhibit 19 1045. 20 A Okay, thanks, all right. 21 Q Do you recognize this document? 22 A Yes; yes, I do. 23 Q Okay, what is this document? 24 A This is the dramatic document. This is the 25 actinium PSMA-617, presumably first in human study,	Page 172 1 stay on the record. I'm not going to have any 2 Redirect. We can go back on the record. 3 Court Reporter: Going back on the record 4 or stay on? 5 Mr. Murphy: Are we still on the 6 record? Yeah, either way, I have no Redirect for you, 7 Dr. Zalutsky. So that ends the deposition. I 8 appreciate your time today. 9 (The proceedings were concluded at 2:58 P.M.) 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Page 171 1 which was done in two patients with a brief follow-up 2 in terms of PSA, but the results are very dramatic. 3 Q And you understand when you say that it was 4 done in two patients, there were actually more patients 5 than two? 6 A There were more. This is what's in my hand. 7 That's what you asked me to comment about, two 8 patients. 9 Q Okay, so my question for you is, you've 10 looked at the '901 patent, correct? 11 A Yes, I have. 12 Q And you've read this as well, correct? 13 A Right. 14 Q Would you say that the technology in this 15 paper is an embodiment of the claims of the '901 16 patent? 17 Mr. Murphy: Objection; form. 18 The Witness: Yes. 19 Mr. Boetticher: Okay, that's it. I'm 20 done. 21 The Witness: Come on. 22 Mr. Boetticher: Really quickly. 23 The Witness: What? 24 Mr. Boetticher: Yeah. 25 Mr. Murphy: We can go -- we can just	Page 173 NORTH CAROLINA WAKE COUNTY C E R T I F I C A T E I, David L. Overby, Notary/Reporter, do hereby certify that Michael Rod Zalutsky, Ph.D. was duly sworn by Megan Fries, Notary/Reporter, prior to the taking of the foregoing deposition; and that this deposition was taken by Megan Fries and transcribed under my direction and that the one hundred seventy- three pages which constitute this deposition are a true and accurate transcript of the witness's testimony. I certify that I am not counsel for, or employed by either party in this action, nor am I interested in the outcome of this action. IN WITNESS THEREOF, I have hereunto set my hand this 15th day of August, 2026.  _____ David L. Overby Notary Public Certificate No.: 19930120037

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