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Transcript of Rebecca Abergel, Ph.D.

Date: November 16, 2023

Case: Fusion Pharmaceuticals, Inc. -v- Universität Heidelberg, et al. (PTAB)

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**Patent Owner Exhibit 2080
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2 (5 to 8)

5 1 EXHIBITS CONTINUED 2 (Previously marked.) 3 DEPOSITION EXHIBIT PAGE 4 Exhibit 1001 US Patent No. 10,980,901 31 5 (21 pages) 6 Exhibit 1002 Declaration of Rebecca Abergel, 52 7 Ph.D. (55 pages) 8 Exhibit 1003 Rebecca J. Abergel - Curriculum 14 9 Vitae (19 pages) 10 Exhibit 1006 2016 Publication "213 bismuth- 147 11 labeled PSMA-targeting agents for 12 alpha radionuclide therapy for 13 prostate cancer (4 pages) 14 Exhibit 1011 2016 Publication "Phase I Trial 156 15 of Targeted Alpha-Particle 16 Therapy with Actinium-225, 17 Lintuzumab and Low-Dose Cytarabine, 18 LDAC, in Patients Age 60 or Older 19 with Untreated Acute Myeloid Leukemia" 20 (3 pages) 21 Exhibit 1013 2001 Publication "Tumor Therapy 89 22 with Targeted Atomic Nanogenerators" 23 (4 pages) 24 25	7 1 EXHIBITS CONTINUED 2 (Previously marked.) 3 DEPOSITION EXHIBIT PAGE 4 Exhibit 1030 2008 Publication "Realizing the 115 5 potential of the Actinium-225 6 radionuclide generator in targeted 7 alpha particle therapy applications" 8 (12 pages) 9 Exhibit 1031 2015 Publication "Ac-225-DOTATOC, 168 10 an empiric dose finding for alpha 11 particle emitter based radionuclide 12 therapy of neuroendocrine tumors" 13 (4 pages) 14 15 16 17 18 19 20 21 22 23 24 25
6 1 EXHIBITS CONTINUED 2 (Previously marked.) 3 DEPOSITION EXHIBIT PAGE 4 Exhibit 1015 2008 Publication "Preclinical 71 5 Evaluation of the Alpha-Particle 6 Generator Nuclide 225-Ac for 7 Somatostatin Receptor Radiotherapy 8 of Neuroendocrine Tumors" (7 pages) 9 Exhibit 1017 2008 Publication "MIRD Pamphlet 153 10 No. 22 (Abridged): Radiobiology 11 and Dosimetry of Alpha Particle 12 Emitters for Targeted Radionuclide 13 Therapy (18 pages) 14 Exhibit 1027 2014 Publication "Synthesis and 123 15 preclinical evaluation of 16 DOTAGA-conjugated PSMA ligands 17 for functional imaging and 18 endoradiotherapy of prostate cancer" 19 (15 pages) 20 Exhibit 1028 2015 Publication "68 Ga- and 132 21 177-Lu-Labeled PSMA-I&T: 22 Optimization of PSMA-Targeted 23 Theranostic Concept and First 24 Proof-of-Concept Human Studies" 25 (8 pages)	8 1 PROCEEDINGS 2 REBECCA ABERGEL, Ph.D., 3 a witness herein, having been first duly sworn by the 4 certified reporter to speak the truth and nothing but 5 the truth, was examined and testified as follows: 6 EXAMINATION 7 BY MR. BOETTCHER: 8 Q. Welcome. For the record, could you state and 9 spell your name? 10 A. My name is Rebecca Abergel, R-e-b-e-c-c-a, 11 A-b-e-r-g-e-l. 12 Q. And where do you work currently? 13 A. I work at the University of California 14 Berkeley. 15 Q. What's your position there? 16 A. I'm an associate professor and associate dean 17 for engineering. 18 Q. Okay. So have you ever been deposed before? 19 A. I have not. 20 Q. Okay. So let me walk you through some of the 21 basics. 22 For starters, this could take a while. But 23 whenever you need a break, all you have to do is say so. 24 All right? For whatever reason, you're feeling tired, 25 you want to get a drink, you want to use the bathroom,

9 1 just say so. Okay? 2 You won't take a break in the middle of a 3 question that I have outstanding, or I might want to 4 wait until I finish a series of questions about a topic, 5 and then I'll let you have the break, but all you have 6 to do is just say so. Okay? 7 I'm going to ask you a series of questions. 8 Your counsel may object throughout. Under the rules, 9 you still have to provide a response unless your counsel 10 actually tells you not to answer, usually in cases of 11 privilege. And that will be questions that -- you know, 12 we'll fight amongst ourselves, and you'll be fine, and 13 then some resolution will come out of it, and then we'll 14 just keep on going. Okay? 15 So right now we have a stenographer here. 16 Now, sometimes we'll have a videographer who will record 17 you. But in this case, she's writing down everything 18 you say. So when you speak, you need to give a specific 19 "yes" or "no," not nodding "yes" or shaking your head, 20 that kind of thing. It's very common when engaged in 21 conversation for people to do that sort of thing. You 22 get very comfortable, but in this case, always be sure 23 to provide a verbal response. Okay? 24 A. Yes. 25 Q. Very good.	11 1 question. Is that fair? 2 A. Yes. 3 Q. Okay. Good. 4 All right. So tell me a little bit about 5 yourself first. I want to know about your education. 6 Could you run through where you started off, where you 7 graduated from, and what your degrees were in? 8 A. Okay. I started my career in France. I 9 graduated with a bachelor's in science from École 10 normale supérieure in Paris, and I moved to the 11 United States to finish my master's degree at the 12 University of California, Berkeley in the chemistry 13 department. I obtained my Ph.D. in chemistry from the 14 University of California, Berkeley in 2006. 15 I did a year of postdoctoral research as a 16 joint appointee at the University of California, 17 Berkeley in the Fred Hutchinson Cancer Research Center 18 in Seattle. I went back and worked for a year as a 19 research specialist at UC Berkeley in the chemistry 20 department and then started employment as a scientist at 21 the Lawrence Berkeley National Laboratory in the 22 chemical sciences division. 23 I grew up through the ranks with different 24 titles from 2009 to 2018, at which point I started a 25 position as assistant professor in nuclear engineering
10 1 So what you just did was take an oath. It is 2 the same oath you would take in court, and it has the 3 same power as an oath you would take in court, which 4 means that you're now under the penalty of perjury if 5 you don't tell the truth, which, I think, is seven years 6 in jail, but I am sure that you're going to tell the 7 truth. 8 Now, before I start, there's one question. 9 It's a standard question. We always ask it. I don't 10 want you to be offended by it. But we always ask: Have 11 you been accused of or convicted of a felony, which is a 12 crime which would have a penalty of a thousand dollars 13 or one year or more in jail? 14 A. I have not. 15 Q. Sometimes you have to speak up a little bit. 16 Another thing for the stenographer -- and I 17 don't think this will be a problem, because we're doing 18 pretty well so far. But try not to speak over each 19 other. I'll be asking you questions. Wait for me to 20 finish my question. I'll try to wait for you to finish 21 your answer. 22 If I ask a question and it's not clear, it's 23 really up to you to let me know that it's not clear to 24 you. If you don't tell me it's not clear or ask me to 25 rephrase it, I'll have to assume that you understood the	12 1 at the University of California, Berkeley. And I kept 2 an appointment as a staff -- or faculty scientist at 3 Berkeley lab, where I also became the group leader for 4 heavy element chemistry and the director of the 5 Glenn T. Seaborg Center. And in 2021, I became 6 associate professor; in 2023, associate professor in 7 chemistry as well and associate dean in the college of 8 engineering. 9 Q. So it sounds like you came to Berkeley and 10 you just couldn't leave after that. 11 A. That's right. 12 Q. You just loved it here so much, huh? 13 A. Uh-huh. 14 Q. It happens to a lot of people. 15 A. I don't know. 16 Q. Can you tell me, what is heavy element 17 chemistry? 18 A. So it is, in general, studying the chemistry 19 of heavier elements in the periodic table. Depending on 20 who you talk to, it will encompass a different set of 21 elements, but in my community, my closer community, we 22 consider heavy elements to be the 4f and 5f elements, or 23 lanthanoids and actinoids. 24 Q. Okay. And so you're not an M.D., correct? 25 A. I am not an M.D.

13 1 Q. Okay. So you haven't administered 2 radiotherapeutics to any patients, correct? 3 A. That's correct. 4 Q. Okay. And you haven't treated any patients 5 or diagnosed any patients, correct? 6 A. That's correct. 7 Q. Okay. Let's get a little bit more detail 8 into your background. So we'll pull out the CV at this 9 point. 10 THE REPORTER: Exhibit 1? 11 MR. BOETTICHER: Exhibit 1. 12 MS. CIPRIANO: Should we go by the exhibits 13 in the -- rather than stamping them now, they already 14 have exhibit numbers. 15 MR. BOETTICHER: Do we want to start from 16 their exhibits or from the 2000s? 17 MS. CIPRIANO: It makes the record much -- 18 MR. HASAN: It makes the record a lot easier. 19 So if we can -- we can follow it that way. If we need 20 to add any new exhibits, we can give it a sequential 21 number. 22 MR. BOETTICHER: Sure. Let me look up where 23 we left off. 24 MR. HASAN: Is that okay, Linnea? 25 MS. CIPRIANO: Yeah. That's perfect.	15 1 that's in front of you? 2 A. I do. 3 Q. So it's been marked as Exhibit 1003 4 previously. Can you tell me what this document is? 5 A. It is my CV from January 2023. 6 Q. Okay. I'd like to look down at the bottom of 7 the first page, entitled "staff scientist, Chemical 8 Sciences Division, LBNL, 2010-2017." Do you see that? 9 A. Uh-huh. I do. 10 Q. So I want to ask you a few questions. You 11 said you -- it says that you led and managed heavy 12 element decorporation and biological chemistry programs. 13 Can you explain to me what heavy element 14 decorporation is? 15 A. Well, decorporation is a term that was coined 16 maybe 20 years ago. It's about removing elements -- 17 specific elements from a living organism. And so heavy 18 element decorporation would be removing heavy elements 19 from a specific living organism. 20 Q. Okay. So this is not radiotherapy, correct? 21 A. It is not radiotherapy. 22 Q. Okay. This is, in fact, taking the radiation 23 out of people or out of a living thing. Is that right? 24 A. It is taking specific elements out of a 25 living organism.
14 1 MR. BOETTICHER: All right. Let me take a 2 quick look and see where we left off. 3 MS. CIPRIANO: This has been marked 4 Exhibit 1003. 5 MR. BOETTICHER: Let's remark that as 2007. 6 Is that the next one in the list? 7 MS. CIPRIANO: We can refer to it as 8 Exhibit 1003. 9 MR. BOETTICHER: Oh, I see what you're 10 saying. 11 MS. CIPRIANO: It's already been marked in 12 the record. 13 MR. BOETTICHER: Yeah, yeah. Okay. 14 MR. HASAN: We can follow the consistent 15 exhibits that we have on our list. 16 MR. BOETTICHER: Right. Right. Okay. 17 MS. CIPRIANO: If you have any new exhibits 18 then -- 19 MR. HASAN: Then we can -- yeah. 20 MS. CIPRIANO: -- we can add numbers, if 21 that's... 22 THE REPORTER: Okay. So no stickers. 23 MR. BOETTICHER: No. 24 (Exhibit Number 1003 introduced.) 25 Q. All right. So do you recognize the document	16 1 Q. So with "specific elements," you mean you 2 might shoot for a particular thing that is 3 contaminating, like uranium or tritium or something like 4 that. 5 A. Uranium would fall under a heavy element 6 category. Tritium would not. 7 Q. Okay. So under -- titled "I," it says 8 "studies of heavy element biological coordination and 9 toxicology." Can you tell me what that was? 10 A. This is about understanding the coordination 11 chemistry in the biologically relevant environment of 12 those heavy elements. And "toxicology" means 13 understanding the toxicology of those elements. 14 Q. Okay. And so when you say the "the 15 coordination chemistry," what is that? 16 A. It means understanding what those elements 17 are bound to in the living organism, depending on how 18 they were introduced in that living organism. 19 Q. Okay. And so, again, would this fall under 20 the decorporation? 21 A. Not necessarily. "Decorporation" means 22 seeking path to remove those elements from a living 23 organism. Understanding the coordination chemistry 24 means understanding what the fate of those elements are 25 from the time they are introduced in the living

17 1 organism; from the time they are removed, if they're 2 removed; or throughout the period where they are in that 3 living organism. 4 Q. Okay. I'll tell you now that many times 5 these depositions are very educational. So you're doing 6 a nice job so far. 7 But I still want to be clear on this. So 8 were you looking at heavy elements that you were 9 introducing to a biological subject to see what they 10 did? Or were you looking in an attempt to remove those 11 heavy elements from biological subjects? 12 A. Both. 13 Q. Okay. Was this part of radiotherapy? Or was 14 this removing just the heavy elements alone? 15 A. Both. 16 Q. And so at that time you did radiotherapy 17 work? 18 A. I don't know if I have an exact date in mind. 19 But yes. We started looking at different constructs 20 that would be used for radiopharmaceutical therapy, in 21 which case you would introduce a heavy element. That is 22 the radionuclide for radiopharmaceutical therapy in a 23 living organism. 24 Q. Okay. And so where were you -- strike that. 25 Who were you working with at the time that	19 1 Q. Okay. And that was from 2010 to 2017? 2 A. That was somewhere in that period. 3 Q. Okay. So can you narrow it down a little bit 4 for me? Like, approximately which year? I mean, we 5 have 2010 to 2017 here. Can you narrow it down a little 6 bit more? 7 A. I can. I'm looking for specific funding 8 information so I can tell you exactly. 9 So there is a funding period from 10 October 2013 to February 2018. That is about the 11 coordination chemistry of actinides by selective 12 metal-binding molecules. So that would have been the 13 start of these studies in 2013. 14 I worked with thorium-227 15 radiopharmaceuticals that were supplied by Bayer 16 Healthcare from 2015 to 2018. 17 And then we worked with actinium-225 18 radiopharmaceuticals from February 2016 to 19 September 2017. 20 Q. Can you tell me what page you're looking at 21 there? 22 A. I'm looking at page 4. 23 Q. Could you tell me again what the -- I'm 24 sorry. Could you tell me again what those titles were? 25 A. The DOE grant from 2013, that's the third
18 1 you were doing the work with the radiotherapy between 2 2010 and 2017? 3 A. Who was I working with... 4 Can you be a little bit more specific in 5 terms of -- I mean, the community is a lot of different 6 people. 7 Q. Sure. So it says here that you were a staff 8 scientist. So whose staff were you on? Whose lab were 9 you in? 10 A. So I was a staff scientist in the chemical 11 sciences division. My immediate colleagues were about 12 10 investigators, but I also supervised anywhere from 13 5 to 15 people, depending on the particular date. And 14 that would be research associates, undergraduate 15 students, graduate students, and postdoctoral 16 researchers. 17 Q. Okay. And the radiopharmaceuticals that you 18 were working on at that time, what was the goal of those 19 radiopharmaceuticals that you were working on? 20 A. So the specific radiopharmaceuticals we 21 worked with, the goal was to target cancer cells, 22 deliver alpha particles in the vicinity or within those 23 cancer cells through the use of radioactive heavy 24 elements like actinium-225 or thorium-227. And there 25 were several constructs.	20 1 bullet from the bottom, "Coordination and Solution 2 Chemistry of Actinides." 3 The one right above, "Coordination Chemistry 4 Characterizations of Conjugated Th-Chelators," and the 5 one above, "Biodistribution and Toxicity Evaluation of 6 Accelerator-Produced actinium." 7 Q. Okay. Now, were these for cancer treatments? 8 Were these for viral treatments? Or were these for 9 antibacterial treatments? 10 MS. CIPRIANO: Objection; compound. 11 A. Those were mostly thinking about cancer 12 treatments, but my focus was really on understanding 13 their fate and behavior in living organisms in general. 14 Q. So did any of these projects lead to the 15 production of a radiopharmaceutical? 16 A. I believe Bayer went ahead with their thorium 17 radiopharmaceuticals. 18 Q. And so your role in this was determining the 19 fate of the radiopharmaceuticals or the radionuclides in 20 the system. Is that right? 21 A. My role was to seek fundamental understanding 22 of the coordination and the fate of those elements. 23 That's right. 24 Q. But as far as giving the treatments to 25 patients to test it, you weren't involved in that, were

21 1 you? 2 A. I was not. 3 Q. And in determining whether or not the 4 compounds had clinical utility, you weren't involved in 5 that, were you? 6 A. I was not directly involved, but I believe 7 that some of my team's findings were used for those 8 determinations. 9 Q. And when you say your team's findings, do you 10 mean the clinicians? 11 A. I mean the publications and reports that came 12 out of our studies were used in documents that were 13 submitted to the Food and Drug Administration, for 14 example. 15 Q. But were you involved in the clinical aspects 16 in producing the data for those reports? 17 A. I was not. 18 Q. So I want to go back to the first page. 19 Listed as Number iii, "The development of new ligand 20 platforms for f-elements." Do you see that? 21 A. I see that. 22 Q. So what is that? Is that what you were just 23 talking about before? Or is that something else? 24 A. That is something else. It's developing new 25 chelating structures to coordinate f-elements.	23 1 you perform the dosimetry studies yourself? Or did 2 somebody else perform them? 3 A. I did not perform the dosimetry studies 4 myself. 5 Q. And what sort of data did you provide for the 6 dosimetry studies? 7 A. Biodistribution studies for radionuclides. 8 Q. Could you explain what that means? 9 A. It means the exact location of ionizing 10 radiation emitting radionuclides in different 11 compartments of living organisms. 12 Q. Now, have you ever done work with PSMA? 13 A. I have not. 14 Q. Okay. Have you ever done work on prostate 15 cancer? 16 A. I have not. 17 Q. Okay. So the drug that Bayer was making, 18 that was not a prostate cancer drug? 19 A. It was not. 20 Q. Okay. And it wasn't -- or it didn't have 21 a -- strike that. 22 It didn't have a PSMA ligand involved in it, 23 correct? 24 A. It did not. 25 Q. Can I ask, was it a targeted
22 1 Q. Okay. 2 A. And it is part of what I was describing, 3 since we are looking at the coordination and fate of 4 heavy elements in radionuclides, whether they're 5 coordinated by this or the structure or whether they're 6 not coordinated and bound to biological molecules, so... 7 Q. Okay. And the next item is the decorporation 8 program. There was a therapeutic radionuclide 9 decorporation agent as a new medical countermeasure 10 against nuclear threats. Is that different from the 11 Bayer product you were talking about before? 12 A. Yes. 13 Q. Do you know the name of the product that 14 Bayer produced from your research? 15 A. I don't know the exact name. 16 Q. Is that included on your CV anyplace? 17 A. I don't believe so. 18 Q. Okay. So did you do studies in dosimetry? 19 A. I provided data for dosimetry studies. 20 Q. And how would you define dosimetry? 21 A. How would I define dosimetry... 22 It is understanding the evolution and effect 23 of ionizing radiation dose in different compartments of 24 living organisms. 25 Q. And so you provided data for dosimetry. Did	24 1 radiotherapeutic? 2 A. It was a targeted radiotherapeutic. 3 Q. And how was it targeted? 4 A. It was targeting through an antibody. 5 Q. So do you have experience using ligands for 6 targeting the radiotherapeutic? 7 A. When you say "ligands," do you say small 8 molecules, peptides? 9 Q. I would say a small molecule that binds to a 10 receptor? 11 A. I do have not direct experimental experience 12 with small molecule targeting vectors. 13 Q. And so the dosimetry that you were doing, was 14 this related to your decorporation projects? Or was 15 this related to your radiotherapeutics projects? 16 A. It was related to the radiotherapeutic 17 projects. 18 Q. So as part of your decorporation work, would 19 you study which organs received the radioactive 20 elements? 21 A. Yes. 22 Q. And so which organs typically are the 23 repositories of radiation? 24 A. It depends on the radionuclide. 25 Q. Okay. So, for example, with actinium, where

25 1 does it usually end up in the body? 2 A. It also depends on what compound the actinium 3 was incorporated into when it was introduced in the 4 body. 5 Q. So when you say "the compound," are you 6 referring to, like, a chelator that it was bound to? 7 A. I'm referring to a chelator. I'm referring 8 to -- yes, a chelator or whatever entity it was bound 9 to. 10 Q. Okay. So let's say you had actinium that was 11 free floating in the body. Where would it most likely 12 pool? 13 A. Most likely in the liver and in the skeleton. 14 And that would be -- it also depends on the organism. 15 So I'm assuming you're asking about humans. 16 Q. Let's say yes. 17 A. So liver, kidney, and skeleton. 18 Q. And what sort of effects do they have 19 there -- let me break that down. 20 What sort of effects would actinium arriving 21 in the liver have on the liver? 22 A. Well, the effects will vary based on the 23 isotope. So I'm assuming you're talking about 24 actinium-225. 25 Q. Let's assume I'm talking about actinium-225.	27 1 they will deposit energy that is high enough to break 2 chemical bonds. And that means breaking DNA in cells. 3 It means impacting the function of the cells where this 4 energy is deposited. So you would see different effects 5 from impairment from those cells. 6 Q. What about actinium appearing in the 7 skeleton? What sort of effects would you see there? 8 A. The same type of effects. 9 Q. How would you measure the effects of actinium 10 pooling in the skeleton? 11 A. How would you measure the effects... 12 Q. When you're looking at the effects of 13 actinium on the skeleton, what do you look at? What are 14 you assaying for? 15 MS. CIPRIANO: Objection; outside the scope. 16 A. I don't know that you could look for 17 measurable effects at the tracer levels that are used 18 for -- I mean, I don't know what you would be looking 19 for to assay in the skeleton. 20 Q. What about the daughter elements of actinium? 21 Would they pool in the same places? 22 A. I believe this is a question we are still 23 trying to answer today. 24 Q. Okay. 25 A. So it depends on a lot of different things.
26 1 A. There will be delivery of alpha particles 2 mostly. I would assume the radiological toxicity is 3 more predominant than the chemical toxicity. So the 4 effect would be mostly coming from the dose imparted by 5 those alpha particles emitted from the actinium. And -- 6 I mean, that's what it is. 7 Q. So what sort of effect would the 225 actinium 8 have on the liver? 9 MS. CIPRIANO: Objection; asked and answered. 10 THE WITNESS: Did you ask me not to answer? 11 MS. CIPRIANO: No. Go ahead. 12 Q. Unless she says privilege or -- 13 A. No. Sorry. I -- 14 Q. -- specifically tells you not to -- 15 THE WITNESS: I didn't hear what you said. 16 Q. So let me ask the question again. 17 So what sort of effects would you see on the 18 liver from actinium-225 pooling there? 19 MS. CIPRIANO: Same objection. 20 A. When you're asking about effects, I'm not 21 sure what you're asking for. Because I, you know -- to 22 my knowledge, we have not performed an experiment where 23 we've had -- we have injected free-floating actinium-225 24 in people. 25 In terms of effects from the alpha particles,	28 1 Q. So we're getting into cutting-edge science, 2 then. 3 A. Uh-huh. Yes. 4 Q. Okay. So would you expect, for example, if 5 you had actinium or one of the daughter elements 6 appearing in the skeleton, a long-term effect might be 7 leukemia? 8 MS. CIPRIANO: Objection; incomplete 9 hypothetical. 10 A. I'm not sure that I would expect specific 11 effects without knowing exactly what the form of the 12 actinium was and how much was delivered and where it 13 went. 14 Q. So I'd like you to look at page 11 of your 15 CV. 16 Okay. So for entries 69 and 73 and 75, I see 17 titles that are related to cancer. 18 A. That's right. 19 Q. Are those the projects you were working on 20 for Bayer? 21 A. Can you repeat the numbers, please? 22 Q. 69, 73, and 75. 23 A. No. 24 Q. Okay. So did you publish any articles based 25 on the radiotherapeutics you were working on that became

29 1 the Bayer product? 2 A. Yes. 3 Q. Can you point them out to me, please? 4 A. Number 55 on page 10. 5 Q. Okay. Is there anything else that emerged 6 from that project as a -- 7 A. No. 8 Q. Was this your first radiotherapeutic directed 9 towards cancer? 10 A. That was not mine. I don't know -- first, 11 what do you mean? 12 Q. Was this the first project you worked on that 13 was developing a radiotherapeutic focused towards 14 cancer? 15 A. I don't know if it was the first. It was at 16 the same time as others, so... 17 Q. Was it your first? 18 A. Project? No, it was not. 19 Q. Let me be clear. So was this your first 20 project that was focused towards making a 21 radiotherapeutic for cancer? 22 A. No, it was not. As I mentioned, there was 23 another project that was funded a few years earlier. 24 Q. Okay. Can you point out the articles that 25 emerged from that one?	31 1 A. That's correct. 2 Q. And so usually an article that has influence 3 or has an important finding will be cited more often. 4 Is that correct? 5 A. I think it could be the generality. Yes. 6 Q. We'll put that aside. 7 MR. BOETTICHER: We'll take a short break 8 now, if that's okay. 9 MR. HASAN: Thank you. 10 (Off the record: 9:50 a.m. to 9:56 a.m.) 11 MR. BOETTICHER: Go back on the record. 12 Q. All right. I'm going to hand you what was 13 Exhibit 1001 to your declaration. 14 (Exhibit Number 1001 introduced.) 15 Q. Do you recognize this document? 16 A. I do. 17 Q. What is this document? 18 A. It is a patent. 19 Q. Did you review this patent as part of your 20 declaration? 21 A. I believe I did. 22 Q. So I presume that you are familiar with the 23 claims at the end of the patent. Is that true? 24 A. It is true. 25 Q. So going to page 18 of the document, do you
30 1 A. Number 45 is an example, on page 9. 2 Q. Okay. So you certainly do have a lot of 3 articles here. Are there any -- are you particularly 4 proud of any of your journal publications? 5 MS. CIPRIANO: Objection; relevance. 6 A. Particularly, I don't know. I mean, I'm not 7 more or less proud of any specific publication. No. 8 Q. Okay. So when a publication -- when an 9 article is published, how do you measure the importance 10 of that publication, that article? 11 MR. BOETTICHER: Objection; relevance. 12 A. It depends what it should be important for. 13 If it's to seek funding, I will look at the impact 14 factor of the journal where we publish the article. If 15 it is for my personal satisfaction, I will look at the 16 number of students who have worked on the project and 17 helped with the article. It depends on the metric 18 you're using to define "important." 19 Q. But in terms of the community, the influence 20 of the article, how would you measure that? 21 A. You could measure that by looking at the 22 number of citations. 23 Q. And the citations represent the number of 24 times that other people have referenced the article, 25 correct?	32 1 see Claim 1 on Column 18, line 14? 2 A. I do see. Yes. 3 Q. And it says "A method for treating PSMA 4 expressing cancers, wherein the method comprises 5 administering to a patient in need thereof an effective 6 amount of one or more Ac-225-radiopharmaceuticals." 7 That's how it begins. Do you see that? 8 A. I do see. 9 Q. Okay. Now, the PSMA is not based on an 10 antibody, correct? 11 A. That is correct. 12 Q. Okay. So Claim 1 isn't claiming an 13 immunoconjugate. Is that right? 14 A. I believe that's right. 15 Q. And it's only claiming the Ac-225 16 radiopharmaceuticals. Isn't that correct? 17 MS. CIPRIANO: Objection; incomplete. 18 A. I believe so. 19 Q. So it's not claiming the entire f and d-block 20 of chemicals, correct? 21 A. I believe that's correct. 22 Q. Okay. So a person of skill trying to read 23 this patent wouldn't need to know about the entire 24 d-block of elements, right? 25 A. I don't know that I would tell you "yes" or

33 1 "no" to that as an academic. It depends on what 2 property they need to be aware of. 3 Q. Okay. So, for example, copper is in the 4 d-block of elements, isn't it? 5 A. That's right. 6 Q. Does copper come up in this patent? 7 A. I don't recall. 8 Q. Iron is in the d-block of elements. 9 A. That's correct. 10 Q. Iron doesn't come up in this patent, right? 11 A. It does not. 12 Q. Okay. 13 A. However, on that page, gallium does. It's a 14 d-block element. 15 Q. But titanium is a d-block element, right? 16 A. Titanium does not come up in the patent. 17 Q. Okay. So a few of the d-block elements they 18 should be familiar with, like gallium, lutetium. 19 A. Lutetium is not a d-block element. 20 Q. Oh. Sorry. F-block, right? 21 A. You're citing those elements that are in the 22 patent. So yes, I believe they should be familiar. 23 Q. Okay. But they don't need to know about all 24 of the elements in the d-block. I think that's fair, 25 right?	35 1 A. I don't believe so. 2 Q. And it doesn't claim a new method of 3 attaching radionuclides to molecules, does it? 4 A. I don't believe so. 5 Q. And it doesn't claim a new method of making 6 radionuclides, right? 7 A. I don't believe it claims methods of making 8 radionuclides. 9 Q. I'm sorry. Say that again. 10 A. No, I don't believe it does. 11 Q. Could you explain what is meant by a 12 thermodynamically stable molecule? 13 MS. CIPRIANO: Objection; incomplete 14 hypothetical. 15 A. So I believe what is meant in this patent as 16 a thermodynamically stable molecule refers to a metal 17 complex in which case the thermodynamic equilibrium 18 would be driven towards this complex staying together in 19 the various conditions that are relevant rather than 20 dissociating or falling apart where the metals would be 21 released from the molecules it was bound to. 22 Q. Okay. But the patent doesn't actually use 23 the term "thermodynamically stable." 24 A. I don't recall. It's a long patent. So I 25 would have to go back and read it.
34 1 A. I would say they would need to know about 2 general properties of d-block and f-block elements. 3 Q. Of all of the d-block and f-block elements? 4 A. General properties. 5 Q. And what would those general properties be? 6 A. What defines those elements, for example. 7 Q. So you're saying that a person of skill 8 reading this patent would have to know what defines the 9 element of copper in order to understand the patent? 10 A. Would have to know what a metal is, for 11 example, what -- the general property of an f-block or a 12 d-block element, because there are d-block elements in 13 there. Yes. 14 Q. But why would they need to know about all of 15 the d-block or f-block elements in order to understand 16 this patent? 17 A. I'm not sure how to answer your questions, 18 because knowing about all of the elements doesn't mean 19 being an expert in the coordination chemistry of every 20 single element in those series. So general properties 21 would be a basic understanding. Specific properties 22 about a specific metal in a specific environment may not 23 be needed. 24 Q. Okay. Now, the patent doesn't claim a new 25 method of synthesizing molecules, does it?	36 1 Q. Oh, I assure you this is not a long patent. 2 There are some that are quite painful. 3 A. Well, it's a long enough document that I 4 couldn't tell you every single word that is used in 5 there. 6 Q. So would you consider the claimed 7 actinium-PSMA 617 molecule to be thermodynamically 8 stable? 9 MS. CIPRIANO: Objection; outside the scope 10 of the declaration. 11 A. I think it depends on the conditions. 12 Thermodynamically equilibrium depends on what is 13 included in that equilibrium. So I can't tell you if 14 it's thermodynamically stable if you don't tell me where 15 it is and what it is living together with. 16 Q. I see. 17 So whether or not something is 18 thermodynamically stable depends on its environment, 19 like if it's in the serum or if it's in a buffer or if 20 it's in just water. Is that right? 21 A. That's right. 22 Q. And explain to me again. So 23 thermodynamically stable refers to the molecule breaking 24 apart and losing its radionuclide? 25 MS. CIPRIANO: Counsel, you're using the term

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37 1 "refers to." Are you pointing to a particular 2 reference? 3 MR. BOETTICHER: No. I'm asking for her 4 information and understanding of the topic. 5 Could you read back the question. 6 (The record was read.) 7 A. I think what you're asking me is about a 8 metal complex being thermodynamically stable, and that 9 would refer to the formation of the metal complex itself 10 where we look at the metal and what its bound to as two 11 different entities and the metal complex as the 12 incorporation of the metal into that second entity. 13 Q. Okay. So the metal complex is the 14 incorporation of the metal into the molecule, and you 15 would say it is not thermodynamically stable if under 16 its environmental conditions it lost the radionuclide? 17 A. If the metal was released from the complex -- 18 if the equilibrium was driven so that the metal is 19 released from the complex, yes. 20 Q. So in your declaration you spent a lot of 21 time on the PSMA-I&T molecule, correct? 22 A. I don't know if it's a lot of time. Compared 23 to what? To other things? There's some reference to 24 the PSMA-I&T complex. Yes. 25 Q. Would you consider the PSMA-I&T complex bound	39 1 A. They're looking at the prevalence of the 2 prostate -- sorry. I'm blocking out -- at the antigen 3 in the different patients and how it declines, meaning 4 the disappearance of the cancer, if you will, I believe. 5 Q. So they're measuring the PSA. Do you know 6 what PSA stands for? 7 A. Sorry. I'm -- the words aren't coming out. 8 Prostate surface antigen. 9 Q. Thanks. 10 So have you ever measured the PSA in a 11 patient? 12 A. I have not. 13 Q. Have you ever had a project where it was 14 required to measure the PSA in a patient? 15 A. No. 16 Q. Okay. And, again, you've never used the PSMA 17 ligand in any of your research, correct? 18 A. Correct. 19 Q. What is -- how would you define "efficacy"? 20 A. In what? 21 Q. In terms of a radiopharmaceutical, for 22 example, how would you define "efficacy"? 23 A. I would define "efficacy" as the reduction of 24 living cancer cells after administration of a 25 radiopharmaceutical treatment as a direct effect.
38 1 to actinium to be thermodynamically stable? 2 A. Under what condition? 3 Q. Let's say in serum, human serum. 4 MS. CIPRIANO: Objection; outside the scope 5 of the declaration. 6 A. I would have to go back and look at the 7 numbers. 8 Q. Okay. I'd like you -- so just to be clear, 9 we already agreed that the Claim 1, claiming the PSMA 10 ligand molecule, is not an immunoconjugate, correct? 11 A. If by immunoconjugate you're referring to 12 molecules that are incorporating an antibody, that's 13 correct. 14 Q. And so this Claim 1 would be referring to 15 small molecules? 16 A. Yes, it would. 17 Q. And you haven't previously worked with small 18 molecules, correct? 19 A. I have worked with small molecules. I have 20 not worked with peptides targeting radiopharmaceuticals. 21 Q. I'd like you to look at Figure 1 of the 22 patent on page 2. Do you remember this graph? 23 A. I must have looked at it. 24 Q. Can you tell me what Figure 1 represents, 25 what they're doing here?	40 1 Q. Okay. And how would you define 2 "effectiveness" in a radiopharmaceutical? 3 A. I'm not sure they're two different terms 4 in -- with this general definition. 5 Q. Okay. And so when someone refers to an 6 effective amount of a radiopharmaceutical, what do you 7 think they're referring to? 8 A. I think they're referring to an amount that 9 would lead to measurable efficacy. 10 Q. And what does it mean by a tolerable dose? 11 A. I would define "tolerable dose" as a dose 12 that does not result in such toxicity effects that it 13 impacts the life of the patient negatively. 14 Q. And how would you measure the tolerability of 15 a dose? 16 A. There are several ways. One is just quality 17 of life, symptoms, but also maybe body weight loss, and 18 then you could go down to specific markers. 19 Q. And so the tolerability dose of, say, a 20 radiopharmaceutical is going to be different from the 21 efficacious dose. Isn't that right? 22 A. That's right. 23 Q. So the claims of this patent, the US 24 patent 10,980,901, they're really based towards solid 25 tumors, correct?

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41 1 MS. CIPRIANO: Objection; incomplete, 2 misrepresents the document. 3 A. I don't recall if there's no more reference 4 to non-solid tumors. I would -- I can't give you a 5 solid answer. 6 Q. So let me draw your attention to Column 12, 7 which is page 15 of the document. 8 So Column 12, the second paragraph there 9 beginning at line 3, could you read through that to 10 yourself. 11 A. Okay. 12 Q. So you've read through it. Those all sound 13 like solid tumors, correct? 14 A. It doesn't say "solid tumors." 15 Q. But are you familiar with those types of 16 tumors? 17 A. I am familiar. I don't think it specifically 18 states that and excludes non-solid tumors, so... 19 Q. But the cells -- the tumors that it's listing 20 in Column 12, those are all solid tumors, correct? 21 A. I think you could argue that some of those 22 terms can also include metastasized cancers. So no. It 23 doesn't state specifically "solid tumors." I wouldn't 24 make that assumption. It talks about cancer cells. It 25 does not talk about solid tumors.	43 1 see that? 2 A. Yes. 3 Q. Could you read that to yourself, please. 4 A. Okay. 5 Q. So can you give me an idea of what they mean 6 by "diffuse red marrow" -- excuse me -- "diffuse red 7 marrow infiltration of mCRPC"? 8 A. Not really. 9 Q. So could you explain why it would be a 10 contraindication for treatment with beta emitters? 11 MS. CIPRIANO: Objection; scope, foundation. 12 A. I don't want to give you a faulty 13 explanation, so I won't venture. 14 Q. Okay. So you don't know why it would be a 15 contraindication for beta emitters. 16 A. I don't. 17 Q. Neither do I. 18 Could you look at Figure 12B -- Figure 12. 19 Sorry. Please look at Figure 12. 20 Do you know what this Figure A, B, and C 21 represent? 22 A. I believe I do. 23 Q. Can you explain it to me? 24 A. Those are PET scans of a patient's -- or PET 25 scans of a patient that was treated with actinium-PSMA
42 1 Q. But prostate cancer is considered a solid 2 tumor, isn't it? 3 A. I think you would have to be a bit more 4 specific to claim that it is solid tumors only. 5 Prostate cancer can become more than just a solid tumor. 6 Q. In what way? 7 A. In metastasized prostate cancer. I don't 8 think it excludes any disease evolution in this 9 paragraph. 10 Q. But when prostate cancer forms, it begins as 11 a solid tumor, correct? 12 A. I'm not sure I can give you an answer to 13 that, whether that's correct or not. I don't know 14 enough about cancer biology to tell you that all 15 prostate cancers begin as a solid tumor. 16 Q. Do you know what diffuse red marrow 17 infiltration is? 18 A. I don't have a good definition. 19 Q. Okay. Let me give you some context on it, 20 then. 21 So page 17 of the patent. So this is 22 1001.017 at the bottom right-hand side. This will be 23 Column 16. 24 The last section here, that final paragraph 25 beginning with "Clinical course of Patient A," do you	44 1 at different time points, so before treatment, after 2 three treatments, and after a final one. 3 Q. Okay. And so we can see on the left-hand 4 side there's all those dots throughout the entire body, 5 correct? 6 A. That's correct. 7 Q. And your understanding is that would be 8 metastasized tumor, correct? 9 A. Metastasized cancer, that's correct. 10 Q. And then after three treatments, it has 11 considerably disappeared, correct? 12 A. That's correct. 13 Q. And after the last treatment, it's also gone, 14 correct? 15 A. That's correct. 16 Q. Had you seen this figure before you were 17 engaged as an expert in this case? 18 A. I had. 19 Q. Where had you seen this figure before? 20 A. In many places. 21 Q. So it was a fairly popular figure? 22 A. It is a popular figure. 23 Q. So it received a lot of attention in the 24 field, correct? 25 A. That's correct.

45 1 Q. And it received attention in the field 2 because a lot of people thought it was an unusual 3 result, correct? 4 A. I don't know if I would characterize this as 5 unusual. I would characterize this as the one patient 6 that showed the best response to this treatment, and it 7 is a good visual to argue efficacy. 8 Q. You say it's the one patient. Could you look 9 at Figure 14. 10 So are you familiar with this figure? 11 A. I believe so. 12 Q. Okay. This is a different patient, correct? 13 A. I believe so. 14 Q. Okay. And can you explain to me what's going 15 on in this figure? 16 A. Those are also PET scans of a patient before 17 treatment with lutetium-PSMA and after treatment and 18 after subsequent treatment with actinium-225-PSMA. 19 Q. And so we see that from Figure A to B, 20 there's two treatments with lutetium-PSMA, correct? 21 A. That's correct. 22 Q. And the amount of cancer actually increases, 23 right? 24 A. I wouldn't be quantitative, but it seems like 25 that. Yes, that's correct.	47 1 Q. So it received a lot of attention. 2 MS. CIPRIANO: Objection; misstates 3 testimony. 4 A. It was used by various people. I don't know 5 that it's a lot of attention. Compared to -- I don't 6 know what, so... 7 Q. And so the people, as you recall, when they 8 presented this data, were they speaking of it favorably? 9 MS. CIPRIANO: Objection; outside the scope 10 of the declaration. 11 A. They mostly speak of it as an example of what 12 actinium-225 can achieve. 13 Q. And when they were talking about it as an 14 example of what it could achieve, were they indicating 15 that it was an impressive result? 16 A. I mean, yes. It's an impressive result 17 compared to other results. 18 Q. So let's look at Figure 13. 19 So Section A, can you explain to me what's 20 going on in these three different figures? 21 A. I would prefer not to venture into explaining 22 to you the specifics, because I don't have the right 23 vocabulary, so... 24 Q. Why don't you have the right vocabulary? 25 A. Because I'm not a cancer biologist.
46 1 Q. Well, earlier when we were discussing PSA, 2 you said it was a measurement of the presence of -- 3 A. That's right. So yes. 4 Q. So we see that the PSA goes from 294 to 419. 5 A. It does. 6 Q. And then in Figure C, after two treatments of 7 actinium-PSMA, the PSA decreases to 3.5. 8 A. That's right. 9 Q. That's a pretty remarkable result, don't you 10 think? 11 MS. CIPRIANO: Objection; calls for 12 speculation. 13 A. It's not as drastic a reduction as in the 14 previous figure. But it's also a good visual. Yes. 15 Q. So you think the previous figure is even 16 better. 17 A. I think it's easier to communicate. 18 Q. And so before, you said that Figure 12 was 19 highly cited in the field. 20 A. I did not say it was highly cited in the 21 field. I said that I saw it many places. Yes. 22 Q. Okay. Can you give me an idea of how many 23 different places you've seen it cited? 24 A. I saw it in various oral presentations at 25 conferences mostly.	48 1 MS. CIPRIANO: Counsel, if you want to point 2 her to where in the patent -- 3 MR. BOETTICHER: Sure. 4 MS. CIPRIANO: -- that might be helpful. 5 Q. Well, we're looking at Figure 13 right now. 6 So the first figure in 13A, it shows "PLT." Do you know 7 what that is? 8 A. Not off the top of my head. 9 Q. Okay. Let's see. If you go to Column 17, it 10 would be the first full paragraph beginning with 11 "Figure 13." 12 A. Okay. 13 Q. So does that help you understand Figure 13A 14 better? 15 A. Yes. 16 Q. Okay. So in the first part of Figure 13A, 17 they're looking for -- they're looking at platelet 18 counts, correct? 19 A. Correct. 20 Q. And these arrows in Figure 13A represent when 21 the therapeutic was added, correct? 22 A. Correct. 23 Q. And so the platelet count remains above 24 100 throughout, correct? 25 A. Correct.

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49 1 Q. Now, would you say that is a Grade 1, 2 Grade 2, Grade 3 negative effect? 3 MS. CIPRIANO: Objection; foundation, scope. 4 A. I don't know. 5 Q. Would you say that is typical or unusual for 6 a radiotherapeutic? 7 MS. CIPRIANO: Same objections. 8 A. I don't know, depending on how many 9 radiotherapeutics you would include in your comparison, 10 so typical. 11 Q. So earlier we talked about the effects that 12 actinium might have if it was in the skeleton. Do you 13 remember that? 14 A. Right. 15 Q. Would one of the effects be damaging the red 16 blood cells that are made in the red marrow? 17 A. It could be an effect. 18 Q. And could it also damage the white blood 19 cells that are made in the bone marrow? 20 A. It could be an effect. 21 Q. And it could reduce the amount of hemoglobin 22 because it's destroying the platelets that are in the 23 red marrow, correct? 24 A. Possibly. 25 Q. Have you ever measured the effects of a	51 1 being treated with a radiotherapeutic and it failing and 2 then treated with a different radiotherapeutic and it 3 succeeding? 4 A. So I don't have direct experience with 5 patients, human patients. From my knowledge, it is 6 expected that an alpha-emitting isotope like 7 actinium-225 would have more effect than a beta emitter 8 like lutetium-177 in the same conditions. 9 Q. When you say it's expected, is that based on 10 actual experiments in which lutetium was used and failed 11 and then actinium was used in the same patient? 12 A. In the same patient, I don't know. Under 13 similar conditions, yes. In models, yes. In the same 14 patient, one treatment following the other one, I don't 15 have direct experience with that. 16 Q. Have you ever seen an example of that other 17 than -- 18 A. Other than that -- 19 Q. -- this patent. 20 A. I don't know. I don't know. 21 Q. So let me ask you this. Figure 14D, the PSA 22 is less than .1 nanograms per mil. Is that considered 23 below detectable levels? 24 MS. CIPRIANO: Objection; foundation. 25 A. Which -- 14D. Okay.
50 1 radionuclide on these particular parameters? 2 A. In humans? 3 Q. Yeah. 4 A. I have not. 5 Q. Let me ask you about Figure 14 again. So we 6 see from Figure A to B that the amount of tumor has 7 increased, and then we see from Figure B to C that it's 8 largely disappeared. That's a fair description, 9 correct? 10 A. Correct. 11 Q. Would you consider this result to be unusual 12 in the sense that the therapeutic for lutetium failed 13 whereas the actinium therapeutic succeeded so well? 14 A. No. 15 Q. Why not? 16 A. Because we're looking at two different types 17 of ionizing radiation from two different radionuclides. 18 Q. Has it been your experience that using one 19 type of radiation will succeed as the therapeutic and 20 the other one will fail immediately following? 21 A. Well, this is the opposite order. 22 Q. I'm sorry. Say it again. 23 A. You told me succeed and then fail following. 24 Q. Sorry. Let me reverse that, then. 25 So have you had experience with a patient	52 1 Q. 14D. 2 So the PSA goes below .1 nanograms per mil. 3 Would that be considered below detectable levels? 4 MS. CIPRIANO: Objection; foundation. 5 A. I don't know what the method was to measure 6 this. I don't know the sensitivity. I think it would 7 be -- I don't know. 8 Q. So to the best of your knowledge, this patent 9 is the first time that actinium was combined with 10 PSMA 617, correct? 11 A. I don't know. 12 Q. Okay. To the best of your knowledge, this is 13 the first time that actinium was used with the PSMA 14 ligand to cure cancer in humans, correct? 15 A. I believe so. 16 Q. All right. Let's move on. 17 All right. I want to spend some time on your 18 declaration. 19 (Exhibit Number 1002 introduced.) 20 Q. Okay. So I'm putting before you something 21 that's been marked as Exhibit 1002 to your -- to the 22 petitioner's brief. Do you recognize this document? 23 A. I do. 24 Q. Okay. What is this document? 25 A. It is my declaration.

53 1 Q. Okay. I would like to ask you about 2 paragraph 5 of the declaration on page 2. 3 So paragraph 5, you're discussing some of 4 your previous experience, correct? 5 A. That's correct. 6 Q. Okay. So you have them itemized out with 7 lower case i's, i, ii, iii, right? 8 A. Right. 9 Q. So looking at ii, you say "The development of 10 new clinical radionuclide and toxic metal 11 decontamination strategies." Do you see that? 12 A. I see that. 13 Q. So this patent doesn't relate to 14 decontamination strategies, right? 15 A. That's right. 16 Q. Okay. For iii, you say "The development of 17 new separation methods for rare earth mining, 18 transuranic waste handling, and purification of metal 19 isotopes." Do you see that? 20 A. I do. 21 Q. So this patent isn't related to the 22 separation methods of rare earth mining, right? 23 A. That's right. 24 Q. Or transuranic waste handling, right? 25 A. That's right.	55 1 to this patent, then. 2 A. To some extent, yes. 3 Q. Okay. And Part i is "The development of new 4 strategies for anticancer, antibacterial, and antiviral 5 radiotherapies," correct? 6 A. Radiotherapeutics. Correct. 7 Q. Sorry. Radiotherapeutics. Thank you. 8 But this patent doesn't relate to antiviral 9 radiotherapeutics, right? 10 A. That's right. 11 Q. And it doesn't relate to antibacterial 12 radiotherapeutics, correct? 13 A. That's right. 14 Q. So of the four different areas that we have 15 here, we've got the development of new strategies for 16 anticancer in the first one. And you say that 17 interrogating the fundamental behavior of heavy and 18 super heavy elements in the fourth one is relevant, 19 correct? 20 A. Correct. 21 Q. Okay. So in your career that you spent on 22 these different topics, what percentage of it did you 23 spend on the strategies for anticancer? 24 A. I don't know if I can give you a -- 25 Q. Just a ballpark.
54 1 Q. Or the purification of medical isotopes, 2 right? 3 A. That's right. 4 Q. Okay. And then for Number iv, "The 5 development of new methodologies for interrogating the 6 fundamental behavior of heavy and super-heavy elements." 7 Do you see that? 8 A. I do. 9 Q. And so this patent isn't related to 10 interrogating the fundamental behavior of heavy and 11 super-heavy elements, right? 12 A. That's right. 13 Q. Okay. So you've listed five things here -- 14 A. I mean, actually, this patent is related to 15 the fundamental behavior of actinium and lutetium. So 16 it is. 17 Q. So when you say "interrogating the 18 fundamental behavior," what does that mean? 19 A. Right. So it means understanding how to 20 understand developing methods to understand the fate of 21 those elements. 22 Q. And do you mean the fate of those elements in 23 humans? 24 A. In various environments, including humans. 25 Q. Okay. So you think that Part iv does relate	56 1 A. I don't know if I can give you a ballpark, 2 because in some aspects, those are all related. So by 3 looking at decontamination strategies, I can understand 4 better the fate of a specific radionuclide, and that 5 will -- may lead me to some studies or some ideas or 6 discussions on how to develop a new radiotherapeutic. 7 So I'm not sure where I would draw the line between 8 those four categories that are highlighted here to give 9 you a number. 10 But I would say that in the past eight years, 11 about 50 percent of the activities in my research group 12 are dedicated to radiotherapeutics. 13 Q. Okay. At paragraph 6, you say "I led a large 14 collaborative effort in the development of new drug 15 products for the treatment of populations contaminated 16 with heavy metals and radionuclides." Do you see that? 17 A. Yes. 18 Q. And it says "One of these products was 19 granted an investigational new drug status from the 20 U.S. Food and Drug Administration in 2014 and is now in 21 Phase 1 clinical trial." Do you see that? 22 A. That's right. 23 Q. Okay. So this isn't the Bayer product that 24 you were talking about before, is it? 25 A. It is not.

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57 1 Q. This is the decorporation product? 2 A. That's right. 3 Q. Okay. Do you list the Bayer product in any 4 of your background information here? 5 A. I don't. It's part of that first bullet, the 6 development of new strategies for anticancer 7 radiotherapeutics. I did not discover that product. 8 Q. So who did discover the product? 9 A. I don't know. Bayer or some -- I provided 10 data to support the development of one of their 11 radiotherapeutics. 12 Q. So Bayer came to you with the product in hand 13 already? 14 A. That's right. 15 Q. And they were testing it clinically? 16 A. They were. 17 Q. And they had you perform research on it as 18 well? 19 A. That's right. 20 Q. And what was the research that you performed 21 on the Bayer product? 22 MS. CIPRIANO: And I'll just caution you. If 23 any of this is confidential, I'll caution you not to 24 disclose things you're bound by confidentiality 25 otherwise. But answer as you can.	59 1 Q. Any other kind of dosages of pharmaceuticals 2 to patients, correct? 3 A. That's correct. 4 Q. Because your background isn't a clinical 5 background, correct? 6 A. That's correct. 7 Q. So what are nanoparticles? 8 A. I guess I would define "nanoparticles" in 9 general as assemblies of atoms into structures that are 10 within .1 to 10 nanometers in diameter. 11 Q. Okay. Let me take you back to your 12 curriculum vitae, your CV, on page 11. I wanted to ask 13 you about these publications that you have here relating 14 to cancer. 15 So for 69, it says "Nanoparticles for 16 targeted cancer radiotherapy." Can you explain to me 17 what that is? 18 A. It is about the use of nanoparticles as a 19 vehicle to carry radionuclides for targeted 20 radiotherapy. 21 Q. And how does it carry the radionuclides? 22 A. Well, it -- those are large molecular 23 structures that can incorporate a radionuclide in 24 various ways through covalent -- or electrostatic 25 interactions.
58 1 A. That research was around the characterization 2 and stability of this product under different 3 conditions. 4 Q. So you weren't involved in any of the 5 clinical aspects of the Bayer product, then. 6 A. I was not. 7 Q. And so your contribution to the Bayer product 8 was strictly in terms of the molecular structure and 9 stability of the product. Is that right? 10 A. It was really around the characterization of 11 the molecular compound. Yes. 12 Q. And you weren't involved in the clinical 13 aspects of the testing of the product. 14 A. That's right. 15 Q. Because you have no clinical experience. Is 16 that right? 17 A. Well, I do have clinical experience related 18 to that other clinical trial. But the reason is 19 it's not what they needed me for. 20 Q. Okay. But you haven't, for example, 21 administered radiopharmaceuticals to patients, correct? 22 A. I have not. That's correct. 23 Q. And you haven't provided any other kind of 24 dosages to patients, correct? 25 A. I have not provided what? I'm sorry.	60 1 Q. How are those different from chelators? 2 A. They're larger, for one. There may be 3 different interactions. So the coordination of the 4 radionuclide is different from that you would see in a 5 chelator metal complex. There are many varieties, so 6 I -- they are different. 7 Q. Okay. 8 A. But they are much larger. 9 Q. Okay. But these aren't -- they're not 10 antibodies, correct? 11 A. That's correct. 12 Q. And they're not ligands, correct? 13 A. They are not peptides. That's correct. 14 Q. And so they'd be different from using small 15 molecules. 16 A. They're not targeting agents. 17 Q. Okay. Let's put that back. 18 Going back to your declaration. On page 5, 19 paragraph 18, you give your opinion of what a POSA -- a 20 person of ordinary skill in the art, what their 21 qualifications should be. Do you see that? 22 A. I do. 23 Q. And so for Number 1, you say "The concept of 24 radioimmunoconjugation." Do you see that? 25 A. I do.

61 1 Q. But we've already discussed this patent does 2 not relate to immunoconjugation, does it? 3 MS. CIPRIANO: Objection; misstates prior 4 testimony. 5 A. We discussed that this patent doesn't relate 6 to radioimmunoconjugates. The conjugation part, in my 7 mind, in the radioimmunoconjugation is about linking a 8 metal chelator complex to a targeting vector. 9 Q. But you specifically have 10 radioimmunoconjugation, and "immuno" refers to antibody 11 or antibody portions, right? 12 A. Right. 13 Q. And this patent is focused towards targeting 14 with ligands, small molecules, correct? 15 A. That's correct. 16 Q. So a person of ordinary skill, in order to 17 understand this patent, wouldn't need information about 18 radioimmunoconjugation per se. 19 A. Well, that information is within 20 radiobioconjugation as a more generic term, if you will. 21 So I still believe that a POSA would need to know about 22 conjugation. 23 Q. Okay. So if they know about radioconjugation 24 but they don't know about radioimmunoconjugation, that 25 would still be sufficient for a person of skill.	63 1 radiometals," what are you thinking of in terms of the 2 environment here? 3 A. I'm thinking about serum, a living organism, 4 any environment that is -- that the metal encounters 5 from production to therapy. 6 Q. Okay. And for Part ii of your requirement, 7 you say "The chemical behavior of radiometals from the 8 d- and f-blocks of the periodic table such as 111"-- 9 what is this? I-n? 10 A. Indium. 11 Q. What is it? 12 A. Indium. 13 Q. Indium. Okay. 14 "And 117 lutetium and 225 actinium." 15 So you still believe that a person of skill 16 needs to know about all of the elements in the f-block 17 and the d-block? 18 MS. CIPRIANO: Objection; misstates -- 19 A. It doesn't say "all of the elements." It 20 says "chemical behavior of radiometals." 21 Q. Okay. 22 A. So maybe you could be more specific and say 23 "relevant to radiotherapy," but... 24 Q. Okay. Relevant to radiotherapy. 25 And you don't say anything here about
62 1 A. Sure. 2 Q. And so for Number iii, you describe the 3 "Design, synthesis, and use of chelators that form 4 kinetically and thermodynamically stable complexes with 5 the radiometals." Do you see that? That's on page 6. 6 A. Yes. 7 Q. Okay. So, again, this patent doesn't relate 8 to the synthesis of chelators and complexes, right? 9 A. That's right. 10 Q. And I think before we were discussing 11 thermodynamically stable -- 12 A. Well, let me walk that back. 13 Q. Okay. 14 A. It relates to the formation of those 15 complexes, so... 16 Q. Well, let me put it this way, then. It 17 doesn't claim a method of synthesis, correct? 18 A. That's correct. 19 Q. Okay. And previously when we were talking 20 about thermodynamically stable, I got the impression you 21 were saying that this was dependent upon the 22 environment, correct? 23 A. That's correct. 24 Q. So when you say "Use of chelators that form 25 kinetically and thermodynamically stable complexes with	64 1 experience with small molecule ligands. Would that fall 2 under our new definition of "radioconjugation" instead 3 of "radioimmunoconjugation"? 4 A. I think it would. 5 Q. Okay. Good. 6 Now, you say "The clinical use of 7 radiotherapeutic agents." What did you mean by that? 8 A. I mean the steps that are needed to develop 9 such agent into something that could be used in the 10 clinic. 11 Q. Okay. That's a little different from what 12 you have here. So it says "The clinical use of 13 radiotherapeutic agents," not "the development of 14 radiotherapeutic agents." 15 So by "clinical use," wouldn't you mean 16 administering them to patients? 17 MS. CIPRIANO: Objection; argumentative. 18 A. That is part of it. 19 Q. Okay. But you haven't administered 20 radiotherapeutic agents to patients, right? 21 A. I have not. 22 Q. Okay. And you've never treated a patient, 23 correct? 24 MS. CIPRIANO: Objection; asked and answered. 25 A. That's correct.

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65 1 Q. And you've never given a patient any kind of 2 dose of drug, correct? 3 MS. CIPRIANO: Objection; asked and answered. 4 A. That's correct. 5 Q. And you never diagnosed a patient for, say, 6 cancer, correct? 7 A. That's correct. 8 Q. All right. So let's look at page 7. 9 Actually, wait. Let's go to page 8 first. 10 Sorry. 11 So you have some nice figures here. So at 12 the top of page 8, you have an example of beta-minus 13 decay. Do you see that? 14 A. I do. 15 Q. So can you explain to me what beta decay is? 16 A. Okay. So if we're looking at beta emitting 17 radionuclides, this is a nuclear reaction in which the 18 emitting radionuclide will release an electron or 19 beta-minus particle and become a different nucleus. 20 I mean, how detailed do you want me to go in 21 there? 22 Q. I'm sure you could get -- 23 A. Yeah. It's the emission of the -- 24 Q. -- very detailed, couldn't you? 25 A. -- electron, or a beta particle in this case,	67 1 that mean by the "recoil"? 2 MS. CIPRIANO: Objection to the extent it 3 mischaracterizes the figure. 4 A. It means that there's an energy associated 5 with that nuclear reaction and that the alpha particle 6 carries some -- there's conservation of energy and 7 conservation of momentum. And your alpha particle 8 carries some energy and has a momentum. The emitting 9 nucleus that becomes something else also has -- carries 10 some energy and has an opposite momentum. 11 Q. Okay. So it moves. 12 A. It moves. 13 Q. Okay. That doesn't happen with the beta 14 emitter, right? 15 A. Not to the same extent. 16 Q. Okay. So when you say "not to the same 17 extent," do you mean that for every action there's an 18 opposite yet equal reaction but it's pretty tiny? 19 A. Right. 20 Q. Okay. And so how much energy does the recoil 21 produce generally for an alpha particle? 22 A. I don't know if I have a number in mind. But 23 we're looking at MeVs. It would depend on the 24 radionuclide. 25 Q. Okay. Let me...
66 1 in the process of a nuclear reaction. 2 Q. Okay. And then on page 7, in the middle of 3 page 7, you give an example of an alpha particle, 4 correct? 5 A. That's right. 6 Q. Can you explain to me what an alpha particle 7 is? 8 A. An alpha particle is a nucleus that's 9 composed of two neutrons and two protons -- so a 10 helium -- a nucleus that is, again, in this case 11 released in a nuclear reaction from an unstable parent 12 nucleus that will release those two protons and 13 neutrons. 14 Q. Okay. And so the alpha particle is 15 significantly larger than the beta particle, correct? 16 A. That's correct. 17 Q. Okay. What's the number? Like, 8,000 times 18 bigger? Is that about right? 19 A. Probably ballpark, yes. 20 Q. You say -- underneath the example of the 21 alpha particle, it says "The daughter nucleus has two 22 fewer protons and four fewer nucleons. It has a small 23 recoil." Do you see that? 24 A. I do. 25 Q. Okay. What do you mean by the -- what does	68 1 MR. BOETTICHER: Something for you to mark, 2 finally. 3 THE REPORTER: What number? 4 MR. BOETTICHER: It's 2007, right? 5 (Discussion off the record.) 6 MS. SCHNEIDER: 2007. 7 (Exhibit Number 2007 marked.) 8 MS. CIPRIANO: For the record, I'll just 9 lodge a provisional hearsay and authentication -- 10 authenticity objections for the record. 11 Q. All right. So I'm giving you a document 12 entitled "A Critical Review of Alpha Radionuclide 13 Therapy - How to Deal with Recoiling Daughters?" by -- 14 the first author is Robin M. de Kruijff. Do you see 15 that? 16 A. I do. 17 Q. Are you familiar with this document? 18 A. No. 19 Q. I'd like you to turn to the third page, which 20 is page 323 in the original document. So on page 323, 21 at the last paragraph, it begins "There is potentially a 22 future for radionuclides" -- or sorry -- 23 "radionuclides." Do you see that? 24 A. Yes. 25 Q. Could you take a look at that paragraph for

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69 1 me, and let me know when you're done. 2 A. Okay. 3 Q. Okay. So the author here says, in the third 4 sentence, referring to the emission of alpha particles. 5 "This energy is in most cases at least 100 keV, more 6 than a thousand times larger than the binding energy of 7 any chemical compound." Do you see that? 8 A. I do. 9 Q. Do you disagree with that? 10 MS. CIPRIANO: Objection; foundation. 11 A. I don't disagree with that. 12 Q. And then it goes on to say "This simply means 13 that bond rupture will always occur subsequent to alpha 14 decay, implying that the released daughters, which are 15 often themselves alpha emitters, might cause 16 considerable harm, as seen in some of the clinical 17 trials with, e.g., for example, AS patients." Do you 18 see that? 19 A. I see that. 20 Q. Do you disagree with that? 21 A. I don't disagree with this. It might cause 22 considerable harm. Those are not -- a strong statement 23 in my mind, so I don't disagree. 24 Q. Okay. So you agree that the amount of energy 25 that is in the recoil of an alpha particle would be	71 1 Q. Okay. And so wasn't this an enormous issue 2 for the use of actinium-225 that it would be released 3 once it fired its first alpha particle? 4 MS. CIPRIANO: Objection; assumes facts not 5 in evidence. 6 A. It is an issue that has been discussed in 7 many settings. Yes. 8 Q. So if it's been discussed in many settings, 9 doesn't that mean that a lot of people were worried 10 about it? 11 A. Yes. 12 Q. I'd like to give you Exhibit 1015 to your 13 declaration. 14 (Exhibit Number 1015 introduced.) 15 Q. Do you recognize this document? 16 A. Yes. 17 Q. What is this document? 18 A. It's a journal publication about the use of 19 actinium-225 for somatostatin receptor therapy. 20 Q. I'd like you to look on page 2 of the 21 document, in the left-hand column, beginning eight lines 22 down. Do you see a sentence beginning with "However"? 23 A. Yes. 24 Q. It says "However, after disintegration, the 25 retention of daughter isotopes within the chelate is
70 1 enough to break it out of a chelator that is holding it, 2 correct? 3 A. That's correct. 4 Q. Okay. And at that point, it becomes a 5 daughter element. Is that right? 6 A. That's right. 7 Q. Okay. So what's the daughter element to 8 actinium-225? 9 A. There are many. 10 Q. What's the immediate -- 11 A. What's the -- 12 Q. -- daughter element? 13 A. What is the direct one? I don't know. Do 14 you have a decay chain? 15 Q. Not handy at the moment. So we'll get back 16 to that later on, I think. 17 So we agree that the amount of energy from a 18 recoil would be enough to break the actinium or its 19 daughter element out of the chelator that's holding it, 20 right? 21 A. Right. 22 Q. And you agree with the statement from this 23 document that the alpha emitters, the daughter elements 24 might cause considerable harm, correct? 25 A. Yes, I agree.	72 1 highly unlikely, either due to the physical recoil 2 energy or the different chemical properties of the first 3 daughter nuclide 221 Fr." Do you see that? 4 A. Yes. 5 Q. Now, this document is one of the ones you 6 relied on for your declaration, correct? 7 A. Yes. 8 Q. And this author, Miederer, he is showing 9 concern about the release of the actinium from the 10 chelator, isn't he? 11 A. No. He's showing concern -- 12 MS. CIPRIANO: Hold on. Hold on. 13 THE WITNESS: I'm sorry. 14 MS. CIPRIANO: It's okay. 15 Objection; calls for speculation. Thank you. 16 A. He's showing concern about the release of 17 daughters, not the release of actinium. 18 Q. Good point. Thank you. 19 So he's showing concern about the release of 20 the daughter elements after actinium releases its 21 initial alpha particle, correct? 22 A. That's right. 23 Q. So he goes on to say "Despite their 24 relatively short half-lives, the alpha-emitting daughter 25 nuclides, 221 Fr, and its subsequent daughters 217 As

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73 1 and 213 Bi, are capable of relocating within the 2 organism and accumulation of 213 Bi originate from the 3 bloodstream into the kidneys with subsequent radiation 4 damage has been shown in non-human primates." Do you 5 see that? 6 A. I see that. 7 Q. Do you disagree with that? 8 MS. CIPRIANO: Objection; calls for 9 speculation. 10 A. I don't disagree with this statement per se. 11 Q. Okay. Can I ask you, what is a nanosafe? 12 A. I'm sorry. A what? 13 Q. Nanosafe. 14 A. I don't know. What is a nanosafe? 15 Q. Okay. So I'm going to give you a document 16 we're going to mark as 2008. 17 (Exhibit Number 2008 marked.) 18 MS. CIPRIANO: And I'll lodge, for the 19 record, objections to the document based on hearsay and 20 authenticity. 21 Q. Do you recognize this document? 22 A. I do. 23 Q. What is this document? 24 A. It is a perspective written by myself and a 25 former postdoctoral researcher in my group.	75 1 Q. And then you go on to say "The design of 2 in vivo stable carriers able to scavenge both actinium 3 and its alpha cascade raises hope for highly efficient 4 cancer therapies with no side effects." Do you see 5 that? 6 A. I do. 7 Q. So do I understand this correctly that your 8 solution for the problem was to introduce additional 9 scavengers? 10 MS. CIPRIANO: Objection to the extent it 11 mischaracterizes the document. 12 A. Not additional, no. Why additional? 13 Q. Well, it says "The design of in vivo stable 14 carriers able to scavenge --" 15 A. Right. 16 Q. -- both actinium and its alpha cascade." 17 What do you mean by scavenge? 18 A. I mean chelating. I mean binding. Yes. 19 Q. But what do you mean by "scavenge" as opposed 20 to merely binding? 21 A. Not really anything else. If -- binding. 22 This paragraph refers to the prose used by other 23 researcher of -- other researchers of lanthanide 24 nanoparticles carrying actinium. 25 Q. I'm sorry. Say that again.
74 1 Q. Okay. Called "Active actinium," correct? 2 A. That's correct. 3 Q. And what is the publication date on this? 4 A. 2016. 5 Q. Okay. What month? 6 A. November. 7 Q. November 2016. 8 And to the best of your knowledge, this is a 9 true and correct copy of the article that you wrote? 10 A. Yes. 11 Q. I'd like to turn your attention to the third 12 column all the way on the right. 13 So it says here in the second full paragraph, 14 beginning "A rising challenge." Do you see that? 15 A. Yes. 16 Q. Okay. You say "A rising challenge for 17 chemists resides in the handling of 225 actinium 18 intermediates and potentially harmful recoiling 19 daughters, 221 Fr, 217 AT, and 213 PO." Do you see 20 that? 21 A. I do. 22 Q. So here you are acknowledging that there are 23 issues with the release of the daughter elements of 24 actinium-225, correct? 25 A. Correct.	76 1 A. This particular paragraph refers to the 2 proposal of using nanoparticles as carriers for actinium 3 for the delivery of actinium in radiotherapeutics. And 4 the scavenging part would be attributed to the 5 prevention of the relocation of the daughters, so 6 scavenging them as they're being released from the 7 actinium. 8 Q. Okay. And then further down here -- I think 9 this is what you were just talking about -- you say 10 "Whereby tumor delivery of 225 actinium through a 11 lanthanide-based nanosafe --" 12 A. Right. 13 Q. -- could neutralize metastasis without 14 leaving radioactive traces in the patient." 15 Again, what is a nanosafe? 16 A. Right. In this particular case, this is a 17 term that was used by the researchers, who proposed to 18 use just lanthanide nanoparticles -- 19 Q. Right. 20 A. -- as a carrier for actinium. Yeah. 21 Q. So they were recommending this as an 22 alternative to using chelators. 23 A. They were. Yes. 24 Q. Okay. In your last paragraph, you say "The 25 quest for an efficient and silent but traceable cancer

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77 1 treatment could turn into reality thanks to an element 2 that has been largely overlooked since its discovery." 3 Do you see that? 4 A. I do. 5 Q. And so by "largely overlooked," you're 6 indicating that actinium -- not a lot of attention had 7 been paid to it at that point. Isn't that right? 8 A. A lot of attention. Compared to other 9 elements, yes. 10 Q. Okay. So you were fully aware when you wrote 11 your declaration that the recoil was an issue for 12 chelated actinium, correct? 13 A. A potential issue. That's correct. 14 Q. But you don't mention it in your declaration. 15 A. I don't think it's relevant. 16 Q. Even though it was a potential issue it being 17 released from the chelators? 18 A. In the daughters being released -- 19 Q. Yes. The daughters being released -- 20 A. -- from actinium? 21 Q. -- from the chelators. Yes. 22 A. I mean, not for the argument that are laid 23 out in my declaration, no. 24 Q. What do you mean "not for the argument laid 25 out in your declaration"?	79 1 made me read a figure that mentions the recoil effect. 2 So it is mentioned in the declaration. 3 Q. But you don't explain in your declaration 4 that the recoil effect could cause the daughters of the 5 actinium-225 to be released. 6 A. Right. That's right. 7 Q. And isn't that an important factor in 8 determining the viability of a targeting molecule with 9 the chelated actinium-225? 10 A. No, not if we are comparing chelated actinium 11 bound to a peptide or an antibody, because we are 12 comparing the same thing. So I -- no. I mean, I -- not 13 in my opinion. 14 Q. So you say it's not important when you're 15 comparing the actinium-bound antibody to an 16 actinium-bound small molecule, correct? 17 A. No. That's not what I said. 18 MS. CIPRIANO: Objection. 19 Q. Okay. 20 A. Well, you asked me if -- the fact is I did 21 not include it here, and I -- it is mentioned, the 22 recoil effect. This is a very long discussion. I don't 23 think it is needed in this particular discussion. I 24 would agree with you that a POSA would know about this. 25 Q. And a POSA would be concerned about it as
78 1 A. I mean that this was a recognized issue prior 2 to this patent, prior to this publication, or my 3 declaration and that this is not something that I needed 4 to mention here. You know, there are a lot of 5 literature that could be mentioned, so I -- no. I did 6 not mention it. 7 Q. So you didn't feel that it was necessary to 8 mention the fact that the daughters of the actinium 9 would be released and possibly cause damage to other 10 organs. 11 MS. CIPRIANO: Objection; relevance and 12 scope. 13 A. No. 14 Q. And you felt that that wasn't necessary 15 because of the argument that you were putting forth in 16 your declaration. 17 MS. CIPRIANO: Objection; misstates the 18 testimony. 19 A. It was not necessary in my line of thought. 20 No. 21 Q. So wouldn't a person of ordinary skill in the 22 art want to know that there was this possible recoiling 23 effect that could cause this detrimental effect? 24 A. Okay. Sure. But actually -- I should 25 restate it. It is mentioned in the declaration. You	80 1 well, correct? 2 A. I don't know that I would use the word 3 "concerned." Not everybody is concerned about a recoil 4 effect. 5 Q. Miederer seemed concerned about it. 6 A. Not everybody is concerned about the recoil 7 effect. 8 And as we are, chelated actinium is being 9 developed for the clinic, and there is recoil effect. 10 So not everybody is concerned about it. 11 Q. You were concerned about it in 2016, weren't 12 you? 13 A. I was -- I was referencing some concern from 14 some members of the community. 15 Q. So would a POSA be concerned about it? Yes 16 or no. 17 MS. CIPRIANO: Objection; asked and answered. 18 A. I don't know. 19 Q. Aren't you a POSA? 20 A. I am a POSA. You asked would a POSA, any 21 POSA. I think it's a consideration to have in mind, 22 potentially, if you were looking to develop new 23 chelators. 24 Q. I'm going to give you a document. This will 25 be 2009.

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81 1 (Exhibit Number 2009 marked.) 2 Q. So this is a publication entitled 3 "Development of radiopharmaceuticals for targeted alpha 4 therapy: Where do we stand?" Do you see that? 5 And this was published in Frontiers in 6 Medicine, correct? 7 A. That's correct. 8 Q. And you're one of the authors on this. 9 A. That's correct. 10 Q. And is it fair to say that this is a true and 11 correct representation of that article? 12 A. Yes. 13 Q. Okay. 14 MS. CIPRIANO: For the record, I'll lodge the 15 hearsay and authenticity objections related to 16 Exhibit 2009. 17 Q. All right. So this article was published in 18 2022, correct? 19 A. Correct. 20 Q. All right. I would like to turn your 21 attention to the second page. On the right-hand side, 22 the first full paragraph there says -- begins "Regarding 23 targeted alpha therapy." Do you see that? 24 A. I do. 25 Q. So this paragraph you're talking about using	83 1 A. That's correct. 2 Q. And you go on to say that "Free radio 3 isotopes and metals, particularly f-block elements, have 4 high-binding affinities for biological receptors 5 resulting in their endogenous chelation and subsequent 6 deposition in tissues," right? 7 A. That's correct. 8 Q. And you say "Internal contamination with 9 radiometals and the decay products cause metal and radio 10 toxicity as multiple biological processes get 11 disrupted," correct? 12 A. That's right. 13 Q. So you're describing the damage that these 14 free radio isotopes could perform on the tissue if 15 they're released, correct? 16 A. Correct. 17 Q. And then you conclude "Therefore, minimizing 18 daughter release is a fundamental step to extend the use 19 of targeted alpha therapy beyond metastatic 20 non-responding patients," correct? 21 A. Correct. 22 Q. So in 2022, you're still concerned about the 23 recoiling effect and the damage that the daughter 24 elements could cause, correct? 25 MS. CIPRIANO: Objection; misstates the
82 1 alpha therapy for radiotherapeutics, correct? 2 A. That's right. 3 Q. Okay. And then ten lines down -- actually, 4 let's begin at nine. Nine lines down, there's a 5 sentence beginning with "Although." Do you see that? 6 A. I do. 7 Q. And you say "Although pre-clinical and 8 clinical studies have highlighted the therapeutic 9 benefits of these conjugates, there are still challenges 10 that need to be solved, such as kinetics and stability 11 of the complexes and retention of the daughters." Do 12 you see that? 13 A. I do. 14 Q. So in 2022, there's still concern about it, 15 correct? 16 A. I don't characterize this as a concern rather 17 than improvement. So yes. That's correct. 18 Q. All right. Well, let's split the baby here. 19 You say it's a challenge -- 20 A. Okay. 21 Q. -- correct? 22 A. That's right. 23 Q. All right. And you point out that "In an 24 alpha decay, the recoiling daughter breaks the chemical 25 bounds by which it is bound to the ligand," Correct?	84 1 document and her testimony. 2 Q. Correct? 3 A. Correct. 4 Q. So just to be sure we're clear. This was 5 published in Frontiers in Medicine, correct? 6 A. That's right. 7 Q. And you're an author on this document. 8 A. That's right. 9 Q. And it was published in December of 2022? 10 A. That's right. 11 Q. And you intended for this document to be 12 published when you wrote it, correct? 13 A. That's correct. 14 MS. CIPRIANO: So, Counsel, we've been going 15 for about two hours. 16 MR. BOETTICHER: Do you want to take a break? 17 MS. CIPRIANO: Do you want to take a break 18 or -- 19 THE WITNESS: No. 20 MS. CIPRIANO: Keep going? Okay. 21 MR. BOETTICHER: You're still good? Okay. 22 THE REPORTER: A break would be good for me. 23 MR. HASAN: Oh, yeah. 24 MR. BOETTICHER: Let me just check to make 25 sure I'm done with this portion of the document.

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85 1 Q. Let me also put in the record. So going to 2 page 11 of "Development of Radiopharmaceuticals for 3 Targeted Alpha Therapy: Where Do We Stand?" On the 4 third paragraph down, beginning with the -- saying 5 "Four," do you see that? 6 A. Uh-huh. I do. 7 Q. It says -- you're listing a number of issues, 8 and you say "Four, the alpha emitters, particularly 9 those with multiple alpha decays in their decay chain, 10 are limited by the recoil effect, which causes the 11 release of part of the daughters from the 12 radiopharmaceutical," correct? 13 A. That's correct. 14 Q. And then the sentence after the next 15 sentence, beginning "Second," you say, "Second, the 16 controlled circulation and deposition of the daughters 17 may damage healthy tissue and induce radiological 18 poisoning. Because this issue is unlikely to be solved 19 by new chelators, a novel method to minimize the release 20 of the daughters is encapsulating the radionuclides and 21 nanoconstructs." Do you see that? 22 A. I do. 23 Q. So, again, you're still concerned about 24 toxicity from the free daughter elements, correct? 25 A. Correct.	87 1 A. Yes. 2 Q. Okay. So this paragraph begins with "The 3 POSA would have understand that 225-Ac would be a 4 promising substitute." 5 I think you're talking about substituting 6 213 Bi. Is that correct? 7 A. That's correct. 8 Q. Bi is bismuth? 9 A. That's right. 10 Q. Okay. So you're talking about replacing 11 213 bismuth, correct? 12 A. Correct. 13 Q. And you say that -- two sentences later, you 14 say, "For example" -- let me start over again. Strike 15 that. 16 So four lines down, in the middle of the 17 paragraph, you begin with "For example, 225-Ac and its 18 resultant decay chain produces more alpha emissions than 19 213 Bi and has a substantially longer half-life of about 20 ten days." Do you see that? 21 A. I do. 22 Q. Then you follow it with -- well, let me stop 23 there. 24 So you expressed that having more alpha 25 emissions is an advantage, but, in fact, as we've just
86 1 Q. Okay. And actinium-225, that is an alpha 2 emitter with multiple alpha decays in the decay chain, 3 correct? 4 A. That's correct. 5 MR. BOETTICHER: Okay. I think we can take a 6 break if you want. 7 Going off the record. 8 (Off the record: 11:29 a.m. to 11:44 a.m.) 9 MR. HASAN: Ms. Cipriano and I spoke. And, 10 you know, she's been making objections certainly to 11 preserve her right to do it. But we've agreed to work 12 it out, which we will do as well, unless there's things 13 like missing pages and the like or something that's -- 14 we're not going to try to belabor the subject, but we 15 agree to do the same thing with your documents. 16 Ms. Cipriano, is that okay? 17 MS. CIPRIANO: Yes. Thank you. 18 MR. HASAN: Okay. Thank you so much. 19 MS. CIPRIANO: And definitely the parties 20 will work in good faith to resolve any objections to the 21 extent it's possible. 22 MR. HASAN: Thank you. 23 Q. Okay. I'd like you to go to paragraph 83 of 24 your declaration, beginning on page 38. 25 Are you there?	88 1 been discussing the recoil, once the first alpha 2 emission occurred, the daughter element of actinium 3 would be released, correct? 4 A. Correct. 5 Q. So having additional alpha emissions would 6 actually cause more alpha emissions in other parts of 7 the body and other organs other than the tumor, correct? 8 A. That depends on the half-life of the daughter 9 nuclides and on their biological half-lives and the 10 circulation times. So it's not necessarily correct that 11 it's in other parts of the body. 12 Q. Well, we know about -- we know what the 13 half-lives are of the daughters, don't we? 14 A. We do. 15 Q. Do you know what those are offhand? 16 A. Well, they're listed here. But the 17 daughters, on the path from actinium-225 to bismuth-213 18 all have less than a few minutes half-lives, so they 19 don't necessarily have the time to relocate. Bismuth is 20 the one that has the longest half-life and may have time 21 to relocate. 22 Q. But the point still remains that it would be 23 released from the chelator once -- 24 A. That's right. 25 Q. -- it fired its first alpha emission.

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89 1 A. That's right. 2 Q. And that could occur not necessarily when 3 it's attached to the target tumor, correct? 4 A. It could. There's a proportionality to keep 5 in mind. Especially with the small peptide targeting 6 molecules, it will be highly probable that you've 7 reached a target before those daughters are released. 8 Q. Okay. I want you to look at what is 9 Exhibit 1013 to your declaration. 10 (Exhibit Number 1013 introduced.) 11 Q. Do you recognize this document? 12 A. I do. 13 Q. What is this document? 14 A. It is a journal publication that I referenced 15 in the declaration. 16 Q. And this is entitled "Tumor Therapy with 17 Targeted Atomic Nanogenerators," correct? 18 A. That's correct. 19 Q. And the first author is Michael R. McDevitt, 20 correct? 21 A. That's correct. 22 Q. I want to draw your attention to Figure 1. 23 Could you tell me what they're doing in Figure 1A? 24 A. They're looking at the relocation of 25 daughters of actinium-225 after contamination of cells	91 1 in a body. Isn't that right? 2 A. Well, I -- I don't know if that's right. I 3 think it depends on the conditions of this particular 4 experiment. 5 Q. Well, when you take the actinium -- let's 6 see. What were they using here? Hold on. 7 So they were using 225 actinium J591, 8 correct? 9 A. That's correct. 10 Q. And so they put that into a cell culture with 11 these cells, correct? 12 A. That's correct. 13 Q. And the moment it hits the fluid, it's going 14 to have access to the cells limited only by the 15 diffusion rate. 16 A. Well, I don't know if this particular 17 antibody gets internalized in the cells, so I'm not sure 18 that it's going to be just diffusion. 19 Q. So you don't know if J591 gets internalized? 20 A. No, I don't. 21 Q. Look at the middle column above Figure 1. 22 And if you look five lines down, it says "The antibodies 23 HuM195, J591, and B4 internalize into HL60, LNCaP, and 24 Daudi cells respectively after binding." Do you see 25 that?
90 1 with actinium-225. 2 Q. So in this experiment, they were taking the 3 actinium-225, putting it in a cell culture, and they 4 were looking to see how many of the daughters were 5 internalized and how many of them were outside the 6 cells, correct? 7 A. That's right. 8 Q. And if we look at the data, it shows that up 9 here in the 800 -- excuse me. 10 If we look at the data, it shows here up in 11 the 800 cpm range we see the 221 Fr and the 213 bismuth 12 that are outside the cell, correct? 13 A. That's correct. 14 Q. And down here in the 400 range, we see the 15 221 Fr and the 213 bismuth that are inside the cell, 16 correct? 17 A. That's correct. 18 Q. So it looks like about two-thirds of the 19 activity is actually outside the cell. Isn't that 20 right? 21 A. In this particular experiment, that's right. 22 Q. And this was done in cell culture, wasn't it? 23 A. It was done in cell culture. 24 Q. And in cell culture, the actinium would have 25 greater access to the cells than they would have, say,	92 1 A. I do. 2 Q. So we understand that the J591s do 3 internalize, correct? 4 A. That's correct. 5 Q. But in this experiment, after adding the J591 6 with the 225 actinium, they found that two-thirds of the 7 radiation was still outside the cells. 8 A. They found that two-thirds of the francium 9 and the bismuth were outside the cell. 10 Q. Right. So two-thirds of the radiation that 11 they measured was outside the cells, correct? 12 A. Two-thirds of the counts coming from those 13 two radionuclides were outside the cell. 14 Q. Okay. I'd like you to look at Figure 1B as 15 well. So do you know what's going on in this particular 16 figure? 17 A. I have to read the legend. 18 Yes, I think I do. 19 Q. Okay. So in this example, they're now 20 injecting the J591 225 actinium into mice, correct? 21 A. That's correct. 22 Q. And they're measuring the daughter elements, 23 the bismuth and the francium, in the blood, tumor, and 24 kidney, correct? 25 A. Correct.

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93 1 Q. And they're comparing what is inside the 2 tumor to what is in the blood and kidney, correct? 3 A. That's correct. 4 Q. Okay. I'd like to draw your attention to, 5 again, the middle column, the first full paragraph that 6 begins with "The in vivo biodistribution." Do you see 7 that? 8 A. I do. 9 Q. And here they're discussing their results 10 with Figure 1B, and they say "The in vivo 11 biodistribution of the generator constructs and the 12 radionuclide daughters was determined in mice bearing an 13 LNCaP carcinoma." Do you see that? 14 A. I do. 15 Q. And they conclude that approximately 18 and 16 21 percent of the injected dose of Ac J9- -- strike 17 that. 18 Approximately 18 and 21 percent of the 19 injected dose of 225 actinium J591 was localized in the 20 tumor per gram at two and three days. Do you see that? 21 A. I do. 22 Q. So they're saying that between 18 and 23 21 percent of the injected dose of actinium was in the 24 tumor, right? 25 A. That's right.	95 1 slower, the small molecule or the antibody? 2 A. The antibody is slower. 3 Q. Now, in paragraph 83 of your declaration, you 4 state, beginning at line 6, "Further studies that 5 directly compare 225 actinium to 213 bismuth in the same 6 antibody constructs have shown that 225 actinium is 7 substantially more potent than the 213 bismuth analog." 8 Do you see that? 9 A. I do. 10 Q. And you refer to 1013. 11 Could you show me the data in 1013 in which 12 they do a direct comparison of the bismuth and the 13 actinium? 14 A. So there is a reference from here that uses 15 the bismuth J591 that is used to discuss the actinium 16 data in here. 17 Q. But there's no direct comparison between the 18 two in this document, is there? 19 A. The experiments are referred to in this 20 document. They were not reported at the same time as 21 this document, so I guess it's not a direct side-to-side 22 comparison. It refers to the bismuth experiments. 23 Q. So you use this document, this Exhibit 1013, 24 to argue that actinium-225 is substantially more potent 25 than the 213 bismuth, correct?
94 1 Q. Which means that 80 percent of it is not in 2 the tumor, correct? 3 A. Of the actinium. That's right. 4 Q. So wouldn't a person of ordinary skill be 5 concerned that 80 percent of the dose does not end up in 6 the tumor? 7 A. Maybe they would be concerned. It's fairly 8 common for an antibody to not show 100 percent of the 9 dose getting in the tumor. 10 Q. But 80 percent is a fairly high percentage of 11 failure, isn't it? 12 MS. CIPRIANO: Objection; calls for 13 speculation. 14 A. I don't know. 15 Q. Well, isn't 80 percent a fairly high amount 16 of radiation to put in the body and not show up in the 17 tumor? 18 A. I don't know. It depends on how quickly it 19 gets cleared. 20 Q. Do antibodies get cleared fairly quickly? 21 A. In a few days, depending on the antibody. 22 Q. How does the clearance of antibodies compare 23 to small molecules? 24 A. It's slower. 25 Q. Just to be sure we're clear, which one is	96 1 A. That's correct. 2 Q. Okay. But this document shows that 3 80 percent of that actinium-225 potency does not 4 actually get into the cells, correct? 5 A. That's correct. 6 Q. And, again, don't you think a POSA would be 7 concerned about that much potency floating around in the 8 body? 9 A. Again, depending on how long it relocates and 10 is incorporated or whether it's cleared. Yes. 11 Q. So in terms of an antibody that takes several 12 days to get cleared -- and I believe that in this case 13 they checked the activity after two or three days -- do 14 you think that would be a matter of some concern? 15 A. Potentially, yes. 16 Q. So looking back at paragraph 25 of your 17 declaration. 18 Are you there? 19 A. Yes. 20 Q. So you say in paragraph 25 "In both 21 radionuclide imaging and radiopharmaceuticals, the 22 challenge lies in the ability to selectively target the 23 desired tissue/cells." 24 A. Yes. 25 Q. So isn't there more than just the targeting

97 1 of the cells? There are other issues that enter into 2 killing the tumor, right? 3 A. Well, not in imaging. 4 Q. Okay. But in terms of radiopharmaceuticals, 5 there's more than simply the targeting of the cells. 6 For example, there's the stability or its clearance of 7 the molecule, correct? 8 A. Correct. But that's incorporated in 9 selectively targeting if you -- 10 Q. Okay. 11 A. -- if you -- yeah. 12 Q. So when you talk about targeting the cells, 13 you're including the entire -- 14 A. Distribution. That's right. 15 Q. -- distribution process, including the 16 stability and the removal. 17 A. That's right. 18 Q. Do you include the internalization of the 19 radiopharmaceutical as well in the targeting? 20 A. Yes. 21 Q. So I have a question about your paragraph 26 22 on page 11. 23 So you show the DOTA chelating molecule, and 24 you show the DOTAGA chelating molecule. Do you see 25 that?	99 1 say "Selection of each of the radionuclide, chelator, 2 linker, and target moiety is key to ensure the 3 radiopharmaceutical is effective in the treatment of a 4 particular cancer a patient may have." Do you see that? 5 A. Yes. 6 Q. And do you still stand by that? 7 A. I do. 8 Q. And so what you're saying here is that the 9 radionuclide, the chelator, the linker, and the 10 targeting moiety are each important to the process of 11 making the radiopharmaceutical effective, correct? 12 A. That's correct. 13 Q. And so, for example, if the targeting moiety 14 was less effective, the overall molecule would be less 15 effective, correct? 16 A. That's correct. 17 Q. And so you could -- if you could switch out a 18 radionuclide, that might also affect the overall 19 effectiveness of the molecule, correct? 20 A. That's correct. 21 Q. And that effectiveness is viewed in terms of 22 that particular cancer, correct? 23 A. That's correct. 24 Q. And so, for example, if you had a 25 radionuclide, chelator, linker, and targeting moiety, it
98 1 A. Yeah. 2 Q. So I'm curious. Do these two molecules 3 chelate at a different affinity or rate? Or are they 4 basically the same? 5 A. They're not exactly the same. I would say 6 they're -- in terms of stability and rates, they're in 7 the same ballpark. 8 Q. Okay. But there's a slight difference in 9 them. 10 A. There is a difference. Yes. 11 Q. And that difference is consistent? 12 A. Consistent with? 13 Q. I mean, do you always find that difference, 14 that one is always more than the other? Or are they -- 15 A. Oh, I don't know that. I don't -- I think 16 some of the differences are with an error, so I'm not 17 sure. Probably consistent, yes. 18 Q. Okay. And so different chelators have 19 different affinities for different metals, correct? 20 A. That's correct. 21 Q. And those affinities are decided by the 22 overall structure of the chelator, correct? 23 A. That's right. 24 Q. So on the next page, 12, paragraph 27. 25 In that last sentence of paragraph 27, you	100 1 may work for one cancer but not work for another. 2 A. That's correct -- well, hold on. Say that 3 again. I'm sorry. 4 Q. So if you had a combination of radionuclide, 5 chelator, linker, and targeting moiety -- 6 A. That's right. That's correct. 7 Q. -- they might work for one cancer -- 8 A. Yes. 9 Q. -- but not for the other, right? 10 A. That's correct. 11 Q. So I'd like to turn back to Exhibit 1015, the 12 Miederer paper. 13 Do you have it? 14 A. I do. 15 Q. Okay. And, again, this was one of the 16 documents you relied on for your declaration, correct? 17 A. I did. 18 Q. So if we look in the abstract, we see under 19 "Experimental Design" the author says "Radiolabeling of 20 225 actinium" -- and I'm not going to read that entire 21 molecule, but he summarizes it as DOTATOC. 22 A. That's right. 23 Q. -- "was done at pH 5 without further 24 purification." 25 What is DOTATOC?

101 1 A. It is another small molecule, as we call 2 them, radiotherapeutic. So a peptide linked to a 3 chelator that is meant to chelate radiometals. 4 Q. And what is the targeting moiety on this 5 small molecule supposed to bind to? 6 A. It's this octreotide peptide. It's a 7 different peptide. 8 Q. So are you talking about the ligand? Or are 9 you talking about the target? 10 A. Sorry. You're asking about the ligand, 11 right? You're asking me about this? 12 Q. Well, let me ask you this. Let's go back. 13 What's the ligand on this molecule? 14 A. It's this tyrosine octreotide. 15 Q. And what is the molecule the ligand is 16 supposed to bind to? 17 A. The somatostatin receptor. 18 Q. Okay. What is that? 19 A. Something different from the PSMA. 20 Q. Okay. And what cancer did he test the 21 DOTATOC molecule with in this paper? 22 A. This neuroendocrine tumors. 23 Q. And do you know if the neuroendocrine tumor 24 has PSMA? 25 A. I don't believe so. I don't know. Maybe.	103 1 speculation. 2 A. I mean, it is a different molecule. I 3 don't -- when you say it's going to be very different, 4 it depends what we're comparing. 5 Q. Well, let's say the effectiveness of it as 6 a radiotherapeutic. 7 A. It may or may not be different, again, 8 depend- -- it's a different molecule. It's a different 9 process. But it depends what we're comparing. So in 10 terms of effectiveness, I, you know -- it may be the 11 same. I don't know that it's different. 12 Q. But it may be different. 13 A. It may be different. 14 Q. And you don't know just by looking at the 15 paper -- at this paper, correct? 16 A. By looking at just this one paper? No. 17 Q. And so you can't say for sure that because it 18 works -- because this molecule works for this cancer and 19 this ligand and this receptor, that you're going to have 20 the same effect or efficacy that you would have with a 21 different cancer, a different ligand, a different 22 receptor, even though you may have the same 23 radioligand -- 24 A. Right. 25 Q. -- I'm sorry -- even though you may have the
102 1 Q. So the success of this DOTATOC molecule, its 2 effect- -- strike that. 3 So the effectiveness of this DOTATOC molecule 4 is going to be based on a number of factors like its 5 ability to bind, its ability to be internalized, its 6 stability, and how well it holds a radionuclide as just 7 some examples, correct? 8 A. That's correct. 9 Q. And if you used a different molecule for this 10 particular tumor, then all those factors could be 11 different, correct? 12 A. A different molecule -- 13 Q. If you use a different small -- 14 A. -- as the whole combination? Or a 15 different... 16 Q. A different targeting moiety, for example. 17 A. That's right. 18 Q. Okay. So along the lines of what you were 19 talking about in paragraph 27 of your declaration, 20 because this molecule, DOTATOC -- it has a different 21 targeting moiety for a different cancer for a different 22 receptor, it's going to be very different from a PSMA 23 ligand attaching to PSMA on a different type of cancer, 24 isn't it? 25 MS. CIPRIANO: Objection; calls for	104 1 same radio nuclide. 2 A. So if I only look at this paper, no. But if 3 I look at this paper with additional data, I might be 4 able to predict the effectiveness. 5 Q. And when you say "predict the effectiveness," 6 what are you talking about? 7 A. I am talking about having an expectation as 8 to how this particular combination of radionuclide, 9 chelator, linker, targeting vector may perform in a 10 specific model. 11 Q. But this paper itself won't tell you how well 12 a PSMA ligand is going to bind to a PSMA receptor, 13 correct? 14 A. That's correct. 15 Q. And it won't tell you how well a 16 PSMA-ligand-based small molecule is going to work on a 17 different type of cancer than what's listed here, 18 correct? 19 A. That's correct. 20 Q. And the reason for that is that all of the 21 features, the radioligand, the -- I'm sorry -- let me 22 start over again. 23 And the reason for that is because all of the 24 features, the radionuclide, the chelator, the linker, 25 and the targeting moiety all work together to produce

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105 1 whatever effectiveness a radiopharmaceutical has. 2 A. That's correct. 3 Q. Do you know what a neuroendocrine tumor is? 4 A. Not in very specific terms, no. 5 Q. Now, Miederer, he uses a xenograft 6 implantation, doesn't he? 7 A. Yes -- transplantation. Okay. 8 Q. What is that? 9 A. This is where you culture cells in vitro and 10 implant them in an animal model, like a mouse, in order 11 to provoke the growth of a tumor that will express 12 specific receptors that the cells carry. 13 Q. So would it be fair to say that because these 14 are cells that are grown in a culture and then injected 15 they're homogeneous cells? 16 A. Okay. Yes. 17 Q. Now, to your knowledge, natural cancer cells, 18 are they homogeneous? 19 A. Not necessarily. 20 Q. So using this model, one mouse to another 21 mouse to another mouse to another mouse is all going to 22 have the same cancer, right? 23 A. Right. That would be the ideal model. Yes. 24 Q. But individual people, even if they have the 25 same type of cancer, are not going to have the same	107 1 than the tumor, doesn't it? 2 A. It's comparable. 3 Q. Okay. What does he show for the bone marrow? 4 MS. CIPRIANO: Objection; misrepresents the 5 document. 6 A. It's not represented in this figure. 7 Q. Now, earlier we discussed that free 8 radionuclides -- sorry. Strike that. 9 Earlier we discussed that free radionuclides 10 end up in the bone or skeleton, correct? 11 A. That's correct. 12 Q. But he doesn't show the amount of 13 radioactivity that's in the bone in this case, correct? 14 A. That's correct. 15 Q. And so from this, you would not be able to 16 conclude what level of radioactivity the bone marrow 17 would receive, correct? 18 A. That's correct. 19 Q. Now, Miederer, he determined what he thought 20 would be -- what he thought was the tolerability of this 21 drug, didn't he? 22 A. Will you point me to it? 23 Q. Let me point you to the abstract. The 24 "Results" section, he says "Activities up to 20 kBq had 25 no significant toxic effects in mice. In contrast,
106 1 responsiveness to radiotherapeutics or particular 2 therapeutics? 3 A. That's correct. 4 Q. And that's because the cells are not really 5 homogeneous from person to person, correct? 6 A. That's correct. 7 Q. And they're not necessarily even homogeneous 8 within an individual person, correct? 9 A. Correct. 10 MS. CIPRIANO: Slow down just a little bit. 11 THE WITNESS: Sorry. 12 MS. CIPRIANO: I'm going to save this court 13 reporter a little bit. 14 MR. BOETTICHER: No, I'm glad she's anxious 15 to agree with me. 16 Q. And in Miederer, look at Figure 1. Do you 17 see it? 18 A. I do. 19 Q. So he shows, for Figure 1, the 20 biodistribution of the 225-actinium-DOTATOC, correct? 21 A. That's correct. 22 Q. And the two highest organs of distribution 23 are in the tumor and the kidney, correct? 24 A. That's correct. 25 Q. And, in fact, the kidney actually gets more	108 1 activities higher than 30 kBq induced tubular necrosis." 2 Do you see that? 3 A. I do. 4 Q. So he's determining the level of 5 tolerability. Is that right? 6 MS. CIPRIANO: Objection to the extent it 7 mischaracterizes the document. 8 A. He has indicated specific activity at which 9 some effects were noted. I don't -- he's not 10 characterizing this as a tolerable dose. 11 Q. Let's take a look at page 3559. 12 So if we look at the right-hand column, nine 13 lines down, the line begins with "Indeed." Do you see 14 that? 15 A. I do. 16 Q. "Indeed," he says, "we found that injection 17 of activities higher than 30 kBq caused 18 radiation-induced acute tubular necrosis in the distal 19 and proximal tubules of the kidneys. As a consequence, 20 in these mice, an increase of renal retention variables 21 such as blood urea and nitrogen and creatinine was 22 found. In contrast, activities up to 20 kBq induced 23 only discrete, non-specific changes in the kidney but 24 significantly reduced tumor growth." 25 So does that sound like he's determining the

109 1 tolerability limit? 2 A. No. He's determining the dose at which there 3 are no significantly toxic effects. He is not looking 4 at the entire tolerability window. 5 Q. What do you mean by "the entire tolerability 6 window"? 7 A. I mean that it did not specify whether 8 this -- higher activities resulted in non-reversible 9 effects in potentially lethal doses. They observed 10 effects, but a level of no observed adverse effects is 11 not the same thing as a tolerable dose. 12 Q. So earlier we defined a tolerable dose as a 13 toxic effect that impacts the life of a patient. So by 14 "impacts" you meant "endangered"? Or do you mean just 15 effects? 16 A. No, I meant endangered, non-reversible 17 toxicity. Yes, not just effects. 18 Q. So your definition of a tolerable dose limit 19 would be the amount that kills the patient. 20 MS. CIPRIANO: Objection; misstates the 21 testimony. 22 A. It would be the dose at which an effect is so 23 toxic and non-reversible that it would accelerate -- it 24 would decrease the life span over time. Not kills right 25 there, but would result in an earlier death.	111 1 actinium remains within the molecule and is fully 2 delivered to the tumor? 3 A. Yes. It is describing the effect of the 4 alpha particles emitted from the radionuclide in the 5 same location as the compared diameter. 6 Q. I'm sorry. Say that again. 7 A. It compares the alpha particles emitted from 8 an alpha-emitting nuclide in the same location as a 9 beta-emitting nuclide. 10 Q. But if you're thinking in terms of just 11 comparing a beta-emitting nuclide and an alpha-emitting 12 nuclide in the same location, then if those two nuclides 13 are in some healthy organ, in fact, the alpha-emitting 14 nuclide would cause more damage, wouldn't it? 15 A. That's right. Yes. 16 Q. So in that case, this sentence would be wrong 17 because it doesn't reduce the likelihood of side 18 effects. 19 MS. CIPRIANO: Objection to the extent it 20 takes the document out of context. 21 A. If the targeting is not achieved. 22 Q. So going back to my original question. This 23 sentence where you say "The more localized impact of 24 alpha decay makes it ideally suited for targeted therapy 25 because the impact of the surrounding tissue is
110 1 Q. And so he describes it "30 kBq caused 2 radiation-induced acute tubular necrosis in the distal 3 and proximal distal and proximal tubes of the kidneys." 4 A. Right. 5 Q. That doesn't sound life-endangering to you? 6 A. I don't know if this is something that could 7 be repaired. This is not a life span study where it 8 demonstrated that those effects resulted in earlier 9 death. It is a dose at which you observed adverse 10 effect. It is not a determination of the tolerability 11 window. 12 Q. Okay. Going back to your declaration, 13 paragraph 29, which begins on page 12 and goes to 14 page 13. 15 So on page 13, ten lines down, there's a 16 sentence beginning with "The more localized." Do you 17 see that? 18 A. I do. 19 Q. You say "The more localized impact of alpha 20 decay makes it ideally suited for targeted therapy 21 because the impact on the surrounding tissue is 22 minimized, reducing the likelihood of side effects." Do 23 you see that? 24 A. I do. 25 Q. Now, doesn't this line assume that the	112 1 minimized, reducing the likelihood of side effects" 2 assumes that the actinium remained within the molecule 3 and was targeted to the tumor. 4 A. That's right. 5 Q. Okay. But didn't we see in the McDevitt 6 paper, your reference 1013, that 80 percent of the 7 actinium -- step back -- the daughter elements are 8 actually not internalized? 9 A. No. That's 80 percent of the actinium in 10 that paper. 11 Q. Okay. So 80 percent of the actinium in 1013 12 was not internalized, which means it wasn't targeted, 13 correct? 14 MS. CIPRIANO: Objection; misstates the 15 record. 16 A. That's correct. In the antibody actinium 17 construct that is investigated in this paper, 80 percent 18 of the actinium was not in the cell. 19 Q. So, in fact, using actinium in this case 20 didn't reduce the likelihood of side effects because 21 most of it was still outside the cell. 22 MS. CIPRIANO: Objection. I'm sorry. 23 This -- 24 A. I don't know if this is -- 25 MS. CIPRIANO: Hold on.

113 1 "This case"? I'm sorry. I lost what you're 2 referring to. 3 Q. So with the McDevitt paper, they found that 4 80 percent of the actinium was outside the cell, 5 correct? 6 A. In that particular case, yes. 7 Q. And you say in your declaration that actinium 8 reduces the likelihood of side effects, correct? 9 A. I say that alpha decay is better suited for 10 targeted therapy because it is more localized in terms 11 of its effects when compared to beta decay. 12 Q. But that statement only holds true if it's 13 been targeted to the tumor, not if it's in healthy 14 organs because it's been released from the chelator, 15 correct? 16 A. That's correct. 17 Q. And so we found in the McDevitt paper, 18 reference 1013, that 80 percent of the actinium was 19 outside of the tumor. 20 A. In that particular case, it was. However, in 21 that particular case, there is no direct comparison with 22 a beta emitter. And I don't know about the clearance of 23 this antibody. I don't know about the residual time. I 24 don't have enough information to draw any conclusion on 25 that particular case.	115 1 molecule with actinium, similar to this McDevitt paper 2 that compares an antibody construct with actinium and 3 the same antibody construct with bismuth as a reference 4 in the paper. 5 Q. McDevitt actually didn't compare the two of 6 them, though. 7 A. He referred to that. 8 Q. He referred to a different paper where they 9 used bismuth -- 10 A. That's right. 11 Q. -- but there's no data in there, correct? 12 A. In this particular paper, no. 13 Q. Okay. So in paragraph 29, you say in your 14 last sentence "Furthermore, because alpha particles are 15 higher energy than the particles resulting from beta 16 decay, alpha-particle emitters can be administered in 17 lower doses than beta emitters, further reducing the 18 risk of adverse effects." Do you see that? 19 A. I do. 20 Q. And you cite to 1030, Exhibit 1030 to your 21 declaration. I'm going to give you Exhibit 1030 to your 22 declaration. 23 (Exhibit Number 1030 introduced.) 24 Q. Okay. I'd like you to look at page 3 of 25 1030. On the right-hand side, do you see the section
114 1 Q. So those factors that you just mentioned, 2 what were they again? 3 A. I talked about the clearance, the conditions. 4 What else? What did I say? 5 Q. So those are things that you need to know in 6 order to make conclusions about the comparison of the 7 different -- 8 A. Yes. 9 Q. -- target molecules? 10 A. No. I'm -- to draw a direct comparison of 11 the toxicity, I would need to have a comparison of the 12 distribution of the construct and its clearance, so 13 looking at a particular molecule. So as an example, if 14 I were to compare PSMA-I&T with actinium and PSMA-I&T 15 with lutetium, that would provide this information. 16 Q. That would provide the information about the 17 clearance? 18 A. About the clearance of the entire metal 19 complex, yes. 20 Q. If you're -- I'm sorry. So if you're 21 comparing what about the actinium and lutetium? 22 A. If I am comparing the pharmacokinetics of the 23 entire molecule and I know the pharmacokinetics of this 24 molecule with a metal like lutetium, I would have some 25 information to understand the pharmacokinetics of that	116 1 entitled "Biological studies"? 2 A. I do. 3 Q. Okay. We're going to go halfway down the 4 page -- halfway down that column. About 20 lines down, 5 there's a line that begins with "Overall charge." Do 6 you see that? 7 A. Yes. 8 Q. Okay. So it says "As will be described 9 below, the 225 actinium complex with HEHA demonstrated 10 less stability than the 225 complex with DOTA in vivo in 11 the experiments described. In addition, the two 12 monoclonal antibody/antigen systems that were examined 13 using HEHA constructs were non-internalized immune 14 complexes and the targeted constructs could still 15 release the daughters systematically." Do you see that? 16 A. I do. 17 Q. And so then it says "The 225 Ac release from 18 the HEHA was distributed to liver and bone, and the 19 subsequent release of the daughters contributed to acute 20 radiotoxicity, as did the daughters from the targeted 21 but not internalized parent." Do you see that? 22 A. I do. 23 Q. So, in fact, the 225 Ac is still able to 24 reduce considerable adverse effects. 25 A. That's right.

117 1 Q. So the idea of the 225 actinium producing 2 lower adverse effects is theoretical dependent upon the 3 actinium remaining within the chelator. Isn't that 4 right? 5 MS. CIPRIANO: Objection to the extent it 6 misstates the record. 7 A. No. This is not a conclusion I would draw 8 based on this. Whether there are more or less adverse 9 effects depends on where those adverse effects take 10 place and what they come from. So here there's no 11 comparison of more or less adverse effects. There is a 12 risk for adverse effects. Whether it's more or less 13 than something else is not a conclusion that can be 14 drawn from this. 15 Q. But you actually cited to this as your 16 conclusion that alpha-particle emitters can be 17 administered in lower doses than beta emitters. So 18 you're saying there's no comparison here. 19 A. Well, there's another exhibit that is cited 20 here. I can elaborate here, saying that if there are 21 lower doses and there is non-targeted actinium, even if 22 there is additional alpha particles coming out of the 23 actinium that are non-targeted, if the dose is lower 24 than a non-targeting beta emitter, there may be less 25 still adverse effects. So, again, I think there's a	119 1 A. That's incorrect. There are direct 2 comparisons as lutetium as a beta emitter or indium as a 3 beta emitter and actinium as an alpha emitter or 4 bismuth as an alpha emitter prior to that patent. So 5 that's incorrect. 6 Q. But this patent was the first time that 7 actinium was combined with a PSMA ligand molecule, 8 correct? 9 A. That's correct. 10 Q. So in paragraph 30, you say in the third 11 sentence, the bottom of page 13, leading with "However." 12 You say "However, as the advantages of alpha 13 emitters were appreciated, alpha emitters like 225 Ac 14 and 213 Bi gained favor." 15 What do you mean by "they gained favor"? 16 A. I mean that their -- those alpha emitters are 17 considered more promising for targeted radiotherapy than 18 beta emitters. 19 Q. And when exactly did they gain favor? 20 A. As studies could be conducted as those 21 isotopes became available. 22 Q. So in November of 2016, in your paper, you 23 said that actinium had been -- pardon me if I don't get 24 this exactly right -- but largely ignored. 25 A. No. In my paper, I say that they've been
118 1 context that needs to be added if you want to 2 demonstrate that there is more adverse effects from 3 alpha particles. 4 Q. But even if the dose is lower, if I 5 understand correctly, the LAT would still be higher for 6 the alpha particles, wouldn't it? 7 A. But in this case, if the dose is much lower, 8 it may still result in less adverse effects. 9 Q. It may -- 10 A. It may. 11 Q. -- result in less adverse effect? 12 A. That's right. That's right. It may. 13 Q. If it's much lower. 14 A. If it is much lower. 15 Q. But then you don't know if you're going to 16 have an efficacious amount. 17 A. Well, you still may have an efficacious 18 amount. It depends on the targeting. Yes. 19 Q. This sounds theoretical to me. 20 MS. CIPRIANO: Objection; argumentative. 21 A. Everything is theoretical until you put it in 22 practice. 23 Q. And this, in fact, wasn't put into practice 24 until the '901 patent, correct? 25 MS. CIPRIANO: Objection. That's unclear.	120 1 overlooked since 18- -- 1980- -- 1889, since its 2 creation compared to other elements. So that's a 3 completely different context. 4 Q. So it was largely overlooked. 5 A. As an element compared uranium or -- here. I 6 will read you the introduction, because that is a very 7 different meaning. 8 "Actinium was discovered around the same time 9 as polonium and radium." And over the next 100-plus 10 years, there was a lot less work dedicated to actinium 11 than radium because of the availability of it as the 12 isotope. We just don't know much about actinium 13 compared to other elements. That's a very different 14 thing from gaining favor in the context of targeted 15 radiotherapy. 16 Q. But it gaining favor was something that was 17 fairly recent in 2016, correct? 18 A. I would say that it was maybe about 20 years 19 old. This paper that you cited that I referred to and 20 that you brought here is from 2001, so it's already 21 15 years before this patent. 22 Q. Okay. 23 A. So I would say a couple decades. 24 Q. So let's see here. In paragraph 32, you 25 discuss some of the history for the treatment of

121 1 prostate cancer, correct? 2 A. That's correct. 3 Q. Now, again, you're not a clinician, right? 4 A. I am not. 5 Q. You've never treated prostate cancer. 6 A. I haven't. 7 Q. Okay. And you say in 32 that "Despite 8 PC's" -- prostate cancer's -- "prevalence up to the 9 mid-2010s, diagnostic tools for the disease remained 10 limited, relying on invasive methods such as blood tests 11 and prostate biopsy analysis," right? 12 A. That's right. 13 Q. And you say "While effective, such methods 14 were not ideal for disease progression monitoring, as 15 they were inconvenient and difficult to rapidly 16 administer," correct? 17 A. That's correct. 18 Q. So it seems like these systems were not 19 effective at the time. 20 MS. CIPRIANO: Objection to the extent it 21 mischaracterizes the paragraph. 22 A. That's not correct. I said they're 23 inconvenient and difficult. It doesn't mean not 24 effective. 25 Q. Okay. Fair enough.	123 1 advantage of a small molecule PSMA-inhibitor as a 2 targeting moiety." And you list the 131 iodine, 3 MIP-1375, and the 131 iodine, MP-1644. Is that right? 4 A. That's right. 5 Q. So do you know what happened with those two 6 products? Were they ever developed into anything? 7 A. I don't know. Are they still in the clinic? 8 I don't -- I don't know. 9 Q. Okay. So you don't know if they succeeded or 10 failed with these iodine versions of the PSMA ligand 11 molecule. 12 A. I don't know if there is a definitive take on 13 those. No, I don't know. 14 MR. BOETTICHER: Do we want to break for 15 lunch? 16 MS. CIPRIANO: Sure. 17 (Off the record: 12:51 p.m. to 2:04 p.m.) 18 MR. BOETTICHER: So going back on the record. 19 Q. I'm going to hand you Exhibit 1027 to your 20 declaration. 21 (Exhibit Number 1027 introduced.) 22 Q. Do you recognize this document? 23 A. I do. 24 Q. Okay. What is this document? 25 A. It's another journal publication that I refer
122 1 But there was room for improvement. 2 A. There was room for improvement. 3 Q. Okay. And that was back in 2010 -- up to the 4 mid-2010s. 5 A. That's right. 6 Q. Okay. And then in paragraph 35, you continue 7 with the history. "Prior to 2014, most therapies for 8 the treatment of prostate cancer were focused on 9 androgen-deprivation therapy and chemotherapy," right? 10 A. That's right. 11 Q. And these were plagued by undesirable side 12 effects, including bone loss, metabolic change, muscle 13 loss, hot flashes, and increased cardiovascular disease, 14 right? 15 A. That's right. 16 Q. So, again, it seems like there was a 17 long-felt need to improve upon these systems, right? 18 MS. CIPRIANO: Objection; calls for a legal 19 conclusion. 20 A. There's always a need for improvement, so.... 21 Q. It had been sitting for quite some time, 22 since before 2010, correct? 23 A. That is correct. 24 Q. And you mention here that "Prior to 2014, 25 only two therapeutics have been evaluated that took	124 1 to in the declaration. 2 Q. It's entitled "Synthesis and preclinical 3 evaluation of DOTAGA-conjugated PSMA ligands for 4 functional imaging and endoradiotherapy of prostate 5 cancer," correct? The first author is Martina 6 Weineisen. 7 What were they trying to do in this article, 8 if you remember? 9 MS. CIPRIANO: Objection; calls for 10 speculation. 11 A. They're looking into evaluating another 12 chelator, linker, PSMA-targeting peptides for imaging 13 and treatment of cancer. 14 Q. Okay. If you turn to page 3. 15 So at the top of page 3, in Figure 2, we see 16 that they've got "DOTA-FFK, sub-KuE," which is 17 apparently drawn from another reference. Do you see 18 that? 19 A. I do. 20 Q. And on page 9, in Figure 4, we see that they 21 have modified it further. And so they have 22 Compounds 10, 11, and 12 on the bottom right-hand side 23 of Figure 4. Do you see that? 24 A. I do. 25 Q. And Compounds 10, 11, and 12 are the ones

125 1 they continue to study in this article, correct? 2 A. Is that right? 3 That's right. 4 Q. And so these three compounds, they consist of 5 a chelator, a linker, and then the PSMA ligand, correct? 6 A. That's correct. 7 Q. So they're the same basic idea, but they've 8 changed this molecular formula slightly, correct? 9 A. That's correct. 10 Q. Okay. I want to look at Figure -- or 11 sorry -- Table. I want to look at Table 1, entitled 12 "PSMA affinities, IC 50, of the compounds investigated." 13 Do you see that? 14 A. I do. 15 Q. So what are they doing in this experiment? 16 A. I believe those are in vitro viability assay 17 where they're testing the toxicity of -- or the -- hold 18 on a second. 19 Q. It's Table 1 on page 10. 20 A. Right. 21 Yeah. So the viability of the cells exposed 22 to different versions. So those compounds bound to 23 different metal. Not radionuclides, but metals. And to 24 look at their -- the binding affinity to the cells. 25 Q. And they didn't use the radionuclides because	127 1 a competitive binding assay using LNCaP human prostate 2 carcinoma cells and the known high affinity PSMA ligand, 3 125 I, I-BA, KuE as the radioligand." 4 So they were completing it against another 5 known ligand, correct? 6 A. That's right. 7 Q. And so they were seeing how much of the -- 8 how much of the PSMA molecule was necessary to displace 9 the radioactive competitor. Isn't that right? 10 A. That's right. 11 Q. And so the more that you need to displace it, 12 the lower your affinity must be. Does that make sense? 13 A. That's right. 14 Q. Okay. 15 A. Yes. 16 Q. So the higher number you have here, the lower 17 the affinity. 18 A. That's right. 19 Q. So if we look at the third, fourth, and fifth 20 line on Table 1, on the far right, we see the numbers 21 13.1, 29.5, and 54.7. Do you see that? 22 A. Yes. 23 Q. And so this is all for the DOTA-FFK sub-KuE, 24 but they differ in that the first one has no metal in 25 it, the second one has gallium, and the third one has
126 1 these are competition experiments, correct? 2 A. I don't know that that's the reason. They 3 just didn't use the radionuclides because we're looking 4 at the viability and the binding to the cells. There's 5 no need to use the radionuclides, so... 6 Q. Okay. So the IC 50 on the right-hand side, 7 it says "nM." That stands for nanometers or nanomolar? 8 A. Nanomolar. 9 Q. Nanomolar. 10 And so the higher the number, the lower the 11 affinity? Is that the way that works? 12 A. The lower the number it should be, I believe. 13 Right? If I'm understanding this correctly. 14 Q. Have you ever done affinity studies before? 15 A. I have done affinity studies, but those are 16 not the conventional namings that I use, so... 17 Q. If you look on page 8, on the right-hand 18 column, there's a section entitled "PSMA binding 19 affinity" that might provide some guidance. 20 A. Okay. Yes. So that's right. The lower the 21 number, the higher the affinity. 22 Q. So this is a competition assay, correct? 23 A. It is an inhibition assay. Yes. 24 Q. Okay. So on page 8, "PSMA binding affinity," 25 it says "The PSMA binding affinities were determined by	128 1 lutetium, correct? 2 A. That's correct. 3 Q. And so even though these are the same 4 molecules, the same carriers, we see that by adding 5 different metals to the chelator, we dramatically affect 6 the affinity of the ligand. Isn't that right? 7 MS. CIPRIANO: Objection to the extent it 8 misstates the document. 9 A. There is a significant difference between the 10 free chelator and the metal complexes. That's right. 11 Q. And we also see a difference between the two 12 metal complexes, with gallium having an affinity of 29.5 13 and lutetium having 54.7. 14 A. In this particular case, that's correct. 15 Q. Okay. You say "in this particular case." 16 So, in fact, for the other ones, the DOTAGA-FFK, we 17 don't see that kind of difference, do we? 18 A. We don't. 19 Q. Although between the empty DOTAGA-FFK and the 20 lutetium-containing FFK -- DOTAGA-FFK, we do see a large 21 difference, don't we? 22 A. We do see a significant difference. 23 Q. So a person of skill reading this would 24 understand that using a radionuclide in a molecule can 25 affect its ligand-binding ability, correct?

129 1 A. That's correct. 2 Q. And they would also conclude that using 3 different types of metals in the chelators would also 4 affect the ligand's binding ability, correct? 5 A. That may affect, depending on the ligands. 6 From this particular table, it does not affect the 7 DOTAGA constructs. It affects the DOTA constructs. 8 Q. But it could affect it. 9 A. It could. 10 Q. Yes. I'd like you to look at Table 2, which 11 is on page 11. Do you see that? 12 A. I do. 13 Q. Table 2 is entitled "Internalization of 14 radiometalated ligands in percentage of external 15 reference." And it gives the external reference as 16 125 I, I-BA, KuE. Do you see that? 17 A. I do. 18 Q. So if we look at this -- okay. So this is 19 measuring internalization, correct? 20 A. That's correct. 21 Q. And that means this is how much the cell 22 takes up, correct? 23 A. That's correct. 24 Q. So internalization is linked to the idea of 25 affinity, correct?	131 1 A. On paper, yes. That's right. 2 Q. That's a good point. So on paper they look 3 like they're really far away, but you're suggesting that 4 in real life they may be coming together? 5 A. I am not suggesting they may be coming 6 together. I'm saying that the arrangement in the 7 three-dimensional space may look a little different. 8 Q. Okay. And so a person of skill, again, would 9 conclude that having different radionuclides in even the 10 same ligand-binding molecule can result in different 11 internalization rates. 12 A. That's right. 13 Q. So I think that we can agree, based on the 14 differences that we see between the radionuclides and 15 your comment about how the three-dimensional structure 16 may differ from what we see on paper, that determining 17 whether or not a radionuclide will affect the binding 18 and the internalization parameters is complicated. 19 MS. CIPRIANO: Objection; calls for 20 speculation. 21 A. It may be complicated. Yes. 22 Q. And, in fact, there's a certain level of 23 unpredictability to it, correct? 24 A. That's correct. 25 Q. Now, in this paper, they only use gallium and
130 1 A. Not necessarily. 2 Q. Okay. Explain how it's not. 3 A. It depends on the mechanism of 4 internalization. 5 Q. Okay. So you could have something that has 6 high affinity but low internalization or low affinity 7 and high internalization, correct? 8 A. That's right. 9 Q. So when we look at this chart, we see that, 10 again, the gallium and lutetium for the DOTA-FFK 11 molecule are significantly different, correct? 12 A. That's correct. 13 Q. And as you just explained, that difference is 14 not necessarily because of the difference in affinity. 15 It could be due to the difference in internalization or 16 uptake, correct? 17 A. That's correct. 18 Q. And then we look at the next line down. 19 That's lines 4 and 5 on Table 2. We see that the 20 DOTAGA-FFK, sub-KuE, also shows a difference between 21 using gallium and lutetium, correct? 22 A. That's correct. 23 Q. Now, in the design of these molecules, the 24 section that binds the radionuclide is on the opposite 25 end from the ligand-binding side. Isn't that right?	132 1 lutetium for their radionuclides, correct? 2 A. That's correct. 3 Q. They do not use actinium. 4 A. They don't. 5 Q. And in this paper, they also do not give 6 these compounds to human patients, do they? 7 A. I don't believe they do. 8 Q. So they don't provide a dose level for using 9 these compounds, do they? 10 A. They do not provide a dose level for using 11 the compounds in humans. 12 Q. Okay. You can put that aside, and I'm going 13 to give you Exhibit 1028 from your declaration. 14 (Exhibit Number 1028 introduced.) 15 Q. Okay. Do you recognize this document? 16 A. I do. 17 Q. What is this document? 18 A. Another journal paper that I cited in the 19 declaration. 20 Q. And this one is entitled "68 Ga- and 21 177 Lu-labeled PSMA-I&T: Optimization of PSMA-Targeted 22 Theranostic Concept and First Proof-of-Concept Human 23 Studies," again, by Martina Weisen, correct? 24 A. That's correct. 25 Q. Okay. So could you look at Figure 1 on

133 1 page 2. 2 And we see in Figure 1 that they've now 3 introduced alongside the DOTAGA-FFK, sub KuE, the 4 PSMA-I&T, correct? 5 A. That's correct. 6 Q. This is the first time, I think, that the 7 PSMA-I&T has been introduced. 8 A. That may be correct. 9 Q. Okay. And if we look at Table 1 on page 3. 10 So this is another IC 50 determining the 11 affinity of the compounds, correct? 12 A. That's correct. 13 Q. So if I look at the DOTAGA-FFK, I get an 14 IC 50 of 13.9, right? 15 A. That's right. 16 Q. And if I look at the PSMA-I&T, which is the 17 fourth line down, I get an IC 50 of 10.2, correct? 18 A. Plus or minus 3.5. 19 Q. Plus or minus 3.5. 20 So is there a significant difference between 21 those? Would you conclude the PSMA has a higher 22 affinity or not? 23 A. I would not. 13.9 plus or minus .4, the 24 lower range would be 13.5. And 13 -- 10.2 plus or minus 25 3.5, the highest range would be 13.7. So I would not.	135 1 lutetium-PSMA-I&T, correct? 2 A. That's correct. 3 Q. And for the kidney, we see a much higher 4 amount in the kidney for lutetium-PSMA-I&T. Is that 5 right? 6 A. That's right. 7 Q. And for the tumor itself, it looks like the 8 lutetium-PSMA-I&T is also higher, correct? 9 A. I believe this is with an error. 10 Q. Okay. But for the kidney, we certainly see a 11 difference, correct? 12 A. That's right. 13 Q. And so even though these are the same 14 molecules, changing the radionuclide caused a different 15 amount of uptake in the kidney. 16 A. That's right. 17 Q. Okay. And if we look at Figure 3 on page 5, 18 they do another comparison across the board, doing a 19 tumor-to-organ ratio. And they find that, if I'm 20 reading this correctly -- and you can correct me. They 21 find that the gallium-PSMA-I&T, when comparing the tumor 22 to the organ, had a lower amount of tumor-to-organ 23 ratio. Does that sound right? 24 A. For gallium, that's right. 25 Q. So consistently, lutetium is being taken up
134 1 Q. In other words, they're overlapping. 2 A. In other words -- 3 Q. -- in that range. 4 A. Yes. 5 Q. So if we look at Figure 2 on page 4, in the 6 top figure, it shows a comparison of the 7 177 lutetium-DOTAGA-FFK with the 177 Lu PSMA I&T, 8 correct? 9 A. That's correct. 10 Q. So what are they comparing here in this 11 figure? 12 A. Well, they're looking at different -- 13 comparing the kinetics of binding for those two 14 constructs. 15 Q. And what do they find? 16 A. They find that there is some significant 17 difference between the two. 18 Q. So even though they're using the same 19 nuclide -- radionuclide, by changing the construct 20 they're putting it in, they get very different results, 21 correct? 22 A. That's correct. 23 Q. Could you look at Table 2 for me, also on 24 that same page below. If I understand this correctly, 25 they're comparing the uptake of gallium-PSMA-I&T against	136 1 more. Is that right? 2 A. It is being taken up more in the tumor 3 compared to other organs? Well, not all the organs. So 4 not the intestines, for example. 5 Q. Okay. But it seems that, for the most part, 6 lutetium is being taken up more in the blood, the heart, 7 the lungs, the liver, the pancreas, the stomach, the 8 brain, and particularly in bone. Is that right? 9 A. In the tumor comparing it to -- compared to 10 the organ, that's right. 11 Q. Okay. And so, again, we see an effect here 12 that's based on the fact that there is a different 13 radionuclide in the same molecule, correct? 14 A. That's correct. 15 Q. So a person of ordinary skill in the art 16 looking through the two Weineisen papers and comparing 17 them would conclude that you can change out the 18 radionuclide in a molecule and get very different 19 affinities and uptake. 20 A. In the case of lutetium and gallium, yes. 21 Q. And it's possible that if you put something 22 else in you would get the same effect, correct? 23 A. That's correct. 24 Q. And it's also -- they also see that even if 25 you have the same radionuclide, putting that in a

137 1 different molecule will give you different -- 2 A. Yes. 3 Q. -- affinity and uptake. 4 A. That's correct. 5 Q. Now, in the Weineisen 2015 paper, again, they 6 don't use actinium for any of those studies, right? 7 A. They don't. 8 Q. They don't even mention actinium in the 2015 9 paper, correct? 10 A. I don't remember. I would venture no, but 11 I'd have to go through it one more time to make sure 12 they don't, but probably not. 13 Q. Okay. Now, in your declaration, you made a 14 comment that only the safest and most promising 15 therapies are used in human studies. Do you remember 16 that? 17 A. Can you point me to it? 18 Q. I can try. 19 Paragraph 77. So you say here in 20 paragraph 77 "Additionally, Weineisen 2015 used 21 177-lutetium-PSMA-I&T in human studies. Due to ethical 22 and safety concerns, human studies are reserved for only 23 the safest and most promising therapies." Do you see 24 that? 25 A. I do.	139 1 A. At the time -- 2 Q. Okay. 3 A. -- I would say so. I mean, I can't speculate 4 for what they were thinking, but... 5 Q. So I think that you've argued that combining 6 the PSMA-I&T with actinium was obvious. Is that 7 correct? 8 A. That's correct. 9 Q. Okay. So my question remains, like, why is 10 it that if it was so obvious they didn't do it? 11 MS. CIPRIANO: Objection to form. 12 A. Well, I don't know why they didn't do it. 13 There are many reasons; availability of the isotope, 14 effort, you know, how many people are available to work 15 on this, timelines. Maybe they did it and they didn't 16 report it on time. I wouldn't know. 17 Q. But as far as effort and the number of 18 people, you've already said several times in your 19 declaration that the Ac was the obvious choice and 20 extremely promising. Wouldn't it make sense that a 21 person of ordinary skill would put their best foot 22 forward for their -- for the most promising therapy? 23 A. It would make sense. However, actinium was 24 not available widely in -- at that time. And it's still 25 not available widely today, so...
138 1 Q. And you conclude that "By selecting PSMA-I&T 2 for human studies, Weineisen 2015 highlighted the 3 construct as a radiotherapy of particular interest," 4 correct? 5 A. That's correct. 6 Q. But by using it with lutetium, Weineisen was 7 also saying that lutetium-PSMA-I&T was the safest and 8 most promising therapy? 9 MS. CIPRIANO: Objection; calls for 10 speculation. 11 A. At the time. 12 Q. So at the time, Weineisen was basically 13 showing that lutetium-PSMA-I&T was the safest and most 14 promising therapy. 15 A. Was among the safest and promising therapies. 16 Q. Well, your statement here is "Due to ethical 17 and safety concerns, human studies are reserved for only 18 the safest -- 19 A. "Safest and most promising therapies." 20 Q. -- and most promising therapies." Uh-huh. 21 A. Right. So that's a plural. It's not the 22 safest and most promising therapy. 23 Q. Okay. But what Weineisen was offering in 24 this paper as her safest and most promising therapy was 25 lutetium-PSMA-I&T, right?	140 1 Q. Could you go to Exhibit 1015. This is the 2 Miederer paper. 3 So as we discussed before, Miederer used 4 actinium with the DOTATOC, correct? 5 A. That's correct. 6 Q. And this is a 2008 paper. 7 A. But this is a different group in a different 8 institution with different means and different access. 9 At the time there were three sources of access for 10 actinium-225. 11 Q. What were they? 12 A. One in Germany for that group, one in Russia, 13 one in the US. 14 Q. Okay. What was the one in the US? 15 A. From the department of energy at Oak Ridge 16 National Lab. 17 Q. Okay. So if we look on page 2 of Miederer, 18 in the materials and methods, he states "DOTATOC was 19 purchased from Bachem, AG. Actinium-225 was received as 20 a solid nitrate from Actinium Pharmaceuticals, Inc." 21 Now, he does say that the source was 22 originally from the Oak Ridge National Laboratory, 23 but -- 24 A. That's right. 25 Q. -- he purchased it from Actinium

141 1 Pharmaceuticals. 2 A. That's right. Right. That's right. So my 3 understanding is that actinium is produced at Oak Ridge 4 National Lab -- or was produced at Oak Ridge National 5 Lab not very often, and it was dispatched to other 6 entities and in this case who would have sent them to 7 Germany. It's not evident to me that this other group 8 had the facilities to handle actinium-225. You need 9 different facilities and different instrumentation than 10 when you're handling lutetium-177, and it's not evident 11 to me that they had the means to purchase actinium-225 12 either. So I wouldn't know why they did not conduct any 13 studies with actinium-225. 14 Q. But the idea that actinium-225 wasn't widely 15 available or wasn't available, I don't think, is quite 16 true if other people were able to access it. 17 A. It's still not available today. If I place 18 an order myself, I may have to wait a month before being 19 able to receive some actinium-225. So, you know, that's 20 more than ten years -- or ten years ago. So no. It's 21 not true. 22 Q. But they were able to purchase actinium-225, 23 and they were in Germany, and they purchased it from, 24 apparently, an American company. 25 A. Sure. They did. And maybe they had, again,	143 1 the literature. 2 Q. Okay. So you're referring to the patent in 3 this case? 4 A. That's right. 5 Q. Okay. Can you show me in the patent where 6 they made the PSMA-I&T actinium? 7 MS. CIPRIANO: Objection; scope. 8 A. Probably not. I don't know. No. There is 9 no methods of making actinium-225 PSMA-I&T -- 10 Q. Right. 11 A. -- in the patent. 12 Q. I would like you to turn to your article 13 "Development of radiopharmaceuticals for targeted alpha 14 therapy" from 2022. 15 Could you turn to page 6. 16 All right. On the left-hand column, about 17 halfway down, there's a line that begins "First clinical 18 data." Do you see it? 19 A. Yes. 20 Q. Okay. So it says here -- this sentence says 21 "The first clinical data of 225-Ac-PSMA-I&T have been 22 published showing comparable biochemical responses to 23 225-Ac-PSMA-617 during the treatment of metastatic 24 castration-resistant prostate cancer patients." Do you 25 see that?
142 1 the resources and the timeline. I'm saying that is 2 not -- that is one of the biggest issues with 3 actinium-225 is that it's very difficult to get some 4 supplies in enough quantities to conduct a study. 5 But, again, I can't speculate as to why this 6 group didn't do an actinium-225 study beyond what's 7 reported. 8 Q. So your testimony is that you aren't really 9 sure why they didn't use actinium-225. 10 A. I mean, I can't speculate as to the order of 11 their experiments and the timeline of their experiments. 12 You're asking me -- I mean, why this group did not do 13 actinium-225 and another group did actinium-225, I -- 14 you know, there are many potential reasons for that. I 15 can't -- 16 Q. So when was actinium-225 used with the 17 PSMA-I&T? 18 MS. CIPRIANO: Objection; scope. 19 A. I -- apparently it was used that year by this 20 other group. 21 Q. By which other group? 22 A. The group that patented actinium-PSMA-I&T. 23 Q. Okay. But when do you actually see it in the 24 literature that something used PSMA-I&T with actinium? 25 A. I believe this is the first report of it in	144 1 A. I do. 2 Q. And you cite to 78 and 79. 3 A. That's right. 4 Q. And if we look at 78 and 79 in your 5 references, we see that those are two 2021 papers, 6 correct? 7 A. That's correct. 8 Q. And we see that the authors for the reference 9 78 is Ilhan, Gosewisch, Boning, Volter, Zacherl, 10 Unterrainer, correct? 11 A. That's correct. 12 Q. And none of those are the same authors as 13 found in Weineisen, are they? 14 A. That's correct. 15 Q. So when we ask about whether or not -- 16 A. Well, actually -- 17 Q. Okay. 18 A. It says "et al." So I don't actually know 19 the other authors. 20 Q. Okay. But we don't see any of the authors 21 that overlap with Weineisen, correct? 22 A. I wouldn't know, because it's missing some 23 authors for both references. 24 Q. Okay. So we don't see that PSMA-I&T is used 25 with actinium until 2021. Is that fair?

1 MS. CIPRIANO: Objection; misstates the 2 document. 3 A. Well, you're assuming that this review is, 4 you know, accurately reporting exactly the truth, 5 you know. I wrote this. We could have cited this 6 patent as well as the first clinical data. So I -- this 7 is what's in here as a reference. 8 Q. Well, I will point out, if you go to page 5, 9 on the right-hand side, on the bottom right, you begin a 10 sentence that says "The first clinical PSMA-based 11 targeted alpha therapy study." Do you see that? 12 Page 5, the right-hand column, bottom. 13 A. I do. 14 Q. Okay. And so you report here "The first 15 clinical PSMA-based targeted alpha therapy study was 16 published in 2016, where two patients with metastatic 17 castration-resistant prostate cancer with challenging 18 clinical situations received 225-Ac-PSMA-617 every two 19 weeks." And you cite to 74. 20 And if we look at 74, the first author is 21 Kratochwil, who is the inventor of -- or one of the 22 inventors of the '901 patent. So you do cite to 23 Kratochwil's work as the first PSMA. 24 A. As the first published work that I'm aware 25 of --	145 1 reference, but if you're going to cite something and say 2 it's the first, you would make sure it's the first, 3 wouldn't you? 4 A. But I would not cite abstracts or conferences 5 or patents, for example, readily. So I -- you know, it 6 says it's the first published report. There are some 7 experiments that are not reported and some that are 8 presented rather than published, so -- I mean, this is 9 semantic in my mind, so... 10 Q. All right. I'm going to give you 11 Exhibit 1006 from your declaration. 12 (Exhibit Number 1006 introduced.) 13 Q. Do you recognize this document? 14 A. I do. 15 Q. What is this document? 16 A. It's an abstract from a journal that I've 17 referenced in the declaration. 18 Q. Okay. So as an abstract, it's fairly short 19 and incomplete, isn't it? 20 MS. CIPRIANO: Objection; calls for 21 speculation. 22 A. It's an abstract. I mean, it's short. I 23 don't know that it's incomplete. It doesn't detail some 24 studies. 25 Q. Well, is there a reason that we don't have,
146 1 Q. Right. 2 A. -- in that review. 3 Q. Right. So that was in 2016, and we don't see 4 a follow-up by somebody else until 2021. 5 A. I mean, I wouldn't characterize this review 6 as the entire literature that's out there. So I won't 7 agree with this, because I don't know that it's the 8 truth. 9 Q. Okay. So when you write a review, don't you 10 make sure that everything is accurate? 11 A. Yes, I would hope so. You know, we don't 12 cite thousands of papers in a review, so I will... 13 Q. So you only cite the more important papers. 14 A. We cite what is relevant for the discussion 15 at the time. And I'm not sure, you know, that the 16 context of the discussion for citing this paper was to 17 say this is the first, rather than those are examples of 18 what has been happening in the field. 19 So, again, I would say this is a paper that I 20 have authored -- coauthored. I'm not sure that this is 21 the accurate truth about this is the first reference 22 ever published for something at this moment, because we 23 don't cite thousands of references. So I won't say 24 "Yes. Exactly. I agree with you." 25 Q. I understand you wouldn't cite every single	147 1 say, a full method section and a full discussion 2 section? 3 A. It's an abstract. 4 Q. So this is all that this reference consists 5 of, correct? 6 A. That's correct. 7 Q. Are abstracts like this peer reviewed? 8 A. Sometimes. 9 Q. But you don't know if this one was? 10 A. It was probably, but I can't say for sure. 11 This is a conference abstract, so it was probably peer 12 reviewed. 13 Q. Okay. So the name of this abstract is 14 "213 bismuth-labeled PSMA-targeting agents for alpha 15 radionuclide therapy for prostate cancer." And the 16 first author is Kristell Chatalic, correct? 17 A. That's correct. 18 Q. Now, you suggested in your declaration that 19 this abstract highlighted the use of PSMA-I&T with 20 213 bismuth, correct? 21 A. That's correct. 22 Q. But, in fact, it really tests two compounds, 23 doesn't it? 24 A. More than two, actually, three bismuth 25 compounds.

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149 1 Q. And it concludes that the 2 213 bismuth-PSMA-I&T and the 213 bismuth JVC 008 are 3 equivalent. 4 A. No, it doesn't. It concludes that they both 5 revealed good tumor targeting and induction of double -- 6 the DNA double strand breaks and PSMA expressing 7 xenografts. 8 Q. And it doesn't highlight one above the other, 9 correct? 10 A. It doesn't, but that doesn't mean they're 11 equivalent or that it's suggested that they're 12 equivalent. 13 Q. Okay. But the reference Chatalic does not 14 suggest 2-1-3- -b-i-s-m-u-t-h-PSMA-I&T is better or 15 worse than 213 bismuth-JVC-008, correct? 16 A. Not directly. However, it reports higher 17 tumor uptake for PSMA-I&T than for the other one. So 18 indirectly, one may deduce that it is better. 19 Q. So previously when we've discussed these 20 numbers, you have said that when the numbers with their 21 standard deviations overlap, that they're really within 22 the margin of error. Isn't this one within the margin 23 of error? 24 A. Sure. Is it? I don't know. I didn't 25 actually check, so...	151 1 A. I do. 2 Q. And then below that, it says "Is administered 3 as unitary dosage of from 3 megabecquerel to 4 30 megabecquerel to said patient." 5 A. Okay. 6 Q. And you understand that in this case, a 7 patient would be a human, correct? 8 A. That's right. 9 Q. So Chatalic is giving 5 megabecquerels to a 10 mouse, which is as much as you would give to a human. 11 So does that not seem like a very large amount of 12 radiation to give to a mouse? 13 A. I mean, I think -- there are a lot of 14 experimental studies that are testing different modality 15 dosing regimens. So I -- and it's bismuth-213. So, I 16 mean, I don't know. 17 Q. So at that level of radiation, is it 18 really -- strike that. 19 So what justification can you think of for 20 having that much radiation to give to a mouse? 21 MS. CIPRIANO: Objection; scope and calls for 22 speculation. 23 A. I did not design that study, so... 24 Q. Do you do work with mice? 25 A. I do work with mice.
150 1 They are. Okay. They are. 2 Q. So, again, Chatalic's data doesn't show that 3 the 213 bismuth PSMA I&T and the 213 bismuth JVC 008 are 4 better or worse than each other, correct? 5 A. That's correct. It doesn't suggest that. 6 Q. Okay. I want to ask you about -- in the 7 second paragraph under "Methods," the third line, she 8 says "Mice engrafted with LNCaP tumors were injected 9 with 5 MBq 213 bismuth-PSMA-I&T." Do you see that? 10 A. I do. 11 Q. 5 MBq is 5 megabecquerels? 12 A. That's right. 13 Q. Does that seem like a lot to give to mice? 14 A. No, not necessarily. 15 Q. Could you turn to the '901 patent. 16 And if you would look at Claim 1 and go to 17 Column 20. 18 A. What page is this on, please? 19 Q. This would be page 19. Column 20 is the 20 right-hand column on page 19. 21 And if you go down to the text past the 22 images, it says "Wherein, the effective amount of said 23 one or more Ac 225 radiopharmaceuticals is administered 24 as a dosage of from 25 kBq to 400 kBq kilograms of body 25 weight." Do you see that?	152 1 Q. Do you work with cell cultures? 2 A. I work with cell cultures. 3 Q. And have you ever given this much radiation 4 to a mouse? 5 MS. CIPRIANO: Objection; scope. 6 A. Possibly. I don't know. 7 Q. Have you ever given this much of an alpha 8 emitter to a mouse? 9 A. I don't know. I've done a lot of studies, 10 so... 11 Q. All right. Another question. So bismuth 12 here is described as an alpha radionuclide -- sorry -- 13 nuclide therapy of prostate cancer, correct, in the 14 Chatalic paper? 15 A. That's right. 16 Q. But, in fact, bismuth isn't just an alpha 17 emitter, is it? 18 A. I don't have the exact decay chain for 19 bismuth. Possibly there are some other branching 20 emission. I don't know. 21 Q. Okay. Let me see. 22 All right. I'm going to give you 23 Exhibit 1017. 24 Is it -- no, I guess I won't, then -- yes, I 25 will. This is Exhibit 1017 from your declaration.

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153 1 (Exhibit Number 1017 introduced.) 2 Q. So look at page 14. 3 So do you see Figure 8 on page 14? 4 A. Yes. 5 Q. It represents the 213 bismuth decay chain? 6 A. That's right. 7 Q. When we look at this -- and correct me if I'm 8 wrong. But when we look at Figure 8, we see that 9 bismuth emits an alpha particle 2.2 percent of the time. 10 Is that correct? 11 A. That's correct. 12 Q. And it emits a beta particle 97.8 percent of 13 the time, correct? 14 A. That's correct. 15 Q. And then it becomes 84 PO and almost 16 immediately emits an alpha particle, correct? 17 A. 213 PO, yes. That's correct. 18 Q. Oh, 213 PO. Sorry. Thank you. 19 So that means that 97.8 percent of the time 20 an alpha particle emitted because you have bismuth 21 present is preceded by a beta particle, isn't it? 22 A. That's correct. 23 Q. So doesn't that represent a significant 24 confound in understanding how an alpha particle would 25 work for this molecule?	155 1 A. Well, I don't know. In this particular 2 abstract, no. But I will point out that the authors 3 here are the same authors -- or the same people as on 4 the patent and on several references that you've -- that 5 we've discussed already, so... 6 Q. I'm sorry. Which patent are you talking 7 about? 8 A. The patent. Three of the authors on this 9 abstract are on the patent. 10 Q. Yeah. 11 A. So they -- I mean, you know -- we could argue 12 whether it's the beta or the alpha emission, but from 13 this particular study, I don't know what they would -- 14 what they inferred actually. They did infer that it was 15 an effective, promising treatment. 16 Q. But you can't infer that it's necessarily 17 because of the alpha particle, can you? 18 A. I think you may, because they talk about the 19 tracks -- the alpha tracks. So potentially, yes. 20 Q. What alpha tracks do you mean? 21 A. I mean that alpha particles are known to 22 cause more DNA double strand breaks than beta particles, 23 and this is what they are discussing in their results. 24 So, again, I -- you know, I think they made that 25 conclusion that it was the alpha particle.
154 1 MS. CIPRIANO: Objection to form. 2 A. I mean, I'm not sure we are looking for 3 understanding how the alpha particle works here, but... 4 Q. Well, wasn't the point of his experiment to 5 show that the use of the B1 -- sorry -- the 6 213 bismuth-labeled PSMA-targeting agents for alpha 7 radionuclide therapy of prostate cancer? 8 A. Right. 9 Q. So if you have a beta particle preceding 10 every alpha particle, or virtually every alpha particle, 11 can you really decide whether or not alpha particles are 12 a useful method of therapy? 13 A. I mean, you could probably infer some 14 conclusions. Yes. Because there's always an alpha 15 particle in addition, in this case, to the beta 16 particle. I mean, I'm not sure where you're trying to 17 go, so I don't know what you're trying to ask. 18 Q. Well, what I'm asking is: Can you conclude 19 from this that alpha particles are effective at causing 20 the DNA breakage that he's seeing if every alpha 21 particle is preceded by a beta particle? 22 A. If you see more damage than you would with a 23 single beta emitter, probably that means you'd need to 24 see other data out there. 25 Q. So he doesn't do that, though, does he?	156 1 Q. But they don't have any evidence it was the 2 alpha particle. It could have been the beta particles 3 as well. 4 A. There is no evidence in the abstract. 5 Q. I think that's my point. 6 A. Okay. That's your point. 7 Q. So there's no evidence in this abstract 8 showing whether or not the damage was caused by beta 9 particles or alpha particles. 10 MS. CIPRIANO: Objection; misstates her 11 testimony. 12 A. I -- no. No. 13 Q. So, in fact, their usage of the five 14 megabecquerel dosage is something closer that's used for 15 beta emitters, isn't it? 16 A. It's closer than -- to what? Than what you 17 end up using with actinium? 18 Q. And correct me if I'm wrong. There's no 19 mention of actinium in this abstract, right? 20 A. That's correct. 21 Q. Okay. All right. I'd like you to look at 22 Exhibit 1011 on your declaration. 23 (Exhibit Number 1011 introduced.) 24 Q. Do you recognize this document? 25 A. I do.

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157 1 Q. What is this document? 2 A. It's a journal paper that was cited in the 3 declaration. 4 Q. Okay. And this is entitled "Phase I Trial of 5 Targeted Alpha-Particle Therapy with Actinium-225, 6 Lintuzumab and Low-Dose Cytarabine, LDAC, in Patients 7 Age 60 or Older with Untreated Acute Myeloid Leukemia." 8 Is that correct? 9 A. That's correct. 10 Q. And this is -- the first author is 11 Joseph G. Jurcic. Is that correct? 12 A. That's correct. 13 Q. So what is Dr. Jurcic doing in this 14 experiment? Can you explain this to me? 15 A. They're reporting a dosing regimen for an 16 actinium antibody targeting construct. 17 Q. And what is that dosing regimen? 18 A. It's looking at fractionated doses, so 19 several doses separated in time. 20 Q. And is there anything else included in the 21 dosage? 22 A. It's combined with -- it's combined with 23 another three agents to prevent nephrotoxicity, mostly. 24 Q. And why would that be included? 25 MS. CIPRIANO: Objection; calls for	159 1 would be that the 225-Ac Lintuzumab doesn't do anything. 2 A. That's right. But -- 3 MS. CIPRIANO: Objection; incomplete 4 hypothetical. 5 A. But this reports that they are not the same. 6 Q. Well, do we have an example where they don't 7 have the LDAC? 8 A. There is a reference to data with LDAC alone 9 with different results. 10 Q. But we don't see that here, do we? 11 A. We don't see that here. It's referenced. 12 Q. Okay. Now, in this case, I think you 13 mentioned before they're using Lintuzumab. Not a small 14 molecule, correct? 15 A. That's correct. 16 Q. And this is for treating leukemia, correct? 17 A. That's correct. 18 Q. And leukemia doesn't have PSMA receptors on 19 it, does it? 20 A. I don't believe so. 21 Q. So what we have here is a different type of 22 molecule, a different binding site, a different 23 receptor, and a different type of cancer. 24 A. That's right. 25 Q. Correct. Okay.
158 1 speculation. 2 A. Because as we've discussed before, with an 3 antibody, there may not be a hundred percent uptake in 4 the cancer cells. There may be some residual 5 actinium-225 that will accumulate other places. 6 Q. So they were expecting kidney damage to 7 possibly occur. Fair assessment? 8 A. It's fair. 9 Q. What is the "LDAC" in the title? 10 A. What is it for? Or, I mean -- I don't know 11 what it's for. 12 Q. So they're not just giving the 13 225-Ac-Lintuzumab. They're also giving a low dose of 14 cytarabine, aren't they -- 15 A. That's right. 16 Q. -- alongside it? 17 And so when we look at the results for this 18 study, how do we know whether the results were caused by 19 the LDAC, the low-dose cytarabine, or the 20 225-Ac-Lintuzumab? 21 A. You compare the results with other data where 22 you have only one agent, like the LDAC. 23 Q. Okay. And if I were to compare it to other 24 data where it's only the LDAC and I find that the 25 results are the same with the LDAC alone, my conclusion	160 1 Additionally, this leukemia is a purely 2 liquid cancer, correct? 3 MS. CIPRIANO: Objection; misstates the 4 record. 5 A. I mean, I would make the same argument as the 6 purely solid tumors that we discussed earlier. So sure. 7 Q. Well, do you know of leukemia ever being a 8 solid tumor? 9 A. I don't know if it's always alone without any 10 solid tumor, so... 11 Q. Well, you're not really a cancer physician, 12 correct? 13 A. That's right. 14 Q. So your experience as far as treating cancers 15 and dealing with them is fairly limited, correct? 16 A. That's right. 17 Q. So given your earlier statement that the 18 combination of the radionuclide, the ligand, the linker, 19 and the chelator each are key, a person of skill 20 wouldn't look at something like Jurcic and think to 21 combine it with something that is completely different 22 like the PSMA-I&T, would they? 23 MS. CIPRIANO: Objection; misstates the 24 record. 25 A. I think they would. I think -- each

161 1 component is important. The combination is not 2 necessarily unexpected. So I think that they would 3 think of combining actinium-225 and something completely 4 different from Lintuzumab. 5 Q. But given the fact that this molecule that 6 they're describing, which is an antibody binding to a 7 different site -- 8 A. That's right. 9 Q. -- which is used for a completely different 10 cancer, there's nothing here that would guide a person 11 of skill in the art to necessarily assume that anything 12 from this could be carried over to a wholly different 13 molecule and work at the same level, correct? 14 A. Again, I think we've touched on this before. 15 Maybe from this particular report alone, maybe not. But 16 with the combination of reports that were available, I 17 believe they would. 18 Q. But the combination of reports that you're 19 talking about -- we have Chatalic that did not use 20 actinium, correct? 21 A. That's correct. 22 Q. We have the Weinenssens which did not use 23 actinium, correct? 24 A. That's correct. 25 Q. And we're just left with Miederer and Jurcic	163 1 thinking about actinium. 2 MS. CIPRIANO: Objection; relevance, calls 3 for speculation. 4 A. I'm not assuming anything. I'm saying that a 5 person of skills would think of using actinium-225 based 6 on the available literature with PSMA-I&T. 7 Q. Now, again, you aren't a cancer physician, 8 right? 9 A. That's right. 10 Q. But you would understand that it would be odd 11 for somebody to want to take a drug that works on one 12 cancer and assume it's going to work exactly the same 13 way on a different cancer. 14 A. But it's not the same drug. It's a component 15 in a radiopharmaceutical. Again, it's a combination of 16 different parts, and the radionuclide is important. And 17 there is no reason to think that if it is working in a 18 specific construct for a specific cancer, that it may 19 not work for another cancer in another construct. 20 Q. But there's no reason to think that it would 21 necessarily work in another cancer in -- 22 A. I think there is. 23 Q. -- another construct? 24 A. I think there is. 25 Q. And what evidence is that?
162 1 which both use actinium, correct? 2 A. That's correct. 3 Q. But they use them for completely different 4 cancers on completely different molecules for completely 5 different receptors, didn't they? 6 MS. CIPRIANO: Objection; misstates the 7 record. 8 A. They did. However, here, in this particular 9 abstract, they say "The therapeutic efficacy could be 10 significantly enhanced by using alpha-emitting 11 radionuclides." You know, to me, this is evidence that 12 they would. Here, they talk about bismuth-213 as an 13 alpha-emitting radionuclide, and then in the next report 14 they would pick actinium-225 when available. 15 Q. But didn't you point out that the authors in 16 the Chatalic were the same authors as in the patent? 17 Who had access to Ac? 18 A. That's right. 19 Q. So they had access to actinium, but they 20 chose to use bismuth-213. 21 A. I do not know the sequence of events. So 22 they may have chosen to do both at the same time and 23 report one or not. Yes. They reported bismuth-213. 24 Q. And yet you are willing to assume that they 25 were going to use actinium next or they were still	164 1 A. This is how we build radiopharmaceuticals is 2 using the radionuclides in different targeting 3 constructs. 4 Q. So a mix-and-match approach. 5 A. That's right. 6 MS. CIPRIANO: Objection; speculation. 7 Q. So your testimony is that when producing 8 radiopharmaceuticals, you take bits and pieces of 9 everything, and you kind of put them together, and you 10 see just whatever works. 11 MS. CIPRIANO: Objection; argumentative. 12 A. No, that's not what I said, not whatever 13 works. What makes sense is that there is a targeting 14 moiety that we know is a good targeting moiety. There's 15 a chelator that we know is a good chelator for a 16 specific radionuclide. There's a radionuclide that we 17 know has more potential to deliver ionizing radiation in 18 a cell. And there is a linker that we know can be used 19 to conjugate a chelator to a targeting moiety. And 20 we -- yes. Then it's a matter of understanding which 21 one could come together. 22 Q. But Weisen showed that if you take a 23 molecule that works and you replace out the nuclide with 24 another one, it's not necessarily going to work the 25 same.

165 1 A. Because in this case, they used gallium and 2 lutetium, which are two different metals in the same 3 chelator. 4 Q. And isn't actinium a different metal from 5 lutetium and gallium? 6 A. It is a different metal, but actinium is an 7 f-element on the same element series as lutetium. So 8 its coordination chemistry is closer to that of lutetium 9 than gallium is. 10 Q. But it's still a different metal, right? 11 A. It's a different metal but with closer 12 coordination properties to lutetium than gallium does to 13 lutetium. 14 Q. And so your argument is that actinium and 15 lutetium would work the same in the molecule? 16 A. There is a higher probability that they work 17 the same way than there is for gallium and lutetium. 18 Yes. 19 Q. I want you to look at -- 20 MS. CIPRIANO: So before -- I think it could 21 be a good time for a bio break. 22 MR. BOETTICHER: Okay. 23 MS. CIPRIANO: But I don't -- if you want to 24 continue, we can go for a little bit longer, or we 25 can --	167 1 Q. And when we talk about absorbed dose, many 2 times we're focusing on the amount of dose that is 3 absorbed by the tumor, correct? 4 A. No. Sometimes it's other organs too. But we 5 define the body that is -- the mass that is being -- 6 absorbing the dosed. 7 Q. When we're giving a radiotherapy, our goal, 8 if I understand correctly, is to try to get as much of 9 the dose to the tumor as possible, correct? 10 A. Correct. 11 Q. And so there's a difference between the 12 administrative dose and the absorbed dose of the tumor 13 because the radiation or the radiotherapeutic is lost in 14 various ways. It breaks down. It leaves the chelator. 15 It doesn't bind properly, for example. Correct? 16 A. That's correct. 17 Q. And also, what affects the difference is the 18 ability of the -- if it's a targeted radiotherapeutic -- 19 to bind to or be internalized. 20 A. That's correct. 21 Q. Because different therapeutics will have 22 different rates of internalization and binding, correct? 23 A. That's correct. 24 Q. And different tumors might have different 25 rates of internalization.
166 1 MR. BOETTICHER: No, we can pause. 2 MR. HASAN: We can take a break. Yeah, no 3 problem. 4 MS. CIPRIANO: Okay. 5 (Off the record: 3:24 p.m. to 3:30 p.m.) 6 Q. What's absorbance dose? 7 A. Absorbance dose? Or absorbed dose? 8 Q. Absorbed dose, absorbance dose. Is there a 9 difference? If there is -- 10 A. I don't know -- 11 Q. -- go ahead and tell me. 12 A. -- what an absorbance dose is. 13 Q. Okay. 14 A. But absorbed dose is the amount of deposited 15 ionizing radiation per unit mass in whatever is being 16 irrigated. 17 Q. Okay. And that differs from the 18 administrated dose. 19 A. That's right. 20 Q. And in what way? 21 A. I believe people talk about administered 22 activity, rather than dose, as the amount of 23 radionuclide that is being administered. And absorbed 24 dose would be the amount of radiation absorbed per unit 25 mass.	168 1 A. That's correct. 2 Q. So if you are looking at the internalization 3 and binding to one tumor with one molecule, you can't 4 assume that you're going to have the same 5 internalization and binding with another molecule of 6 another tumor, correct? 7 A. Correct. 8 MS. CIPRIANO: Objection; incomplete 9 hypothetical. 10 A. Correct. 11 Q. I'm going to show you Exhibit 1031 to your 12 declaration. 13 (Exhibit Number 1031 introduced.) 14 Q. Do you recognize this document? 15 A. I do. 16 Q. What is this document? 17 A. It is a conference abstract that I referenced 18 in the declaration. 19 Q. Okay. And this is entitled "Ac-225-DOTATOC, 20 an empiric dose finding for alpha particle emitter based 21 radionuclide therapy of neuroendocrine tumors," correct? 22 A. That's correct. 23 Q. And the first author is Clemens Kratochwil, 24 correct? 25 A. That's correct.

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169 1 Q. So in this, in the first paragraph, they say 2 "There's no established dosimetry tools to predict 3 toxicity of targeted alpha therapy." And it says that 4 they conducted an empiric dose escalation to find the 5 maximum tolerable dose. Do you see that? 6 A. I do. 7 Q. So remind me again. What would they mean by 8 the "maximum tolerable dose" in this case? 9 A. I would read this maximum tolerable dose as 10 the highest dose at which toxic effects do not 11 accelerate death. 12 Q. And so this is different from an effective 13 dose, correct? 14 A. That's correct. 15 Q. Or an efficacious dose, correct? 16 A. That's correct. 17 Q. And when you're determining the dose, 18 sometimes to increase the efficacy of a pharmaceutical, 19 you also end up increasing the -- increasing it towards 20 the tolerable dose. Is that correct? 21 A. Can you say that again? 22 Q. So sometimes -- strike that. 23 When determining the proper dose, there's a 24 trade-off between efficacy and tolerability. 25 A. That's correct.	171 1 A. That's correct. 2 Q. Neuroendocrine tumors do not have PSMA 3 receptors, correct? 4 A. Correct. They're not targeted for PSMA 5 receptors. 6 Q. And so somebody looking at this wanting to 7 use actinium would not use the doses found in this paper 8 to determine the doses for PSMA-I&T actinium, correct? 9 A. Not necessarily correct. I think this is a 10 piece of data that could be used as information, 11 together with other data, to determine the dose -- the 12 dosing regimen for an actinium-PSMA compound. 13 Q. But they couldn't use it to determine what 14 the effective dose of a PSMA-I&T-actinium compound is, 15 could they? 16 A. So these reports say that the dose also 17 demonstrates promising treatment efficacy in various 18 patients. So not only is it an assessment of 19 tolerability, it also became an assessment of efficacy. 20 Q. And what numbers do they give for efficacy? 21 A. Well, they give numbers saying that it also 22 demonstrated promising treatment efficacy in various 23 patients. So that particular regimen demonstrated 24 efficacy. 25 Q. What numbers do they give for efficacy?
170 1 Q. And the reason is because you want to 2 increase the dose to the point where it's efficacious, 3 but you're getting it closer to that limit of 4 tolerability, correct? 5 A. That's correct. 6 Q. But the two doses of efficacy and 7 tolerability are not the same, correct? 8 A. That's correct. 9 MS. CIPRIANO: Objection; incomplete 10 hypothetical. 11 Q. The point of efficacy could be much lower or 12 much higher than the tolerable dose. 13 A. That's correct. 14 Q. So when somebody determines what the maximum 15 tolerable dose is, it doesn't tell you what the 16 efficacious or effective dose is, correct? 17 A. That's correct. 18 Q. Now, in this case, Dr. Kratochwil is using 19 the molecule DOTATOC. 20 A. That's right. 21 Q. And we've discussed before that DOTATOC is 22 not a PSMA ligand, correct? 23 A. That's correct. 24 Q. And he's using it on neuroendocrine tumors, 25 correct?	172 1 MS. CIPRIANO: Objection; asked and answered. 2 A. It says "Multiple fractions were tolerated 3 with 25 megabecquerel every four months or 4 18.5 megabecquerel every two months. This protocol also 5 demonstrated promising treatment efficacy in various 6 patients." 7 Q. Which section are you reading? 8 A. I'm looking at the conclusions. "We present 9 a well tolerable treatment protocol for TAT with 10 actinium-225-DOTATOC in NET patients that also 11 demonstrated promising treatment efficacy in various 12 patients." 13 Q. Okay. So they don't provide any numbers for 14 what efficacy would actually be, correct? 15 A. Not in the same sentence, that's correct. 16 Q. They don't provide any numbers as to what 17 efficacy would be. 18 A. They provide numbers for a protocol that they 19 referred to as demonstrating promising treatment 20 efficacy. 21 Q. The numbers they provide are what were 22 tolerated, weren't they? 23 MS. CIPRIANO: Objection; misstates the 24 document. 25 A. Yes. It was also tolerated.

173 1 Q. So you're saying here that the toleration 2 level is the same as the efficacy level? 3 A. No. I am saying that within the window of 4 tolerability there was some efficacy demonstrated. So 5 the window of efficacy overlapped with the window of 6 tolerability. 7 This is not a specific dose. There has to be 8 a range. And the range of tolerability overlapped with 9 the range of efficacy because a tolerable treatment 10 protocol demonstrated promising treatment efficacy. 11 Q. But you don't know where that overlap is, 12 correct? 13 A. I don't know exactly where that overlap is. 14 That's correct. 15 Q. Now, you say that it was promising treatment 16 efficacy, but -- 17 A. I don't say it. It's written in the paper. 18 Q. Okay. All right. But that doesn't mean that 19 the efficacy was necessarily tested. It just means that 20 the radiopharmaceutical is promising, correct? 21 A. No. It means that the study was designed to 22 test tolerability, but the data and the results provided 23 efficacy -- the results provided efficacy data. 24 Q. But a person of ordinary skill reading this 25 wouldn't know where that range is for efficacy.	175 1 A. That's right. It gives me a number. 2 Q. Okay. And so we don't know where efficacy 3 falls below that number or above that number. 4 A. That's correct. 5 Q. And the fact remains that this efficacy 6 was -- or this tolerability was determined -- let me 7 start over again. 8 The fact remains that this tolerability was 9 determined for DOTATOC for treating neuroendocrine 10 tumors, correct? 11 A. That's correct. 12 Q. So you wouldn't -- a person of skill would 13 not carry over those numbers to some other completely 14 different molecule. 15 A. A person of skill would take this as a 16 starting point to design a study to assess the 17 tolerability and efficacy of another actinium molecule. 18 Q. So you're saying they would do that even 19 though they would understand that DOTATOC is different 20 from, say, PSMA-I&T. 21 A. That's right. 22 Q. And even though the uptake would be 23 completely different for PSMA-I&T, right? 24 A. I don't know that the uptake would be 25 completely different. Again, we need to look at the
174 1 A. They would know that those numbers fall in 2 the range. They wouldn't know the extent of the range. 3 Q. So these numbers are upper limits for 4 tolerability. 5 MS. CIPRIANO: Objection; misstates the 6 document. 7 Q. So it says "The MTD of a single cycle 8 Ac-225-DOTATOC was considered to be 40 megabecquerels." 9 That's not a range. That's an upper limit, correct? 10 A. Correct. That's correct. The second 11 sentence -- 12 Q. And then it says, "Multiple fractions were 13 tolerated with 25 megabecquerel every four months." And 14 that's an upper limit for a four-month -- 15 A. That is not an upper limit. It's not an MTD. 16 It says "Multiple fractions were tolerated." It's a 17 tolerable dose. It doesn't say it's a maximum tolerable 18 dose. This 25 megabecquerel every four months. 19 Q. Okay. But it's not a range. It's an upper 20 limit. 21 A. It is a number that falls in the tolerability 22 range. It's not an upper limit. It's not given as an 23 upper limit. 24 Q. Okay. But it doesn't give you a range when 25 it says "25 megabecquerel every four months."	176 1 context. 2 Q. It could be completely different, though. 3 They don't know that it's the same, right? 4 A. It could be, or it could be very close. And 5 we know that there was data available at the time where 6 you could compare DOTATOC and PSMA-I&T with the same 7 radionuclides and look at the uptake. And so combining 8 this with a knowledge of the clearance and the uptake of 9 the small molecule will give you a good range to start 10 with. 11 MR. BOETTICHER: I'm sorry. Could you read 12 back her answer. 13 (The record was read.) 14 Q. So there wasn't any data in which actinium 15 was used with DOTATOC and PSMA. 16 A. That's right. 17 Q. Okay. So the person of skill wouldn't be 18 able to make that kind of conclusion concerning actinium 19 because they didn't have those parameters that you just 20 described. 21 A. Well, there was data with 22 lutetium-177-DOTATOC and lutetium-177-PSMA-I&T. And 23 there was a data with actinium-225-DOTATOC and 24 lutetium-177-DOTATOC. So this is about pharmacokinetic 25 modeling and dosimetry.

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177 1 Q. But we've already concluded from Weineisen 2 that when you use a different radionuclide it could 3 change the entire nature of the molecule and its 4 binding. 5 A. Looking at gallium and lutetium, which are 6 two completely different metals. And we've already 7 discussed that actinium and lutetium would have closer 8 properties than gallium and lutetium. 9 Q. But you don't know what the actual effect 10 would be, do you? 11 A. No. I wouldn't know what the effect is until 12 I test it. 13 Q. Okay. So I want to go back to -- I want to 14 go back to your 2022 paper. 15 Could you look at page 5. Under Section 3, 16 "Dosimetry," in that first paragraph, there is a -- 17 let's see. On the sixth line, there is a sentence that 18 begins "While" right after the reference to 1661. Do 19 you see that? 20 A. Yes. 21 Q. Okay. So the sentence reads "While 22 radiobiology and dosimetry for external-beam 23 radiotherapy are well established, their direct 24 extrapolation to a targeted radiotherapy is problematic, 25 as the characteristics of the latter are rather	179 1 MS. CIPRIANO: Objection to the extent it's 2 not talking about what this document says. 3 A. They may be different. That's correct. 4 Q. Okay. And in the next paragraph down, at the 5 front -- in the beginning it says "In the case of 6 targeted alpha therapy, dosimetry calculations are more 7 challenging than other types of targeted radiotherapy 8 since the daughters need to be considered and they may 9 have different pharmacokinetic profiles and chemical 10 profiles." Do you see that? 11 A. I do. 12 Q. And so in this case, this could be talking 13 about actinium, which has multiple daughters, correct? 14 A. That's correct. 15 Q. Okay. So in your declaration, did you 16 consider the factors -- secondary factors? 17 MS. CIPRIANO: Objection; calls for a legal 18 conclusion. 19 A. Did I consider secondary factors. Is this 20 the end of the declaration that we're talking about? 21 Q. I believe it is at the end of your 22 declaration. Yes. 23 A. I considered a lot of other things that are 24 not in the declaration. Is that what we call secondary 25 factors? Secondary considerations? Is that right?
178 1 different, i.e., mixed and heterogeneous irradiation, 2 long exposure times, and low absorbed dose rates." 3 So are you referring here to the idea of 4 trying to figure out the absorbed dose for targeted 5 therapy? 6 MS. CIPRIANO: Objection; relevance. 7 A. I am referring here to the difference between 8 external-beam radiotherapy and radiopharmaceutical 9 therapy. 10 Q. Right. But you're talking here about the 11 radiotherapy -- the targeted radiotherapy, and you're 12 saying it's problematic because of these factors in the 13 parentheses. 14 MS. CIPRIANO: Objection; misstates the 15 document. 16 Q. Mixed and heterogeneous irradiation, long 17 exposure times, and low absorbed dose rates. Isn't that 18 right? 19 A. That's right. 20 Q. Okay. And so these are factors that go into 21 the ultimate exposure of the tumor to the radiation, 22 correct? 23 A. That's correct. 24 Q. And these will be different from molecule to 25 molecule and tumor to tumor, correct?	180 1 Q. There's a lot of different names for it, 2 objective factors, secondary -- 3 A. I did consider some secondary factors. Yes. 4 Q. Oh, you did? So what secondary factors did 5 you consider? 6 A. I mean, I don't know. There are a lot of 7 other literature out there to consider. Right? 8 Q. So did your counsel -- so were you made aware 9 of what secondary considerations are? 10 MS. CIPRIANO: So objection to the extent it 11 calls for privileged information. 12 But you can answer the question to the extent 13 you understand it. 14 A. So my understanding is that there are other 15 considerations in addition to the existing literature to 16 assessing whether something is novel and worth 17 patenting. So yeah. 18 Q. Okay. Did you consider unexpected results? 19 A. I considered the possibility of unexpected 20 results. Yes. 21 Q. Okay. What did you conclude? 22 A. I did not believe that the results or the 23 claims in the patents were unexpected. 24 Q. And why was that? 25 A. Because, as we've discussed all day, I think

181 1 a person of skills would have thought of using 2 actinium-225, and the proposed treatment regimen would 3 have been the starting point based on the available 4 literature at the time. 5 Q. Did you -- so amongst the secondary factors 6 is also commercial success. Did you do any research on 7 commercial success? 8 A. I did not do research on commercial success. 9 Q. So let me ask you this. If there were 10 license offers or multiple license offers for the 11 technology in this patent, would you consider that a 12 commercial success? 13 MS. CIPRIANO: Objection; scope, outside of 14 the scope of her expertise. 15 A. I'm not sure I'm qualified to say what is or 16 is not a commercial success per your definitions. I 17 don't know. 18 Q. Okay. So are you saying that you wouldn't be 19 able to opine on secondary considerations? 20 MS. CIPRIANO: Objection; misstates the 21 testimony, calls for a legal conclusion. 22 A. I would not be able to opine on whether this 23 technology is a commercial success at this point. 24 Q. Do you have any understanding why a third 25 party would want to license a patent that is invalid or	183 1 antibodies as information and the comparison between 2 lutetium-177-DOTATOC and lutetium-177-PSMA-I&T. 3 Q. Lutetium-177-DOTATOC and lutetium -- 4 A. -- 177-PSMA-I&T. 5 Q. And which reference is that that makes that 6 comparison between -- 7 A. There is no direct comparison in a single 8 reference. This is based on my reading of all of those 9 different references that were available at the time. 10 Q. So you're relying on the Kratochwil reference 11 in which he studies the Ac-225-DOTATOC, correct? 12 A. That's correct. 13 Q. So even though that is for a different 14 molecule, a different receptor, and a different cancer, 15 you're relying on that for the dosage. 16 MS. CIPRIANO: Objection; asked and answered. 17 A. I'm relying on that as a piece of 18 information. Yes. 19 Q. Okay. And so based on Kratochwil -- start 20 there -- what dosage is he teaching? 21 A. I'm just going to read in the declaration, 22 because all of the doses are laid out here on the 18 5 23 megabecquerel every two months and 25 megabecquerel 24 every four months that were well tolerated. So they're 25 within the range of tolerability and also within the
182 1 obvious? 2 MS. CIPRIANO: Objection; calls for a legal 3 conclusion, outside the scope of her declaration. 4 A. I didn't know you could license an invalid 5 patent. So no. I don't have an understanding of that. 6 Q. So your assumption is that they wouldn't want 7 to license an invalid or obvious patent, correct? 8 MS. CIPRIANO: Same objections. 9 A. I don't know. I'm not assuming anything. I 10 just don't know. 11 MR. BOETTICHER: Okay. Can we take a break 12 for a little bit? 13 MS. CIPRIANO: Sure. 14 (Off the record: 3:56 p.m. to 4:07 p.m.) 15 MR. BOETTICHER: On the record. 16 Q. So I just want to make sure I'm clear on a 17 couple of things, and then hopefully I can let you go. 18 Thank you for your time today. 19 So on the issue of the dose that is claimed 20 in the patent, what -- I just want to be clear on what 21 prior art you're relying on that would teach that 22 particular dose in those patent claims. Can you help me 23 understand that better? 24 A. I am relying on the doses suggested for 25 actinium-225-DOTATOC as well as what was available for	184 1 range of efficacy, because they do allude to 2 demonstrated treatment efficacy at those doses. 3 Q. And those would be what's called a unitary 4 dose, right? 5 A. That's right. 6 Q. Okay. Now, what if the unitary dose had been 7 less in the patent claims? 8 MS. CIPRIANO: Objection; calls for 9 speculation, incomplete hypothetical. 10 A. Well, so there's more to this, right? This 11 is -- I think we're looking at a range of doses that are 12 provided. 13 Q. Uh-huh. 14 A. And so there is other available data, right? 15 There's -- I think we looked at this reference, right? 16 The Jurcic reference as well? 17 Q. The Jurcic reference which is the antibody, 18 right? 19 A. Was it the one? 20 Yes. 21 Q. So, again, you have a completely different 22 cancer. You have a completely different structure. You 23 have a large molecule instead of a small molecule. 24 A. That's right. 25 Q. You have it being used alongside LDAC, and

185 1 you have it binding to a completely different receptor. 2 A. That's right. 3 Q. Okay. But you think this would teach the 4 dose range for PSMA-I&T. 5 A. It would teach -- it would provide other 6 information for deciding what dose would be effective 7 for PSMA-I&T and safe. And as we've discussed, the 8 thinking, I believe, would be that with a larger 9 molecule and antibody, there is probably less uptake 10 than with a small molecule and the longer circulation 11 time, so more possibility for side effects. Meaning 12 that if the dose is deemed safe with an antibody, it is 13 very likely going to be safe with a smaller molecule. 14 So yes. It would teach something about the dose. 15 Q. So when you say "safe for an antibody," 16 you're looking at the level of radiation exposure, 17 right? 18 A. Yes. 19 Q. But you don't know what is efficacious. 20 A. That's right. 21 Q. Okay. And so what dosage does Jurcic teach? 22 A. There are four different doses, I believe, 23 and they are per kilogram. They're not unitary doses, 24 so we'd have to convert them. 25 Q. So what dose do you get out of Jurcic?	187 1 Q. No. I mean, what if it turned out that 2 Jurcic's -- the data was off because he doesn't have an 3 example without LDAC? 4 MS. CIPRIANO: Objection; incomplete 5 hypothetical, calls for speculation. 6 A. Again, he does refer to additional data that 7 doesn't show efficacy with just LDAC. 8 Q. Have you seen that data? 9 A. I did not look at that data. 10 Q. So, again, I ask. What if it turns out that, 11 looking at that data, looking at other data, it wasn't 12 effective? 13 MS. CIPRIANO: Objection; calls -- 14 Q. Would you still hold to those numbers? Or 15 would you throw out Jurcic? 16 MS. CIPRIANO: Objection; incomplete 17 hypothetical, calls for speculation. 18 A. I would still keep those numbers, because it 19 also referred to safety and tolerability. 20 Q. But safety and tolerability, as we discussed 21 before, is separate from efficacy. 22 A. Right. Right. So I wouldn't throw it out 23 because I would still want to know. Again, I think 24 nobody wants to look for the window of efficacy alone 25 without the window of tolerability or the window of
186 1 A. Well, here, there were four doses that were 2 determined to be safe and effective between 18.5 and 3 74 kilobecquerel per kilograms. 4 Q. Can you direct me to that number? 5 A. So they're microcurie per kilograms. So we'd 6 have to do the -- we did the conversion in here. So .5, 7 1, 1.5, and 2 microcurie per kilogram per fraction. 8 Q. Okay. So you're saying that Jurcic teaches, 9 for an antibody, 18.5 through 74? 10 A. Kilobecquerel per kilogram, uh-huh. 11 Q. Okay. So what if the dose range within -- 12 strike that. 13 Again, this level that you're using here, 14 this is assuming it's effective, correct? 15 A. Yes. 16 Q. What if it were found that this was not 17 effective? 18 A. It was found that it was effective here -- in 19 here. 20 Q. But what if it turned out that it wasn't 21 effective? 22 MS. CIPRIANO: Objection; incomplete 23 hypothetical. 24 A. What if it turned out it wasn't effective 25 with PSMA-I&T?	188 1 tolerability alone without knowing a presumed efficacy. 2 So no. I wouldn't throw this out, as you say, but... 3 Q. But the patent claims an effective dose. 4 A. That's right. That's right. Yeah. I mean, 5 there is a claim here that this is effective, so... 6 Q. So what if the amount of dosage claimed in 7 the patent claim was less than 18.5 kilobecquerel? 8 MS. CIPRIANO: Objection; incomplete -- 9 Q. -- per kilogram? 10 MR. BOETTICHER: -- incomplete hypothetical, 11 calls for speculation. 12 A. Well, it's not. The range overlaps. So if 13 you're asking me what if it was an order of magnitude 14 lower, then I would say maybe this is unexpected if you 15 see such high efficacy at such a low level. 16 Q. Okay. And would the same thing hold for the 17 unitary dose, the 25 MBq and the 18.5 MBq? 18 A. I think if I saw an order of magnitude 19 difference, yes. 20 Q. So you mean it would have to be ten times 21 less. 22 A. That's right. 23 Q. All right. So this particular patent, we 24 agree, does not relate to all cancers, correct? 25 A. Correct.

189 1 Q. The field of this patent is just cancers 2 expressing PSMA, correct? 3 MS. CIPRIANO: Objection to the extent it 4 misstates the document. 5 A. Correct. 6 Q. And so when we talk in terms of mixing and 7 matching various elements to make new 8 radiopharmaceuticals, shouldn't we stay within the field 9 of PSMA-expressing cancers? 10 A. Not in my opinion. 11 Q. So do you think it's appropriate to take 12 molecules from cancers that don't involve PSMA and then 13 use those molecules to make decisions about treatments 14 that do involve PSMA-expressing cancers? 15 MS. CIPRIANO: Objection; incomplete 16 hypothetical. 17 A. No. That is not what I meant. I think it is 18 reasonable to consider components of a molecule that is 19 used for different cancer treatments and use that 20 information to apply it to a specific cancer treatment 21 that uses, for example, PSMA-targeting molecules. 22 And you're asking me if within the field we 23 should restrict it. You pointed to one of the reviews 24 that I coauthored. There was a table in there that 25 lists quite a lot of different treatments with different	191 1 lutetium-PSMA-I&T and the bismuth-PSMA-I&T, because they 2 are targeting PSMA. 3 Q. But DOTATOC does not. 4 A. DOTATOC does not. But in this case, it is 5 taken into consideration because it includes a 6 component, actinium-225, that is in the 7 actinium-PSMA-I&T. 8 Q. And so you think that the pieces from one 9 compound can just be switched over to another compound 10 in sort of a mixing-and-matching strategy to see what 11 works. 12 MS. CIPRIANO: Objection; misstates her 13 testimony. 14 A. I think in this case it is important to 15 consider that information. Because it's not only 16 actinium-225. It's the actinium-225 and the chelator 17 that are the same. So it's even more than just one 18 component in this whole construct. 19 Q. And so you consider it obvious because a 20 piece of one component -- let me start that -- you 21 consider it obvious because a component from one 22 molecule could be brought over and made into part of 23 another molecule. 24 MS. CIPRIANO: Objection to the extent it 25 misstates her testimony.
190 1 alpha-emitting radionuclides. And a lot of reviews out 2 there do this. So no. I think we need to be 3 considering data from different molecules whether 4 they're antibodies and peptides -- or peptides, and we 5 need to consider different cancer treatments to have a 6 better informed -- to make a better informed decision on 7 treatment. 8 Q. But in terms of studying whether or not 9 something will work, don't we have to keep in mind that 10 we're looking at PSMA-expressing cancers only? 11 A. We have to keep in mind that we are targeting 12 PSMA-expressing cells. But we have to keep in mind that 13 actinium-225 has specific properties that have been 14 tested under different conditions, and that is useful 15 information. 16 Q. But I'm not talking about the actinium 17 portion of-- 18 A. That's right. 19 Q. -- the issue. I'm talking about the focus on 20 the cancer. So when we're talking in terms of a 21 molecule that's going to be binding to a cancer as part 22 of a therapeutic, shouldn't we focus on those molecules 23 that bind to PSMA? 24 A. That should also be taken into consideration, 25 hence the taking into consideration the	192 1 A. I consider it expected that you would observe 2 efficacy and tolerability with actinium-225 in this 3 particular construct, because there was information 4 about actinium-225 in a different construct and this 5 construct with other radionuclides. It's not just one 6 thing that we're switching. It's that we're switching 7 different components under different conditions, and 8 there's enough evidence all together that points to 9 where it's -- you know, the natural progression of those 10 results. Yes. 11 Q. But, again, you're not a cancer therapist, 12 and you haven't -- you haven't looked at the various 13 treatments that have been used to study different types 14 of cancer, correct? 15 MS. CIPRIANO: Objection; asked and answered. 16 THE WITNESS: Did you ask me not to answer? 17 MS. CIPRIANO: No, no, no. 18 A. I haven't looked at every cancer treatment 19 that's available for treating all cancers. I've looked 20 at many radiopharmaceuticals for different cancer 21 treatments. Yes. 22 Q. But as somebody that's not a cancer 23 specialist, you can't really decide or have a full 24 understanding of what would and wouldn't work within a 25 biological system.

193 1 A. Well, I have -- 2 MS. CIPRIANO: Objection to the extent it 3 misstates her expertise. 4 A. I have an understanding of the effects of 5 radiation on cells. And yes, cancer cells may be 6 different depending on the cancer, but the composition 7 of a cell is a general composition of a cell. I know 8 about how ionizing radiation delivers radiation to the 9 components of the cell and destroys the cells. So yes, 10 there are different cancers and different treatments, 11 but there are commonalities among the treatments and 12 among the cancer cells that leads me to believe that a 13 person of skills would make those inferences. 14 MR. BOETTICHER: Okay. Thank you very much 15 for your time. 16 I'm sorry you had to change your flight. 17 MS. CIPRIANO: That's okay. 18 I do have two questions. 19 MR. HASAN: Yeah, please. 20 EXAMINATION 21 BY MS. CIPRIANO: 22 Q. So, Dr. Abergel, could you look back at 23 Exhibit 1027. It's the Weineisen -- I know -- it's the 24 Weineisen 2014 article. 25 I probably have a clean copy if you can't	195 1 that they are different. 2 Q. And that's in reference to the standard 3 deviation -- 4 A. The standard deviations of the numbers that 5 are presented. Yes. 6 Q. Okay. So it's a statistically significant 7 difference. 8 A. That's right. 9 MR. BOETTICHER: Objection; leading. 10 Q. Okay. And I think -- one more question about 11 this document. 12 Do you recall being asked about whether 13 Weineisen -- I don't remember the exact phrasing -- but 14 whether Weineisen contemplated use of actinium-225? 15 MR. BOETTICHER: Objection; misstates prior 16 testimony. 17 A. I recall -- opposing counsel? Is that how 18 you say it? 19 MR. BOETTICHER: That's the polite way. Yes. 20 A. -- stating that there's no actinium data in 21 this paper and asking me to confirm. That's what I 22 recall. 23 Q. Okay. So there is no data in Weineisen 2014 24 about actinium. That's what you testified? 25 A. That's correct.
194 1 find it. 2 A. It's okay. I'll find it. 3 2014. 4 Q. Did you find it? 5 A. Yeah. 6 Q. Okay. So do you recall being asked about 7 this document earlier today? 8 A. Yes. 9 Q. If you could turn to page 11 of the document. 10 And I believe you were asked about the data 11 in Table 2. Do you -- 12 A. That's right. 13 Q. -- see that? 14 Okay. And please correct me if I'm wrong, 15 but I understood that your answers -- you classified 16 some of the differences in this table as being 17 significant. Do you recall that? 18 A. Yes. 19 Q. When you use the term "significant" in 20 relationship to data and comparing data, what do you 21 mean by "significant"? 22 A. The data from the experiment shows 23 differences. I don't mean -- I don't imply anything 24 about the amplitude of the difference but that they are 25 different when I say "significantly different," meaning	196 1 Q. Now, does that mean -- is it your testimony 2 that Weineisen 2014 does not provide any information 3 about actinium-225? 4 A. I think I said I would have to read the whole 5 paper again in detail to make sure actinium is not 6 mentioned. I believe it's not mentioned, but, again -- 7 yeah. 8 Q. Okay. If you could turn back to page 11. 9 A. I am at page 11. 10 Q. Okay. And in the discussion section. 11 A. It is right there. Okay. Actinium-225 is 12 mentioned in there. 13 Q. Okay. So in the -- and just so the record is 14 clear, nine lines down from the "Discussion" heading, do 15 you see the sentence that begins "Our approach"? 16 A. That's right. "Our approach was therefore 17 focused on the development of a PSMA ligand allowing for 18 both complexation with gallium 68 or indium 111 for PET 19 or SPECT and with therapeutic metal 3 plus radiometals, 20 177-lutetium, yttrium-90, or actinium-225 for 21 endoradiotherapy." 22 MS. CIPRIANO: Okay. Thank you. That's all 23 I have. 24 MR. BOETTICHER: All right. That's it. 25 You're free.

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1 THE WITNESS: Thank you.	
2 MR. BOETTICHER: Thank you.	
3 (Discussion off the record.)	
4 MR. BOETTICHER: So to let you know, we are	
5 going to get an expedited copy of this. We'll get it	
6 tomorrow. But you will get a chance at some point --	
7 probably not between now and then. It would be too fast	
8 for you -- to review the record and to make changes to	
9 it. Okay?	
10 THE WITNESS: Okay.	
11 MR. BOETTICHER: So if you do make changes,	
12 of course, we'll be able to point that out. If there	
13 are changes that are important or changes to the quality	
14 or course of your answer, you know, we'll still be able	
15 to point that out in the briefs or to the PTAB or	
16 whatever. Okay?	
17 THE WITNESS: I understand.	
18 MR. BOETTICHER: All right.	
19 THE REPORTER: Off the record?	
20 MR. BOETTICHER: Off the record.	
21 MS. CIPRIANO: Yeah, off the record.	
22 (Proceedings concluded at 4:33 p.m.)	
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1 CERTIFICATE OF SHORTHAND REPORTER	
2	
3 I, CRYSTAL HEREFORD, Certified Reporter	
4 within and for the State of California do hereby	
5 certify:	
6	
7 That REBECCA ABERGEL, Ph.D., the witness	
8 whose deposition is hereinbefore set forth, was duly	
9 sworn by me before the commencement of such deposition	
10 and that such deposition was taken before me and is a	
11 true record of the testimony given by such witness.	
12	
13 I further certify that the adverse party,	
14 FUSION PHARMACEUTICALS, INC., was represented by counsel	
15 at the deposition.	
16	
17 I further certify that the deposition of	
18 REBECCA ABERGEL, Ph.D., occurred at the OAKLAND MARRIOTT	
19 CITY CENTER, 1001 Broadway, Oakland, California 94607,	
20 on Thursday, November 16, 2023, at 10:15 a.m. to	
21 4:33 p.m.	
22	
23 I further certify the inspection, reading	
24 and signing of said deposition were NOT WAIVED by	
25 counsel for the respective parties and by the witness.	
15 I further certify that I am not related to	
16 any of the parties to this action by blood or	
17 marriage, I am not employed by or an attorney to any	
18 of the parties to this action, and that I am in no way	
19 interested, financially or otherwise, in the outcome	
20 of this matter.	
21	
22 IN WITNESS WHEREOF, I have hereunto set my	
23 hand and affixed my signature this 17th day of	
24 November, 2023.	
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