UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GE HEALTHCARE LTD.,

Petitioner,

V.

THE JOHNS HOPKINS UNIVERSITY,

Patent Owner.

Case No. PGR2025-00059

U.S. Patent No. 12,115,233

Case No. IPR2026-00069

U.S. Patent No. 11,938,201

Deposition of HENRY F. VANBROCKLIN, PH.D.

Washington, D.C.

Wednesday, July 29, 2026

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Reported By: Karen Young

Deposition of HENRY F. VANBROCKLIN, PH.D., held at the offices of:

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Pursuant to notice, before Karen Young, Notary Public in and for the District of Columbia.

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C O N T E N T S

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P R O C E E D I N G S

HENRY F. VANBROCKLIN, PH.D.,

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR GE HEALTHCARE LTD.

BY MR. KUSHAN:

Q Good morning. Can you state your full name for the record?

A My name is Henry Fred VanBrocklin, spelled H-E-N-R-Y, F-R-E-D, V-A-N, capital B-R-O-C-K-L-I-N, all one word.

Q And just explain your affiliations.

A I'm a professor in department of radiology and biomedical imaging at the University of California in San Francisco.

Q Have you ever been deposed before?

A I have been deposed before.

Q How many times?

A Twice.

Q Was it in connection with a patent issue?

A One was a trade secret issue.

Q And the other one was a patent issue?

A The other one was a -- it was many, many

years ago. It was an HR -- HR issue.

Q Okay. Just some ground rules for the deposition. I'll ask you questions. You have to answer my question unless your counsel instructs you to not answer the question for a basis of privilege or work product. One thing I would like you to do -- I was a chemistry major. My intervening years have diluted my ability to accurately describe chemical structures, so if you hear a question from me that is imprecise, wrong, you know, don't hesitate to tell me what is wrong with my question so I can ask you a better question.

A Okay, all right.

Q If you don't understand a question in any other context, just let me know. I'll try to give you a better question.

A Okay.

Q When you answer questions, if it's a yes or no, do it verbally because we have to capture it on the transcript.

A Yes.

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Q All right. If you need a break, just let me know. Typically -- we'll -- typically we'll try to do a break after we've finished kind of a sequence of questions, so if I'm in the middle of a question, we'll just finish the question and get to the -- the point of a break.

A Okay.

Q Just let me know in advance.

A Will do.

Q You understand your oath -- you're under oath, correct?

A I understand that, correct.

Q And are there any reason you cannot give any -- you cannot give truthful testimony today?

A No, there's no reason.

Q No medical issues or anything like --

A No medical issues.

Q Okay. Can you give me an estimate of when you were first contacted by counsel -- well, let me start with the basics. Were you contacted by counsel to work on this matter?

A I was contacted by counsel to work on this

matter.

Q And do you remember when approximately that was?

A It was in early 2025, so probably the -- either late winter, spring 2025.

Q Okay, and who contacted you?

A Olga Partington contacted me.

Q All right. Do you recall just generally what the context of the request to have you work on this would concern?

MS. PARTINGTON: I'm just going to instruct the witness not to disclose any substance of the communication with counsel. Otherwise you may answer.

A As -- as I remember, Olga had contacted me to see if I would be willing to serve as an expert on a patent case, and she presented some of the high-level information, and then we discussed whether or not this would be something that I would be interested in participating in.

Q And then you agreed to proceed with them?

A And then we agreed to proceed, and

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obviously signed documents and things like that to make that happen.

Q Okay. Do you recall -- can you remember approximately how many hours you have worked on this matter? And when I say this matter, their retention of you in connection with these proceedings at the patent office.

A I don't have an exact number, but it's over a hundred hours over the last year, and probably year and a half.

Q Okay. And you recall that you have filed four separate declarations so far in connection with this work?

A Yes.

Q Okay, great. Just so -- I'll get to those in a minute. Just conceptually, there was one that was at the beginning of each case, and there was a second one in that same case, and that was done twice, right?

A Yes, that's correct.

Q Okay. Can you give me a sense of for the later two cases or declarations that you filed, do

you recall there being an overlap between the two in terms of the opinions you were expressing? Like there were two proceedings. The second declaration in each proceeding, I'm just asking if you recall those having overlap in terms of what you were addressing in each of those declarations.

MS. PARTINGTON: Objection, form.

A It's my recollection that yes, there's overlap in those declarations.

Q And the reason I ask that is just to get an understanding, did you -- do you recall doing additional investigations or research between the first one being finished and the second one being finished for that second set of proceedings?

A I remember doing research almost the entire time that we've been working on these declarations, so yes, there was more -- more research was done prior to each declaration being prepared.

Q Okay. I see you have some folders with you. Can you tell me what you brought to the deposition?

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A Yes, so these are clean copies of all four of the declarations.

Q Okay.

A And this is some errata that were identified as we were working and preparing for the deposition.

Q Okay. Just for the -- just so you know, a lot of the exhibits are already marked, so if there's a new document, we'll give it a new number, and I have a starting exhibit number to put on that. Why don't you hand me the errata.

A There's copies for everybody there.

Q All right. Are these just identical copies of the same set of the same set of errata?

A They are identical copies.

MR. KUSHAN: All right. Why don't you mark this as Exhibit 1063.

(Deposition Exhibit Number 1063 was marked for identification.)

BY MR. KUSHAN:

Q Just so -- I'm going to take a quick look at this and then I'll have a couple questions to

make sure I understand it. So as I'm looking at this, you have errata in your -- so Exhibit 2001 is your first declaration in the PGR proceeding, PGR 2025-00059, and then Exhibit 2029 is your second declaration in that PGR proceeding, right?

A That is correct.

Q Okay, and so you have errata for each of those two declarations?

A That is correct.

Q All right, and then there are errata again in Exhibit 2001 of the IPR2026-00069 proceeding, as well as the second declaration in that proceeding, which is Exhibit 2047. So you have errata in each of the four declarations you have filed; is that right?

A That is correct. Some of these were -- some of these appear twice in each of the early dec and the later declaration, and there were just some inconsistencies in the structure, so you can see inconsistency in some of the shading, and there was one -- most of these are structural, and then there was one entry on a table in the Exhibit

2047 in the IPR, so that would have been the second POR.

Q Can you give -- sorry, excuse me.

A Page 8.

Q Page 8, okay.

A Right, there was one -- one change there in the table entry.

Q So that -- that's the change from --

A Yes.

Q -- 6 to 3?

A From --

Q Oh, so 3 --

A Three to 6, correct.

Q All right.

A All the rest are pretty much structural changes in the -- in the chemical structures, and a couple of shading -- shadings that were incorrectly -- incorrectly shaded in the --

Q So --

A -- earlier decs.

Q Could I have you look at page 4?

A Yes.

Q This is the IPR -- sorry, Exhibit 2001 in the IPR. Actually, just pause. So like in that page 4, in the top row, you've moved the carbonyl group from what is shaded as the FAPi part into the -- into the B group part; is that right?

A Yes, in this particular case, the B group did contain the carbonyl, and in the text that goes along with this figure, it was as -- as it is now correctly shaded. That's how it was worded in the text, that the carbonyl was part of the B group, and that's where the attachment is made to the amine on the FAPi A portion of the molecule, and similarly, with the figure below, the iodophenol group also has that carbonyl, and that's where the attachment is made to the FAPi group.

Q And how did you come to discover that -- this error?

A As I reread declarations, I noticed that the shading was inconsistent with other shading that was done in the declaration regarding similar structures, and so we pointed it out and we

correct -- now corrected that.

Q So basically you're treating the text in paragraph 42 as indicating what your opinion was and then correcting your figure to match what is in the text?

A That is correct, the text was correct. We did not change anything in the text of my opinion, but the shading was just incorrect on the figure.

Q All right. Do you recall when you discovered these errors?

A Within the last few weeks.

Q Sorry. All right. Give me a brief description of what you did to prepare for the deposition today.

MS. PARTINGTON: Again, I'm just going to caution the witness not to disclose any substantive conversations with attorneys.

A Okay. It started probably a month and a half ago or so. We had -- I've had a few Zoom conversations with counsel. I also went back through and read all of my declarations, looked at the exhibits and references that are -- were

incorporated into the declarations. Then I came here to Washington, and we met on Monday and Tuesday with counsel, and we went through the declarations, the information related to the -- my opinions that were formulated in the declarations.

Q Can I confirm that all the information that you reviewed are documents, patents, publications that you had considered prior to signing your declarations?

A Yes, all of the -- all of the documents with the exception of some documents that came in just late, this is post my second declaration, this had to do with the assay -- some assay results from Dr. Pomper, that was the only information that I did not see before, that came prior to signing the declarations, it was the only other information that I've reviewed.

Q Okay, and since you reviewed that information only in the last couple of days, that information hadn't been part of what you considered when you prepared your opinions, correct?

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A It had not been part of what I considered for the opinions, but I can definitely say that it did not change or alter my opinion in any way, the opinions that I have and signed off on in the declarations.

Q When you reviewed these materials, do you recall if they had legal markings at the bottom of the page, like exhibit numbers or other kinds of coding?

A Could you be more specific on which materials --

Q Yeah.

A -- you're referring to?

Q So the new materials that you looked at before the deposition, I just want to understand, were those marked with exhibit or document identifiers like JHU and then a number sequence at the bottom of the page?

A Yes, they were -- they were marked with a number at the bottom of the page. I believe they were JHU numbers, yes.

Q All right. Let's do this. Can we

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introduce the four declarations? I don't want to overload the table with paper. You have -- could I just take a quick -- you have no markings on these four documents?

A These are completely, completely clean.

Q All right, so we'll treat those as your copies during the deposition today.

A Okay.

Q We can put more paper on the paper -- paper on the table if you want it. Otherwise we're happy to go with that. What I'd like you to do is go to your Exhibit 2029 in the PGR proceeding number.

A Okay.

Q If you could, go to page 15. Do you see on page 15 a start of exhibits?

A Yes, I see that.

Q And that runs through page 26. My question is did you read all those exhibits before you executed your declaration.

A I reviewed all of the exhibits here before signing off on the declaration, yes.

Q Were they -- at the time you -- you know, you did this review up to the time you signed this declaration, did you review any other documents that are not listed on that exhibit list?

A No, I did not review any other documents that are not listed here on the exhibit list.

Q There are a number of scientific publications listed on that exhibit list. Are all of those papers ones that you had seen before you were retained to work on this project?

A Some of these I may have seen before. Some of them may even be publications that I was an author on, so I can say that I probably have seen some of these papers. I don't know that I could sit here and check off which ones I have seen before, but yes, I'd seen some of these before.

Q Okay. Did you personally locate all of the exhibits that are listed in the exhibit list?

MS. PARTINGTON: Objection, form.

A Some of these I actually went on line and downloaded, and some of them were provided by

counsel.

Q Can you give me an example of one of the ones you located?

A That's a good question. So yeah, there's a couple here that are mine that counsel did not provide, so Exhibit 2016, 2017 would be -- would be a example for sure. I know that example 1042, I've seen that paper before prior to this. There are probably, you know, a few others that -- that -- Dr. Mankoff's paper, 1028, is an example, yeah.

Q Do you -- for the ones that you didn't identify, where did you get those from?

A Either they were in my own personal -- my own personal papers file, or I downloaded them from the publisher.

Q Let me give you a better question. How did you come to pick the ones in your exhibit list that were not the ones you located yourself?

MS. PARTINGTON: Again, I just want to make sure that you're -- I'm going to caution you to be very careful about disclosing any substantive conversations with attorneys or

attorneys' mental impressions along this line of questions.

BY MR. KUSHAN:

Q I can ask it more simply.

A Could you -- could you repeat or rephrase the question please?

Q Sure. Some -- some of the exhibits on your exhibit list you indicated, you had located those and retrieved them in the course of your work on this matter, right?

A So I may have miss -- I may have misunderstood the previous question. Some -- some of these -- obviously my publications with my name's on it, I provided those to -- you know, as part of the -- as part of the evidence and exhibits. When I say that I found some of these elsewhere, it means that I knew -- I had the declaration. We had -- we had put into the declaration these various references, and I had actually found the references separately. I did not receive them from the -- but I knew about them, how to go and find them or where to go and

find them, what references they were. When we reference something, I would then -- sometimes I would get copies, a physical PDF file, right, from counsel. Sometimes I would go and find the references. So I wasn't -- and some of these that in working with the counsel, we -- that I then -- you know, that I would have added to the -- you know, to the work, and I can't tell you, you know, which of these that I -- you know, aside from my own that I know that I brought in, I can't tell you which of these that I, you know, had brought in from the -- you know, to add to the list.

Q Okay, so is it fair to say that there was a list of references that had been identified to you that you may have been supplemented with additional publications or documents?

MS. PARTINGTON: Objection, form.

A Again, I -- there are a few documents that I contributed to this research, including those that I published, those that I was an author on, and the list here compiled, I either received a paper -- you know, PDF copy or went and found the

original copy from the journal. That's what I'm stating.

Q And my focus was more about just the entries on the list of the table as opposed to the physical or PDF version of the paper. Just --

A And I'm sorry, that was my misunderstanding. I was thinking that you were referring to who -- who -- who went to the journal and picked out the reference. That's -- that's why I was answering it the way -- the way I was.

Q You mentioned in the course of preparing for the deposition today, there were certain papers that you reviewed. Were they on this list? I think you said all but one were on this list of exhibits; is that correct?

MS. PARTINGTON: Objection, form.

A Could you -- I'm sorry, I'm --

Q Yeah.

A Would you --

Q So earlier -- earlier, I asked what you had done to prepare, and you'd indicated that -- to prepare for the deposition, you indicated that

you had reviewed certain materials before today as part of your preparation, right?

A Correct.

Q Okay. Did you review any of the scientific publications on your exhibit list?

A Yes, I did.

Q Do you recall which ones?

MS. PARTINGTON: Again, I'm going to caution the witness to -- to the extent that you can answer this question without divulging any information that has to do with your communications with counsel, do so, but please keep it at a high level and please be very careful about divulging any information.

BY MR. KUSHAN:

Q Sorry, I'm going to correct her instruction. She wants you to not reveal communications with her that occurred, okay? The information is -- you can tell me what you looked at, and that's what I'm trying to understand, what documents.

MS. PARTINGTON: Counsel, I think your

probing into which documents he reviewed reveals privilege.

MR. KUSHAN: I'm not asking about the conversations he had with you about what he was looking at. I'm asking just to understand which documents he looked at, which he can answer just by exhibit numbers if he wishes.

MS. PARTINGTON: Well, I think he already answered that he reviewed all of the documents that were on the exhibit list.

BY MR. KUSHAN:

Q That's not my question. My question is in the preparation -- well, did you review all 40 so -- some publications in the last period before the deposition to prepare for the deposition?

A I reviewed all of these documents in the preparation of the declaration, and reviewed many of the documents, and I could not go through and pick out which ones that I didn't review, but reviewed many of the documents here prior to the deposition.

Q And would that have been over a period

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extending more than a couple of days before the deposition?

A That would have been over the last two months.

Q Okay. Can I have Exhibit 1003 in the PGR proceeding? You might as well get the 1003 in the IPR proceeding as well. While he's doing that, could you -- let me back up a little bit. Your appointments at the UCSF, does that involve teaching courses at the university?

A Yes, it does involve teaching courses.

Q What courses do you teach?

A I teach a course in nuclear and optical imaging probe. It's a one quarter course taught in the winter quarter every year.

Q Are there others?

A I lecture occasionally in other courses, but none that I am the principal and lead teacher on.

Q Is the remainder of your time focused on research activities?

A The remainder of my time is focused on

research and some administrative activities.

Q Do you hold positions at the university beyond your teaching and professor positions? Like are you chair or some other designation within the department?

A I have no other chair positions. I'm the director of radiopharmaceutical research, which is a position I've held at University of California San Francisco since I started. I'm also the director of the Center for Infectious Disease Molecular Imaging, which is a new center we started over -- a little over a year ago.

Q Okay. For your lecturing that's outside of your formal teaching assignments, how frequently do you do that?

A I have some regular lectures that I give to residents and fellows. In our department, I also have a regular lecture that I give to some medical physics students in the department of radiation oncology, and then I'll be asked occasionally by colleagues at UCSF, at UC Davis to come and provide lectures, and Stanford, to come

and provide lectures in some of their classes.

Q If I understand, your -- your course that you teach was a winter course? Does that end in -- I don't -- are you on a quarter system at UCSF?

A Yes, we are on a quarter system at UCSF.

Q So that -- when does the winter quarter end?

A The quarter runs from the beginning of January to the middle of March.

Q Okay. Between let's say about the middle -- the end of that first quarter until today, have you been involved in providing lectures outside of your normal course that you teach?

A I can't -- I have given a couple of other lectures this spring, and I don't remember if they were in that January to March time frame or after that time frame. I gave a lecture at a course in -- at Stanford, and also to residents and fellows in our department, and that happened sometime in the -- I want to say spring. I don't remember if it was before or after -- I believe one of them was after the end of the winter quarter.

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Q Are these lectures that you have kind of -- you give frequently, so it's the same content at the lecture?

A I -- I think that's -- it's safe to say that -- that the content of these lectures is similar when I give them each time.

Q Are these -- are these lectures that occur within a single day or do they span a longer period?

A With the exception of the course that I teach and oversee, these lectures are typically one hour on a given day.

Q Between about -- if I could -- I don't want to test your memory excessively. I know my date memories are also challenging, but if you go from the time where you finish your declarations in the proceeding, the PGR proceeding sometime around May of this year --

A Uh-huh.

Q -- until today, have you had obligations of, you know, where you provide lectures or participated in seminars or conferences?

A Yes, I've participated in at least two conferences I believe since the end of May.

Q Where were those?

A One was the Society of Nuclear Medicine and Molecular Imaging in June at the -- at Los Angeles, and the second was CAFACHEM, C-A-F-A-C-H-E-M. It is a -- it was a student -- or what we call a summer school, and I provided a plenary lecture for the summer school.

Q Do you remember the dates of those, of the second --

A That was a couple of weeks ago, mid-July. July 15th through 19th I believe.

Q Okay. Did you have any other -- did you have any vacations or other activities between May and July?

A I -- not -- I don't believe I had any other except for my research obligations, any other obligations.

Q When you are doing work at the UCSF, do you do collaborations with private companies in research?

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A Yes, I have done and have some ongoing collaborations with private companies, yes.

Q When I -- when I hear you describe your research, does that word kind of cover both the research you might do in your own UCSF-directed work as well as these collaborations?

A Yes, it's similar work in both cases.

Q All right. Do we have Exhibits 1003? I'm going to introduce what is marked Exhibit 1003 in the PGR proceeding. This is already marked. You can just take it.

A Thank you.

MS. PARTINGTON: Thank you.

BY MR. KUSHAN:

Q This is a declaration of Brian Zeglis that was filed in the PGR proceeding. Do you recall reviewing this declaration from Dr. Zeglis?

A Yes, I do.

Q When you reviewed Dr. Zeglis' declaration, I wanted to direct you to the back end of the document. There's a similar exhibit list there which is marked page C-2 is the beginning of it.

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It's an appendix. It's appendix C. I have a really simple question, which is I just want to know if you reviewed all of the exhibits that Dr. Zeglis had included with his declaration.

A Well, many of these are similar or overlap with documents that are listed in my declaration, and I reviewed -- I'm sure I reviewed most of the ones that are in here, and certainly those that overlap between the two I definitely reviewed.

Q When you reviewed Dr. Zeglis' declaration, you encountered a paragraph that had a citation to a paper or patent. Would you also review the referenced paper or patent along with the statements Dr. Zeglis made?

A Certainly if it referenced patent materials that I was not familiar with, I would review those, and on -- I would also then for those that had -- for those that had references to journal articles, I would look and see which -- you know, which articles they were and open them and look -- you know, do a brief review of the article.

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Q All right. Before I get too far into this, other than the errata that you provided which is marked Exhibit 1063, did you find any other errors in any of your four declarations?

A No, those were the only ones that I discovered.

Q I'm going to ask you some science questions now. Thank you.

A Good.

Q So this field involves imaging agents and radiotherapeutic agents generally, and you're familiar with this field, correct?

A I'm very familiar with this field, yes.

Q Okay. Sometimes the imaging that's performed is imaging within an animal or a human, so that's -- we'll call that an in vivo imaging, and if there's a better description or term you use, just tell me what that is.

A In vivo imaging is a term that's very -- that is common in our field, yes.

Q Okay. It's also possible to use a radioimaging agent or an optical imaging agent to

analyze tissue taken out of the body, correct?

A Yes, it's quite common to perform in vitro studies with -- with these agents. They're very useful for a number of different things as you're, you know, able to follow the radioactivity that's attached to the molecules that you're investigating, so in vivo -- sorry, in vitro assays using radiometric assays, using radioactive materials, in vivo studies, from animals to humans, and then ex-vivo studies, mostly involving animal tissue, is -- are very common in the field.

Q So in that setting where you're doing the ex-vivo study of the tissue, you're -- you're using the radioimaging agent to detect, for example, where cells that express the target of the radioimaging agent are located within the tissue. Is that fair?

MS. PARTINGTON: Objection, form.

A Were you specifically asking about ex-vivo?

Q Yes.

A Okay, so ex-vivo is commonly where you

introduce the radioactive isotope into the system. Then you take the tissues out. Then you measure the activity.

Q Oh, so you inject the radioimaging agent into the person or the animal.

A Yes.

Q And then you take a tissue sample -- sorry, let me finish. That's one of our also rules. So in an ex-vivo example that you just referenced, you're injecting the radioimaging agent into the person or the animal, and then you at some point later take a tissue sample out of that individual or animal, and then you study the tissue.

A Yes, or you can remove some of the tissue and then, as you had indicated, you can stain that tissue with the radioactive -- with the radioactive isotope and then analyze the -- the interaction of the isotope with that tissue.

Q What are you looking for when you are staining the tissue with the radioimaging agent?

A We are typically looking for interaction

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of the radioactive isotope or the molecule with a particular protein that you might -- that might be its target, and also maybe looking at the tissue surrounding the areas that maybe don't have target to make sure that we see a discrimination between areas that contain target, areas that don't contain target.

Q And you can detect that because the radioimaging agent -- the radionuclide on it has accumulated in certain portions of the tissue and has not accumulated in other portions of the tissue. Is that fair?

A That is fair to say that the discrimination between two tissues in -- there are two regions in the same tissue slice, let's say, this might be -- or piece of tissue would be looking at the relative concentrations of the radioactivity in one section versus another.

Q Okay, and what you do with the results then is you try to determine if the tissue that has been stained where the radioimaging agent has accumulated correlates to cells that express the

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target as opposed to not expressing the target? And again, this is -- I'm just trying to get a high-level orientation. If this is inaccurate, just tell me.

A No, so your description is correct. You're looking to see where the material sticks, right, what does it interact with. Now, it could be -- it could be interacting with things that are nonspecific, right? That happens quite often, that you get what we call nonspecific binding because the structure of the molecule has some characteristic that it interacts with other proteins in there. Doesn't mean it's not also interacting with the target of interest, but it could -- it could be -- it could be accumulating there just because it has a charge or something, and it's interacting with something else in the tissue that's charged, and typically what we would then do is we map this using the autoradiography techniques, right, where we look at the distribution of the tracer in the tissue, right, and -- and then we look to see relative to each

other the quantities of the radioactivity in the various regions in the tissue.

What's also subsequently done is staining of the tissue, usually for the particular target that you're interested in, so then you could overlay the stained tissue with the tissue that has the radioactivity in it to show that you've accumulated your tracer in the same regions where you expect there to be the protein of interest or whatever your target may be, and then look to correlate those two and show that oh, yes, we see that region is -- has the activity in it.

Q And so for example, if you're seeing accumulation in a region where there are no cells that express, for example, in this case FAP, then that -- you view that as a not accurate map of where FAP is being expressed in -- in the tissue using the radioimaging agent.

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q I might ask you a better question. Let me try that one again. So when you are analyzing the

stained tissue or the tissue that has been treated with the radioimaging agent, if you're seeing regions or areas of the tissue sample where the cells don't express FAP, and you're using a FAP-specific radioimaging agent, those areas where there's no cells would be the nonspecific or off-target accumulation of the radioimage agent.

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q And if I misstated this, correct my description.

A Yeah, as I've stated, the -- where the targeted molecule binds to the target, right, you might see a greater accumulation, and tissues surrounding that that don't have the target, you may see less background nonspecific binding. That's --

Q So is -- is the -- so do scientists use the term "selectivity" to refer to how closely there's a correlation of the radioimaging agent binding to the tissue that is expressing, or has cells that express to your target as opposed to

binding to other tissue that does not express that target?

A So "selectivity" I think is a completely different term here because molecules can have properties that they will bind not only to their target, intended target, but they will bind to other proteins of similar nature.

Q So --

A And so that is part of the off-target or background activity or nonspecific -- what we would call perhaps nonspecific binding or not binding specifically to the target that we're going after, and selectivity would refer to the interaction of your radiopharmaceutical with your intended target and with any other targets that it might also interact.

Q So for example, with FAP, with agents targeting FAP, one issue is that those agents often will interact with other similar enzymes like PREP or other enzymes in that enzyme family. That's an issue of selectivity, right?

MS. PARTINGTON: Objection, form.

A So again, the definition of selectivity is binding to the intended target of the -- of the radiopharmaceutical or the molecule that you're going off, and any unintended binding to other proteins, other tissues, if we're doing this in tissue assay, other cells, those would be off-target or nonselective -- nonselective binding.

Q Okay, so one reason it may be off target is a nonspecific interaction of the radioimaging molecule with material tissue, materials outside of the area that has the FAP-expressing cells. That's one possibility, right?

A I'm sorry, is there -- was there a question?

Q Yeah, I'm just confirming. So the reasons why you may see accumulation of the radio -- radioimaging agent that's off target is that there are interactions of the molecule that is a radioimaging agent with material that's creating a kind of an association, an accumulation that is not driven by the targeting moiety of the molecule

binding to its target in that region.

A So when we perform these in vitro assays, the -- the -- we -- we introduce the radioactivity to the entire sample, and then what we do is we have to rinse or clear the excess radioactivity from the sample. So this radioactivity has seen all of the cells, has seen all of the tissue, right? And so what we're looking at when we take the image, autoradiograph, if we count the cells separately, you know, in a counter, where we do any of the -- any of the workup, what we are doing is comparing the amount of radioactivity in one region, in one set of cells versus another set of cells, and we -- we -- all we know is that the radioactivity is there for some reason.

It's bound to either the target that we're going after, or it's bound nonspecifically to something else. It could be interacting with another protein. It could be interacting randomly with other material. As I said, there could be a -- a charge relationship or something with the materials there.

So there are a number of different reasons for the nonspecific background. Sometimes we call it background activity, and -- and it could relate to interaction with nontarget proteins as well as just a general -- because we've introduced the sample -- we've introduced the radioisotope or radiopharmaceuticals to the entire sample, right?

So you'll have -- I mean, if I put radioactivity on a piece of paper and it adhered to ink, right, I'm going to still see some background on my piece of paper, but what I'm aiming for is to be able to see enhanced imaging of the ink, right? So that's a --

Q Okay, that -- that's very helpful. So you mentioned I think in the course of that explanation or in the previous one, sometimes there could be a charge interaction that causes that nonspecific interaction, right?

A Yes.

Q And then another kind of interaction might be a hydrophobic type of interaction with another hydrophobic area or surface?

MS. PARTINGTON: Objection, form.
BY MR. KUSHAN:
Q These are the nonspecific interactions, so the molecule may have hydrophobic characteristics that cause a hydrophobic interaction that could be a nonspecific?
A It could be hydrophobic interaction, hydrophilic interaction, charge interaction, yeah, there's a number of different nonspecific interactions that could -- could retain some of the radioactive material.
Q Okay, and then going back a little bit, you used the word "autoradiograph," and that's a device?
A Well, it used to be film. We used to take -- in my day, we used to take film and expose the tissue samples to film, and then what we would do is we'd develop the film and actually then have to determine the quantity of activity. Nowadays there are -- there are instruments that are either direct reading of the radioactivity that's coming off of the tissue or indirectly. These are

instruments called phospho-imagers where you actually expose the radioactivity -- radioactive sample to a phosphor plate, and then you would then -- and very similar to what you do with film, you would then read the plate, or actually the instrument will then actually read the plate to see where the preponderance of radioactivity is.

Q Okay. When you're doing imaging in vivo, you use different kinds of instruments; is that right?

MS. PARTINGTON: Objection, form, foundation.

A Gamma counting is very -- or isotope counting is very prevalent, and it's used for all -- it could be used for cell studies, it could be used for tissue studies, and it could be used when we're doing in -- in vivo studies as well in addition to imaging devices that are specifically built for imaging materials in living systems.

Q Right, so there's a couple of terms you see in the patents. One is PET scanners or PTE apparatus, and the other one is an SPECT

apparatus. Those are devices used with organ -- you know, humans or animals to measure imaging; is that right?

MS. PARTINGTON: Objection, form, foundation.

A So they could be used for a variety of applications. We've actually -- we've actually done a lot of in -- in vitro studies using these imaging instruments in addition to the in vivo studies, right, the live systems, but we've actually used these to measure activity in cells and measure activity in tissues that we're perfusing with radioactive materials.

We've used these to image inanimate -- you know, inanimate objects. So -- so one -- these are not -- these are not strictly -- even the human scanners we have used for other -- for -- we measure phantoms all the time. We measure -- and have done, you know, some tissue studies and things like that on larger tissues.

So even -- you know, the scanners that are small animal scanners, the scanners that are human

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scanners can be used for not only the in vivo by -- the distribution studies, imaging studies, but also for in vitro assays as well, and we have used them for both.

Q So to be clear, the -- the machine that is a PET scanner or a SPECT scanner is designed to accommodate a fairly large thing, a portion of the body or can be a small animal. I just want to understand, when you're doing investigations where you're using a PET or SPECT scanner, do you tend to focus on articles, ex-vivo, as you mentioned, where it's a -- has some three dimensionality to it because you're trying to understand where the distribution is within a three-dimensional object?

MS. PARTINGTON: Objection, form, foundation.

A So in the -- in any of the studies, in vitro, in vivo studies that we do in the scanner, it may be just a detection technique that -- but what we want to do is look at it in realtime over an area. Doesn't have to be three dimensional. Could be two dimensional, but the scanners

themselves collect decays from all angles out of the source, and so the T in each of these, PET and SPECT, refers to tomograph, right? So you end up with a three-dimensional -- three-dimensional image at the end of the day if you're -- as you're collecting that data.

Q I'm just going to hand you what's been previously marked as Exhibit 1008. This is a paper by Meletta.

A Yes.

Q Did you review this paper?

A I did review this paper.

Q Okay. If I could have you look at figure 3, which is on page 2088? Figure 3.

A Oh.

Q Yes.

A Yes.

Q You see in the key to the figure, it indicates that these are in vitro autoradiograms of representative sections of the human carotid plaques under baseline and blockade condition. Are you familiar with these kinds of images coming

off of autoradiograph or autoradiograms?

A Yes, I am familiar with these.

Q Okay, so this was a study that was done, or at least this image was created -- sorry, I'll be more precise. As the paper's indicating, these are images generated as an audio -- autoradiograph based on samples of tissue that had been stained with this I 125 MIP-1232 imaging agent; is that right?

A As I read here, this is an in vitro autoradiogram of these plaque sections, human carotid plaque sections that have been stained with the iodine 125 radiopharmaceutical.

Q All right, and based on your review of Meletta, it's described in the results of an in vitro imaging experiment; is that right?

A This is -- this is an in vitro experiment.

Q All right. You can go to page 2090. Sorry. I gave you the wrong page. 2090 is the start of the experimental method section, and if you kind of -- sorry, you have to go through a few more pages. 2094 is the start of what's --

section 3.7, in vitro autoradiography. Do you see that?

A Yes, I see that.

Q And that's describing how they prepared the samples of tissue and then performed this imaging and measuring of the imaging agent within the tissue; is that right?

A Yes, this is the method that -- that they're describing the autoradiography for these sections.

Q Could I have you go back to page 2089, and look at the paragraph -- the second to last paragraph on the page. They're indicating that they're assessing this radiotracer that was investigated by in vitro autoradiography with human carotid plaques, but they found -- they found pronounced binding to the carotid plaques; however, with no difference in average specific binding between stable and vulnerable plaques, between plaques and normal arteries after correction for tissue sample sizes, and then they continue on.

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In the next paragraph, they start by saying, "Based on our data, we cannot conclude on the selectivity of the I 125 MIP-1232 for FAP," and then they continue on, and you've -- you've reviewed this section previously, right?

A Yes, I have read this section.

Q So the -- the results of use of this in vitro assay was a conclusion by the Meletta authors that this particular I 125 MIP-1232 agent was not sufficiently selective for FAP to be a viable imaging agent. Is that what they concluded?

MS. PARTINGTON: Objection, form.

A So their conclusion was not that this was not a viable agent for FAP because the -- they had -- they had already established that the molecule had some affinity for the FAP protein, and the conclusion here was that in this particular assay, they were not able to differentiate between the uptake of this molecule that is likely binding to FAP, they could not differentiate the uptake of this molecule in this tissue specifically between

the plaques, which they believed had excess -- sorry, increased levels of FAP protein, and the background tissue, which is the normal arteries, and of course, they also look between -- the difference between stable and vulnerable plaques, which they could identify, and they did not see any difference.

This is not a -- this is not conclusive in any way, shape or form that it did not bind to FAP. It just was not -- it just did not work in this particular example that they put here.

Q If you could just turn -- turn the page, and at the top of page 2090, they state, "For future studies, more selective inhibitors are needed to reduce nonspecific tissue accumulation." That's the problem we were talking about earlier with in vitro tissue staining studies, right?

A Yes, so this is -- I mean, this molecule is one of many that were known in the art prior to 2017, which is of course the date that we're talking about with the patent in the current case, and in this particular case, this was one of the

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first radiopharmaceuticals I believe that was prepared from -- from FAP molecules, and indeed, this did not show the desired properties. In this particular case, it did not show the desired properties to separate between the tissue that had the plaques and the tissue -- and the surrounding normal artery tissue, or could not differentiate between the two different types of plaques, so it was not as -- they needed a better molecule.

Q They needed -- they needed a more selective inhibitor, right? That's what they said?

A Their terminology here is selective inhibitor, but they needed something that was going to be able to differentiate between the surrounding tissue and the affected tissue that they were trying to investigate.

Q Okay.

A But this was not -- nothing here is -- is -- you know, this is not -- this is very common with radiopharmaceuticals. They will work in certain applications and not in others depending

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on, you know, the conditions under which they're being studied.

Q And just to confirm, they're pointing out there was -- they had too much nonspecific tissue accumulation of this agent, right? That's at 2090 at the top.

A They were unable to differentiate the plaque tissue and the normal tissue.

Q Right, and non -- but they say the -- they -- more selective inhibitors are needed to reduce nonspecific tissue accumulation. That was the nonspecific interactions of the imaging agent with the tissue that we were discussing earlier, wasn't it?

MS. PARTINGTON: Objection, form.

A Again, they needed to be able to differentiate between the normal tissue and their disease tissue, and they were not able to do that in this particular case.

Q Right. We've been going for about an hour and change. Do you want to take a break?

A Sure, that sounds like a good idea. Thank

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you.

(Recessed at 10:20 a.m.)

(Reconvened at 10:33 a.m.)

BY MR. KUSHAN:

Q I'm going to hand you the two exhibits, they're both marked Exhibit 1001. These are the patents --

A Okay.

Q -- in each proceeding. I'm going to refer to the first one in the PGR proceeding as the '233 patent, which is the last three digits.

A Yes.

Q And then the other one is the '201 patent, and that's in the IPR proceeding.

A Yes.

Q Give you those. Let's work from the '233 today, and if there's something specific about the '201, I'll let you know.

A Okay.

Q All right, and before we get into the details, during the break, did you have any conversations with counsel?

A I didn't even see counsel except walking out the door, so no.

Q Great.

A Correct.

Q Great. And just so you understand, when you're in the course of the deposition, you should not have conversations with counsel about anything about the deposition or your testimony.

A Understood.

Q All right. When you reviewed the patents, did you review the patent claims?

A I reviewed the -- I reviewed the entire patent, including the claims.

Q Great. If you could go back to -- on the '233 patent, go to column 64, which is where you see the beginning of claim 1?

A Yes, I'm there.

Q Okay, and the claim is directing to low molecular weight compound of formula 1, and it has the B-L-A formula. That's formula 1, right?

A That is correct.

Q All right, and then it defines A, B -- A,

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B and L throughout the text of this claim, right?

A The -- yes, the remainder of the claims explain B and L and A.

Q Okay, and then --

A Structurally.

Q Okay, so let me -- let's start with the section A, and there's a chemical structure marked X in the section that's defining what A is, right?

A I see the X structure, yes.

Q Okay. If you can go down, there's another structure after a chunk of text below -- it's representing a quinolinol ring. Do you see that?

A Yes.

Q Okay, and there's text right under that -- under that structure that says represents a quinolinol ring having a point of attachment to a remainder of the FAP-binding moiety at the 4 position of the quinolinol ring. Do you see that?

A Yes, I see that.

Q And so if I'm looking at the structure X, the pyrrolidine five-member ring, and its imid bond fragment connects to the quinolinol ring at

position 4 of the quinolinol ring. That's what it's saying? And again, if I've used imprecise chemical language, sometimes -- you can also mark the document if you want to do that, but I just want to confirm that there's a requirement in this claim that the point of attachment to the quinolinol -- quinolinol ring is at position 4 of the quinolinol ring, right?

A So as stated there, the quinolinol ring position 4 is the attachment point to the remainder of the molecule that is shown in structure X.

Q So everything in structure X other than the quinolinol ring is that remainder.

A The quinolinol ring is shown in structure X. This specifically identifies where on the quinolinol ring it's attached to the rest of the molecule.

Q Right, right. If I could have you just put the '233 patent to one side, and let's pick up the '201 patent, and we're going to go to claim 1 of the '201 patent, and I'm going to ask you here,

this is -- if you go to the last page of the patent, which is -- has a column 68 on it, all right, and then --

A Yeah, 68 is blank.

Q Yes. Turn the page one page, and there's a thing called a certificate of correction.

A Yes.

Q We're going to use this because they corrected the claim language, and this is the current claim, so I just want to use this text, and in this section, you see again the same kind of format, the molecule X, and then the quinolinol ring after some text, and then there's a -- some text after the quinolinol ring depiction. Do you see that?

A I see that.

Q All right. So in this patent, it says that the illustration is just -- represents a quinolinol ring, and it doesn't require a point of attachment at position 4 of the quinolinol ring; is that right?

A That would be how I read this text, yes.

Q Okay, so the fragment of the X structure that is not the quinolinol ring can be attached at any other position on the quinolinol ring that's available; is that right?

MS. PARTINGTON: Objection, form.

A I'm seeing this just as it -- it's depicting that it represents this as the quinolinol ring. That's -- that's just the way I read it.

Q And this patent claim does not also require that the point of attachment of the rest of the fragment of the X molecule is attached at one specific location on the quinolinol ring, right?

A As I indicated before, it's defining -- as I can see, it's defining this structure here or this -- this drawing, it's defining what is meant by this drawing as a quinolinol ring. That's all I can see that it says here.

Q Yeah, so if you have the other patent next to you, you can just take a look at the text underneath the quinolinol ring representation, and

you see it's saying there that that molecule represents a quinolinol ring having a point of attachment to the remainder of the fat-binding moiety at the 4 position of the quinolinol ring, so this -- this is just one additional requirement imposed by the '233 patent that is not imposed by the '201 patent, right?

A So this one, the '233 patent does specify the binding at position 4 on the quinolinol ring according to this set of claims.

Q And '201 does not impose that requirement, right?

A All I'm seeing is a structural definition there.

Q All right, and I'm going to hand you Exhibit 1006, which is the Jansen paper. You've reviewed the Jansen paper before?

A Yes, I have.

Q You see in the abstract, there's a molecule 60 depicted?

A Yes.

Q All right, and this is just a simple

orientation point. That is attaching the fragment of the FAP inhibitor to the quinolinol ring at position 4 of the quinolinol ring, right?

MS. PARTINGTON: Objection, form.

A Yeah, that is position -- the attachment to the FAPi molecule is at position 4.

Q Okay. So you can put Jansen aside for a minute. I just want to make sure we have a single molecule so you can see what point of attachment a position 4 means on the molecule, and that's an illustration, right, in the Jansen paper?

A I understand that, yes.

Q Okay. So let's do this. Let's go back to the '233 patent if we could, and keep the page with the claim in front of you, which is column 4 -- I'm sorry, 64.

A Yes.

Q All right. This difference between the '201 and '233 patent and the point of attachment requirement, were you aware of that before you prepared your opinions?

A I reviewed both -- I reviewed both patents

and read both sets of claims, so I was aware of the -- what the claims had indicated.

Q Did you attribute any significance to the fact that the point of attachment in the '201 patent can be at more than the position 4 on the quinolinol ring to any of your opinions?

MS. PARTINGTON: I'll object to form.

A Would you please -- please just restate the question so -- I was --

Q Sure.

A -- thinking and --

Q When you formed your opinions, did you attribute any significance to the fact that the '201 patent allows the point of attachment to be at more than just position 4 of the quinolinol ring as compared to the '233 patent, which restricts it to position 4?

MS. PARTINGTON: Objection, form.

A I attributed my -- or my opinions come from review of multiple documents, including the information in the claims here in the '233, as well as the claims in the -- in the '201 patent,

and all the information that I have as exhibits attached to my declarations.

Q So nothing specific in your opinions relate to the positional attachment of the remainder of the FAP inhibitor molecule to the quinolinol ring in the '201 patent, right?

MS. PARTINGTON: Objection, form.

A Again, my opinions are based on all of the information that I, you know, had available through the references that you have seen in my declaration, as well as the information in the patent claims here in the '233 and the '201 patent.

Q Is the same variety of A moieties defined by this A section in the '201 patent as the A moiety definition in the '233 patent as you understand the claims?

MS. PARTINGTON: Objection, form.

A I mean, I can see from -- you know, that comparing these two, there's more description in the '201 patent. The general structure X for both patents is -- is -- is -- is the same.

Q So given the lack of restriction in the '201 patent about the point of attachment to the quinolinol ring, does that suggest that there are more varieties of A molecules encompassed by its language relative to the '233 patent?

MS. PARTINGTON: Objection, form.

A I mean, both -- both patents -- the claims in both patents describe multiple groups that are attached obviously to the -- to the A structure, or structure X in the '233 patent, and so -- and just -- and just reviewing this, the claims were for the various -- you know, the molecule that was being prepared under this patent, and I considered all of the information in the claims for both -- for both patents.

Q Yeah, I'm just homing in on a particular question, which is, you know, the -- if I were imagining the universe of possibilities of the A moiety in the '233 patent, that universe would be somewhat smaller than the universe of A moieties in the '201 patent because the '201 patent doesn't restrict the point of attachment to only one

position on the quinolinol ring, right?

MS. PARTINGTON: Objection, form.

A Again, I can see from the two patents that the two descriptions are slightly different. The A molecules are the same, and there's a list -- you know, there's qualifications for all of the materials that are -- that are attached here, and, you know, at least for these two descriptions in both of the patents, that's, you know, what I can say about -- you know, about these patents, or about these claims, right? I mean, they're prescribed here. I see what they're -- see how they're prescribed. I see how the different attachments are also described here, and so each has their own set of -- of -- of groups that are -- that are attached and their attachment points as referenced in the claims.

Q Just so I'm clear, so you appreciate that the number of A moiety choices permitted by the claim of the '233 patent is smaller than the number of A moiety choices in the '201 patent, correct?

MS. PARTINGTON: Objection, form.

A As described in the claims for the '233 patent, you have the A moiety with its particular attachments with the description of the quinoline ring, and then you have sub-claims which further define and refine the claims for A in the -- in claim 1.

Q Right. You may not have understood my question. I'm just focused on what the A choices are in each of the two patents. You're with me on this? I'm trying to see the universe of choices, right?

A I understand.

Q Okay, and because the '233 patent restricts the point of attachment to one position on the quinolinol ring, its universe is smaller than the universe of the '201 patent, which does not restrict the point of attachment to a specific point of attachment on the quinolinol ring, correct?

A I mean, again, as I read the patent, the structures here for X and the structure in column

66 of '201 are the same. The description here provides the information about the quinoline ring and the attachment and the -- and in each of the cases, you have constituents that are bound to A, which encompass the full scope of what a -- what A covers, and so as written here, right, I can differentiate between -- differentiate between the two or see the differences on the paper, and I stand by that I understand what the claims are here, and that the claims for A encompass all of these -- you know, all the prescribed attachments to A in -- in patent '233 versus '201.

Q Sure. I'm not trying to be difficult. I just want to make sure that you appreciate that the choices available as dictated by the claim of the '233 patent for your A moieties is a smaller number of choices than are available or dictated by the language of the '201 claim for its definition of the A moiety, right?

A As I see here in the '233 patent, there's a list of substituents. Some of them are similar to the substituents that are in the '201 patent,

and so the number of compounds defined here are different than the number of compounds described in the -- in '201.

Q When you prepared your opinions, did you attempt to calculate the number of choices there were for the A moieties under each of the two patents?

A In preparing my deposition -- or sorry. In preparing my declaration, I did look at the numbers of the compounds here, and Dr. Zeglis actually provided in his deposition some -- some specifics relative to those numbers, and I reviewed the numbers that he had -- that he had prepared, and I can tell you that the -- you know, that the numbers of -- you know, as -- as claimed here, the structural claims, I mean, it's claiming a -- you know, a specific set of compounds from which one could choose in order to make the molecules as prescribed here, the B-L-A molecules.

Q And the number that Dr. Zeglis calculated was on the order of about 31,000 options for the A moiety, right?

A I think I had this in my -- in my declaration. Let me just --

Q Sure.

A -- double-check that.

Q This is for the '233 patent. Do you want to look at page 118, paragraph 52?

A Thank you.

Q Any time you need help, I'm happy to point you to the paragraph.

A Okay. So yes, in the '233 patent, around 30,000 targeting moieties.

Q Did you attempt to independently calculate the number of choices in forming your opinions?

A I reviewed the calculation that Dr. Zeglis had done, and I confirmed it.

Q Okay. One last question with the point of attachment. Does the point of attachment of the remainder of the FAP inhibitor structure of -- in compound -- in the formula X, does that point of attachment on the quinolinol ring influence the selectivity or affinity of the A moiety for FAP?

A Could you just repeat the question? I was

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--

Q Sure.

A -- looking at the structure while you were talking. I just want to --

Q Of course. Does the point of attachment of the fragment of molecule X to the quinolinol ring influence the affinity or selectivity of the X moiety, the A moiety, for FAP?

A Any changes made to a molecular structure can influence its -- can influence its properties, its physical properties in many ways, and so it could -- it could alter -- like I say, it could alter a number of properties in any way, so you're making a new molecule, so it will have its own set of prescribed properties.

Q So -- so for example, if the point of attachment moved from position 4 to position 6 on the quinolinol ring, your expectation was -- would be that would be a molecule that may have different selectivity and affinity for FAP?

MS. PARTINGTON: Objection, form.

A As -- yeah, as I just stated, when you

move -- when you move connections around a ring, any ring in a structure, you will make new molecules, and new molecules will have new properties.

Q Did you -- when you formed your opinions in the '201 patent, did you take into account the possibility of the point of attachment varying on the quinolinol ring as to the characteristics, binding characteristics for FAP of the A moiety?

MS. PARTINGTON: Objection, form.

A As I formed my opinions in this case in its entirety, I took into consideration the various structures that had been developed, and saw -- you know, and had been -- and those that had been tested, I took into consideration the different combinations of molecules that could be made as part of the claims and -- and the information that I had from the rest of my -- from the rest of the -- sorry, from the rest of the -- from the rest of the -- the publications and the patents that we had available for this -- that were available -- or I reviewed for this

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particular case.

Q If you had found something of consequence of the impact of shifting the point of attachment away from position 4 on the quinolinol ring of that remainder of compound X, would you have pointed that out in your declaration?

MS. PARTINGTON: Objection, form.

A In my review of the compounds for this case, I looked at the entirety of the claims and the information that was provided in the reference -- the reference patents to this, as well as the reference information that was available at the time before 2017, in looking at the various molecules that were made or could be made and the properties that those molecules had.

Q And just to be clear, my question was pretty narrow, which was after doing that, if you had found something of significance to your opinions, you would have noted that in your declaration, right?

MS. PARTINGTON: Objection, form.

A My -- my declaration was constructed and

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-- and -- by reviewing the documents, including the '233 patent, the '201 patent, the claims in those patents, and all the reference materials that are referred to in the patents, as well as the reference materials that I have -- the reference materials that I reviewed as part of the patent investigation, that's -- and I stand by the declaration and the opinions that I had in here relative to the structures of the molecules and the impact of the various components or the various structures that were made here and their -- and their physical characteristics or their -- yeah, their properties.

Q So just to be very crystal clear, I'm just confirming that if you had found some consequence to the affinity or selectivity of the A moiety based on the possibility of changing the point of attachment on the quinolinol ring, you would have pointed that out in your declaration someplace, right?

MS. PARTINGTON: Objection, form.

A I stand by the declaration that I have

here, the opinions in my declaration, and again, it was based -- any information in here was based on how I reviewed the B-L-A -- excuse me, how I reviewed the claims constructed in the '223 -- '233 patent and the '201 patent, and the properties that those molecules had that were available, you know, at the time of this review.

Q Yes, I think you've said that a few times, so I understand that you're standing by your declaration, and you described now I think four times --

A Yes.

Q -- how you put -- how it came to be. I just -- this is a very narrow question. I want to make sure you understand my question, so I'm going to ask you, just tell me what you understand my question to be before you answer it, and my question is when you prepared your declaration in the '201 patent, did you observe anything of consequence to the ability of the fragment of that structure X being attached at a position other than position 4 of the quinolinol ring?

MS. PARTINGTON: Objection, form.
BY MR. KUSHAN:
Q So do you understand what I'm asking?
A I understand the question that you're asking. Again, my opinions were based on the information that is here, and in the declarations, I would have documented on the molecules themselves, the properties of the molecules themselves that was available in the -- from the information in the patent, for the references that I reviewed, and so I'm just saying I'm standing by whatever I said --
Q Right.
A -- in my declaration relative to these claims, it's in the declaration.
Q Right.
A That's what I'm saying. I --
Q Yes, I've heard that answer a few times. I'm just -- sometimes I have to be very precise in my question so that we understand particular issues, and here, I'm just trying to -- if you had found some issue or consequence to your opinions

based on the possibility of moving the point of attachment around to different positions of the quinolinol ring, is it fair to assume you would have pointed that out or explained it in your declaration in the '201 patent?

MS. PARTINGTON: Objection, form.

A I understand the question, and I am -- I have to say that in the declaration, I reviewed the information that were -- as part of the patent claims and the claims and how they were constructed, right, and -- and the various compounds that are here. My comments in my declaration are opinions made based on the information that was in here that we have already discussed the differences between the two patent claims, and that would be in my declaration discussion of the various compounds were made and those that were known at the time that this patent was -- you know, the art prior to 2017, and the -- the properties of the molecules that were known at that time, right, is what I would have used and seen relative to what was in the -- relative to

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what was in the claims.

Q All right.

A That's --

Q And then one last question about this. To be clear, do you recall preparing and filing declarations in a third proceeding involving this patent, the '201 patent?

MS. PARTINGTON: Objection, scope, relevance.

BY MR. KUSHAN:

Q Let me ask you an easier question. Do you remember -- the first time you prepared your declaration for the '201 patent, was that before or after you prepared your declaration for the '233 patent?

A Excuse me. Yes, I prepared a declaration for the '201 patent prior to the -- prior to the '203 patent.

Q The '233.

A '233 patent. Apologies.

Q That's fine. If you could go -- let's go back to the '233 patent and claim 1. At the very

first line of the patent claim right after the number 1, it indicates that the claim is to a low molecular weight compound of formula 1, and then it has B dash L dash A. Do you see that?

A That's correct, yes.

Q So this is a molecule, a compound where the moiety that is the B moiety is attached to the L, which is the linker, right?

A Correct.

Q And then the linker is attached to the targeting moiety, which is the A, right?

A That's correct.

Q Okay. Do you agree that -- and if you go down to the definition for A, it says A is a targeting moiety for FAP alpha, right?

A A is a targeting moiety for FAP alpha as described there. These claims are structural -- structural claims, so A claimed here is -- you know, it's claiming the structure.

Q So what does -- what does the word a targeting moiety for FAP alpha mean to you?

A In the context of this -- in the context

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of this patent, the targeting moiety of FAP alpha is describing the utility of this molecule once it is combined with a linker L and a imaging tag B.

Q Okay, and that is -- that utility is based on the ability of the A moiety to bind to FAP alpha; is that right?

A The ability of the binding moiety to bind to FAP alpha in vitro, in vivo applications.

Q And if you could, why don't you go back a bit to column 7 of the patent. If you could look at lines 41 to 45 of column 7 and just read that one and let me know when you're done.

A Is that the paragraph that's right below the table?

Q Exactly.

A Okay, I've read that paragraph.

Q So you -- you mention the utility of the molecule. Does that correspond to it being a highly potent and specific binding moiety targeting FAP alpha? That's what enables its use in nuclear radioimaging and radiotherapy?

A So the ability of the molecule to bind to

FAP can be used in a number of applications, including in vitro use as well as in imaging and therapy use as described here.

Q Okay, and so that's -- that capability to be used in that manner is based on the ability of the A moiety to bind in a highly potent and specific way to the FAP alpha protein, right?

MS. PARTINGTON: Objection, form.

A In order for this molecule to have utility, it has to bind to the FAP alpha, and again, can be used in a number of applications in the nuclear imaging and radiopharmaceutical space, including in vitro applications as well.

Q All right, so if you go back to the claim language, we're on column 64, in this molecule, the part of the molecule -- of the B-L-A molecule or compound that interacts with FAP is the A part, right?

A The A portion of this molecule is what binds -- is what interacts with FAP.

Q Okay.

A Correct.

Q The B and L moieties are doing other things in the molecule, right?

A The linker is there to connect the imaging moiety to the A group.

Q Okay, and so we talked about this before, but the claimed B-L-A compounds are useful because when you -- they will accumulate in tissue having cells that express FAP, and the A moiety is interacting with the FAP, which helps it retain -- stay in the region of that tissue where the cells having FAP are found, right?

MS. PARTINGTON: Objection, form.

A Again, yes, there are multiple applications that can be performed with the radiolabel B-L-A compounds, including in vitro assays with protein, in vitro binding assays with cells and tissues, and subsequently imaging is also a potential utility -- is a utility for these molecules.

Q Just for -- well, so one last question about the A moiety. So the A moiety and what it is is defined in part by this chemical formula

that's designated X, right?

MS. PARTINGTON: Objection, form.

A As I understand it, the A moiety is defined by the structure that is here and the description of the groups that bind to that structure.

Q And all the different choices for the parts of the structure, such as the R groups, are then explained in the following text after the word "wherein," right?

A The structure of A is defined here in the claims with the various attaching groups highlighted as part of this description.

Q And those are listing kind of options for the different substituents that may be attached in all those different R numbers, right, all the --

A This defines the scope of the structures claimed in this patent.

Q Okay, of the A portion of --

A Of the A portion, yes.

Q Okay. If you could go down in the second to last paragraph of the claim that starts with

the letter B, and I want you to go to the portion of that after the word "and," and there's a definition of L in the patent claim, right?

A Yes.

Q All right. What is the language in the claim that defines the requirements of the L moiety?

A So the L moiety in this B-L-A compound is the chemical structure that attaches and reacts with the B, the imaging tag, and then couples that to the A group. So that is the linker. It is the -- the molecule that will react and form the entire B-L-A structure.

Q Okay, so let me make sure I understand that. So you have the B moiety, and the L attaches on one side of L to the B moiety, right?

A That's -- yes.

Q And then you have an A moiety, and the other side of the L attaches to the A.

A That's correct, it is a bi -- as described here, a bifunctional molecule, so it means it can interact with the A and interact with -- react

with A, react with B, and form the full structure.

Q Does the definition of L in the claim use a chemical formula like the definition of A uses to define the identity of the chemical structure that is L?

A The L structures are not listed here. However, in the specification, they point to the breadth of Ls that were known in the literature at the time, so these are known bifunctional ligands. They're bifunctional molecules that can perform linkers, and by reference in the specification and also references to prior art from before this was filed in 2017, those L groups are adequately described.

Q So the linker moiety can vary in size, right?

MS. PARTINGTON: Objection, form.

A The linker moiety can come in -- as I stated, there's a number of different linkers that could be developed, and they would be -- everything here would be confined, constrained by the molecular weight of the compound.

Q So there's no explicit maximum length of a linker in terms of bonds or atoms in that linker, right?

MS. PARTINGTON: Objection, form.

A Again, the linker comes from what's described in the specification as well as what was known in the patent literature prior to 2017, and there -- there are a number of different structures that could fall into this -- right, could fall into this description for L.

Q Right.

A Yeah.

Q So the -- the claim language itself doesn't place some maximum length of atoms found or -- sorry, what's the best way to describe it if we can speak the same language? So a linker will have a number of atoms that are in the linker that represent kind of a in one sense length of the linker, right? So typically a carbon or heteroatom in a -- in a chain of atoms, right?

MS. PARTINGTON: Objection, form.

A Yes, I understand your description, and

again, these are -- you know, would have been -- linkers would have been known in -- of various sizes would have been known in, you know, the prior art before 2017. They were used for these purposes of coupling two halves of a -- or two components of a molecule together, and again, as they're listed in the specification as well as referenced, you know, to prior art.

Q Are the -- so let me just try and use your question. What requirements of the linker are listed in the claim language?

A The -- the requirement here is that it has the bifunctionalization to be able to connect B to A. That is the -- that's what it states there.

Q And that requirement is met if the assembled B-L-A molecule basically has two chemical bonds, one on either end of the linker, one to the B and one to the A, right?

MS. PARTINGTON: Objection, form.

A The -- the -- it's described here, right, this linker has a reaction with B and connects it to A, right, and is a bridge, a tether, a linker.

There are several terms that we could use here, between the two. It has reactive -- it has reactive groups on either end, or groups that one could react to attach the B and groups that could be used to attach or attach to the A, right, depending on the direction of the chemical reaction. So that's what this states, is that is what its purpose is.

Q Is there any minimum length required by the language defining L of the L component of the B-L-A molecule?

MS. PARTINGTON: Objection, form.

A The L -- the L components can -- are comprised of many different groups and many different chemicals and form that was known in the -- in the prior art, and again, it's -- there's some that are described in the specification, as well as by reference to prior art, and there can be a number of different chemical structures that would fit into that -- into that -- into the L category.

Q Right, and you may not have heard my

question where I was -- I was asking about whether there's a minimum length that's required by the language in the claim of the L moiety.

MS. PARTINGTON: Objection, form.

A In the claimed -- in the claim here, this does not prescribe any length of -- in the claim, there's no prescribed -- there's no prescribed length, but it has to -- you have to have some number of -- you have to have some number of bonds or molecules in between the A moiety and the -- and the B imaging group. That is not prescribed -- either how long or how short is not prescribed in the -- in the claim.

Q Okay, so I could have as my L a molecule that has a single carbon atom and two functional groups that will react one with the B molecule and one with the A molecule to join those two through that linker, correct?

MS. PARTINGTON: Objection, form, foundation.

A So I believe in my -- I believe my declaration does describe this and discusses the

length of the L.

Q So we'll -- we can go there, but I'm just wondering, as we've just been walking through this, the linker has to have two functional groups available to join the B and L -- sorry, right, it has to have two functional groups, one that connects the L to the B, and one that joins the L to the A moiety, right?

A That is correct, it has to have -- the B has to have -- sorry, the L has to have function -- functionality on two parts in the molecule, right, that allow it to make the attachment to A and the attachment to B.

Q In a -- in a single molecule, or -- I'm sorry, in a molecule that has a single carbon atom, a hydrogen and two functional groups that are reactive with corresponding groups on the B and on the A could function to join those two molecules to the L, right?

MS. PARTINGTON: Objection, form, foundation.

A The molecule L has to have two functional

groups that allow it to be connected to B and to A.

Q Okay. Am I right to interpret that answer as being yes to my previous question?

MS. PARTINGTON: Objection, form.

A I am just saying that the L has to have the functional -- functionality of being able to connect B to A functional groups, two functional groups there that allow the attachment of B to the -- to the linker group, and then the linker group to the -- to the A FAP-binding molecule.

Q Okay. Let's go a bit earlier in that paragraph that has L in it. There's another definition, and that's of B, the B moiety. Could you just read aloud what the definition of the B moiety is as it's defined in the claim?

A So B is an optical or radiolabel functional group suitable for optical imaging, positron emission tomography, PET imaging, single photon emission computed tomography, SPECT imaging, or radiotherapy.

Q And as I look at your answer, you said and

optical, and the word in the claim is "any," right?

A B is any optical or radiolabel functional group.

Q And then the optical or functional -- sorry, the optical or radiolabeled functional group has to be suitable for optical imaging, positron emission tomography, PET, imaging, single photon emission computed tomography, SPECT, imaging, or radiotherapy, right?

A So it's defined here. This has to be -- a molecule has to be suitable and contain either the optical or radioactive groups so that one could visualize these using a number of different techniques or instruments that would be involved in optical imaging, positron emission tomography, single photon imaging, and of course, those -- PET and SPECT define the type of radioactive isotope, right, the two different -- two different types of emissions there that are -- and that's what that defines.

Q And just so I have my terminology, first

of all, I think we can use PET and SPECT, right?

A Correct.

Q That'll save us both some effort.

A Yes.

Q Second thing is when you're dealing with the radioactive version of this, it's the radionuclide in the B moiety that is being detected by the PET or SPECT device, right?

A It is the radionuclide that is being detected by the nuclear detector devices, yes.

Q Okay, and this may be a dumb question, but can B moieties be suitable for use in optical imaging, PET imaging, SPECT imaging or radiotherapy without being attached or associated in some way with the targeting moiety, A?

MS. PARTINGTON: Objection, form.

A I mean, one can use the radioactive isotopes themselves individually. One can attach the radioactive isotopes to a number of different molecules, and they can have -- they can have utility. In this particular case, right, that this -- the optical group is the B group or the

radiolabeled molecule is the B group that would then provide the radioactive or the optical imaging component of the B-L-A molecule.

Q What makes a B moiety suitable for optical imaging, PET imaging, SPECT imaging or radiotherapy?

MS. PARTINGTON: Objection, form.

A The ability to -- actually, to -- the ability to get a signal in a device that would be optical device or a radioactive -- radioactive detector.

Q If I made a B-L-A compound, and the B portion of the compound were cleaved from the L and A portion of the compound shortly after I injected it in the subject, would that B moiety be suitable for optical imaging, PET imaging, SPECT imaging or radiotherapy?

MS. PARTINGTON: Objection, form, foundation.

A It would not be suitable for -- for its intended purpose. Perhaps the signal would still be given off by the -- by the molecule. The

molecule, you would still see it in a optical -- through imaging, optical gamma detectors, gamma counters, right, you would still see the radioactive isotope, but it would not -- as you indicated, it would not be intact.

Q Doesn't the B-L-A molecule have to remain intact at least to the point where it has arrived at the target tissue in order for it to be suitable for optical imaging, PET imaging, SPECT imaging or radiotherapy?

MS. PARTINGTON: Objection, form.

A As described here in the claims, the utility of this molecule, the B-L-A molecule, requires that you have an A, a linker, a B, and the B can be either optical or radioactive. So the utility here in this particular patent is based on the ability of the B-L-A molecule to interact with the FAP. Whether that FAP is in the laboratory, in a in vitro assay, or whether it's in ultimately an in vivo assay, it would have to interact.

Q So it's fair to say that the B-L-A

molecule has to stay intact long enough for it to bind to the FAP target and be detected by the optical imaging device, the PET imaging device, the SPECT imaging device, or in the case of radiotherapy, I guess it has to be in a person, right?

MS. PARTINGTON: Objection, form.

A So the utility of these molecules is as stated here, you have a B-L-A molecule, right. It is that molecule that in its total form B-L-A takes the signal, carries the signal from the optical, the PET or the SPECT or the gamma or the positron emission, right, if you're doing in vitro binding, so gamma -- you know, gamma counting, it carries that along with it to interact with the FAP protein.

Q Could I have you go to column 36 of the patent, and go down to -- and you're familiar with patent column and line number?

A Yes, yes.

Q Okay, great. So go to column 36 and read line 20 through 31, and when you're done reading

that, let me know.

A I've read that paragraph.

Q Is this passage at column 36 lines 20 to 31 explaining what imaging is?

A This is a one-paragraph description, very high level of looking at radioactive decays, and it does reference different cameras and different methods of quantifying radioactive -- and it does also include florescence, which would be the optical emission, so this is a one-paragraph definition that would be -- you could write books on how this is done, and given that this is one paragraph.

Q Do you believe it's accurate?

A The -- the description here, again, is very high level, and it covers the -- a number of different aspects of imaging. I don't -- you know, I don't dispute this paragraph.

Q Okay, so it's correct that imaging involves use of this imaging agent, and that image -- sorry, if you look at the second sentence, imaging can be generated by virtue of differences

in the spatial distribution of the imaging agents, which accumulate at a site when contacted with FAP alpha, that -- that's kind of the heart of imaging, right?

MS. PARTINGTON: Objection to form.

A Images are created by the distribution of imaging agents. In -- you know, as we've been talking here, a number of different circumstances, right, and by virtue -- using the language there, that you're looking at the -- as we even described earlier, the differences in two different regions within whatever material it is that you are looking at with the different imaging agent, and this being targeted, as it describes here, to FAP alpha, would be looking for that FAP alpha interaction and differences in different tissues, in different cells, in different -- you know, whatever the situation that you're using it in as an imaging agent.

Q And as it points out, that's possible because the imaging agent is accumulating at the site when it's contacting the FAP alpha, right?

A That's what it says here, but as we discussed earlier, that molecules don't -- you know, if FAP alpha is there and it's a FAP alpha targeting molecule, it can bind -- may bind, but it may bind to other things that are also there, background nonspecific binding, as we discussed earlier, right? So this is -- this is just a high-level -- again, a high-level paragraph trying to describe something that's very complex.

Q And as the B-L-A molecule kind of is designed here, the A moiety is what's going to be doing the contacting with FAP alpha, right? That's the selective binding of the A moiety to the FAP alpha to enable the imaging agent to accumulate at that site where the FAP alpha is located, right?

MS. PARTINGTON: Objection, form.

A The molecules that are described in the claims, the structures that are described in the claims have the utility, that is, their usefulness is in binding to FAP alpha -- targeting FAP alpha. That's the description, and that's the utility

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that's -- that is demonstrated by the molecules that are described in the structural claims that are here as part of this -- part of this patent.

Q All right. So the B moiety -- well, you referred to the radionuclide or the optical -- like a dye, right? Those are the kind of chemical structures that are used for optical image areas, is a dye?

A They can -- yes, they are -- they are -- they are called dyes, yes.

Q Okay, so for the radionuclides, one way of associating a radionuclide to the B-L-A or to the B moiety of the B-L-A molecule is with a chelator, right?

A I'm sorry, could you -- could you just --

Q Yeah, so --

A You don't have to rephrase. Just repeat the question again. I'm sorry, I just missed part of it.

Q Yeah, so one way of associating a radionuclide with the B moiety is to use a chelator as your B moiety.

A So there are multiple -- there are multiple ways to incorporate radioisotopes into radiopharmaceuticals, and one of those is to use a chelate, typically used for radio metals. You can use prosthetic groups, which are radio -- are moieties which have the radioactive isotope already incorporated into it and react it, or you could do a direct labeling onto the molecule itself.

So these are the three general, and in each of these classes, there are multiple ways to develop and multiple structures that you can use to -- to -- to attach or form a bond between -- or multiple bonds in the case of the chelates, between the radioactive isotope and the molecule that you're trying to label.

Q So some of those cause a noncovalent association of the radionuclide to the chemical structure that is the remainder of the B moiety, right, such as a chelator? And again, as I said at the beginning of the deposition --

A Yeah.

Q If my -- I'm mangling chemistry and chemical words, point that out. I'm just --

A Okay.

Q Let me just pull the question back and give you a slightly better one. You just described three general approaches to, if I can call it, associating a radionuclide to the B moiety, right?

A I would call it -- well, I would call it a bonding, bonding, right, that would be -- of the isotope to the molecule, bonding.

Q Right, okay, and just to be clear, are all -- every kind of radionuclide detectible by both PET and SPECT scanners?

A So in PET scanners, it -- it's based on the positron emission, so you need isotopes, radioisotopes that emit a positron, and it is annihilation of the positron that gives the gamma rays that you can see in the PET scanner.

In a SPECT scanner, the single photon refers generally to classes of radioisotopes that give off a single gamma ray, and you are measuring

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the single gamma ray in the camera detector. In your question, it is possible to use a SPECT camera to look at PET because PET does give off gamma rays. It gives off two gamma rays, so you could actually look at -- but they're higher energy. It's a different instrument, right? There's other caveats there, but you know, you have gamma rays that you can detect.

Q And the reason for this question, just to kind of understand that when I'm dealing with a radionuclide that is in a chelate complex to form the B moiety, particular radionuclides require particular structures to kind of form that bond between them. Is that fair?

A All of these radioactive isotopes are elements we find on the -- on our periodic table, and each of those has its own physical characteristics and how it can be incorporated into larger molecules, larger meaning more than one, that is, bonding to some other molecule. Let's not get in -- about size here, but incorporating the -- the elemental isotope into a

molecule.

Q And the reason for my question was that when I'm thinking of the different options that may be implicated by this claim for the B moiety, it will include a variety of chelate structures which each relate to a particular type of radionuclide or multiple radionuclides with which it can form a stable complex, right?

MS. PARTINGTON: Objection, form.

A So much like the -- much like L in this description, B is not defined by particular groups as A has shown here, and again, in the specification, there are examples of chelates. There are many chelates that were well known before the patent was filed, and this is in 2017, so by way of the specification, there are a few examples I can show in the specification as well as by reference, right, to other -- to previous known art, right? There are a number of different chelates that are well known that can serve as the B for this -- you know, in this case.

Q Does -- if you want to use a radionuclide,

do you need to use a chelator?

A As I think I -- I pointed out a few minutes ago, that you can do a direct labeling onto a molecule that does not involve a chelator, right, so you can exchange the radioisotope for another element on that -- on that molecule. Could be a hydrogen, could be a leaving group that will be displaced by the radioactive isotope coming in.

The other method that could be used besides a chelator would be to incorporate the radioisotope into another molecule, which of course would involve some sort of exchange of an element on that molecule with the radioactive isotope, and then use that as a -- what we call a prosthetic group to actually then radiolabel the molecule.

So -- and then -- and then as -- as you described, for certain elements, we need the chelating groups to be able to capture the radioactive isotope, and that would also be then attached. In a way, that is also a prosthetic

group because you're -- you can radiolabel that first and then incorporate it into the molecule.

Q That last category, those would be the radio metal radionuclides, right, for the chelators?

A Generally it is the radio -- it is metal, metallic isotopes that require the chelate in order to form the -- the radioactive entity, yes.

Q So -- so there's a variety of chemical structures that are captured by the B moiety language in the claim. Is that fair?

A As -- yes, as I indicated in the specification, there's some examples as well as it was well known in the literature in 2017, a variety of different -- a variety of different chelates that could be used for capturing radio metal isotopes.

Q And the claimed B moieties don't have all of -- the set of B moieties covered by the language in the claim don't have a common set of structural features, do they?

MS. PARTINGTON: Objection, form,

foundation.

A Again, the B moieties are -- as -- as shown here in the claims, it describes what the B moiety does, and that it binds obviously with the L, binds to the L. That incorporates it into the whole molecule B-L-A. In the specification, there's definitions for well known chelates, so by reference to the prior art as well as the examples shown in here, the -- the inventors have sort of the full breadth of chelates that were known at the time to incorporate into the B-L-A structure.

Q Right, and those -- those structures have diverse structural features, right?

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q Of the B -- sorry, the B moieties that you just reference have had diverse chemical structures, right?

MS. PARTINGTON: Objection, form.

A Again, the B moieties have a range of structures, right, different -- I mean, there's a range of molecules. They have characteristics

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that allow them to interact with the radio metals and to capture the radio metals, and again, some listed here in the specification as well as by reference to the prior art.

Q In your opinion, are there any chemical structures excluded by the claim language for the B moiety of the B-L-A compound?

A Again, the B structures were going off the specification, defined -- defined in the specification or shown in the specification, and also, those were in the prior art, I don't -- the options are all sort of available in the art and on the table. I don't have any -- there's -- there's nothing there that I can't say that -- you know, you can't exclude or -- you know, these are based on what was known in the literature at the time that this was made, so that's the full breadth of what B could be.

Q So basically any chemical structure as long as it's suitable for optical imaging, positive emission tomography, PET imaging, single photon emission or computer tomography, SPECT

imaging or radiotherapy. Is that fair?

A So it would be defined, and I know I've been focusing on the radioisotopes. We've been talking about radioisotopes, but of course, there's a number of optical florescence dyes, optical dyes that were known in the literature prior to, so any of those could be utilized here, and any Bs, radioactive B groups.

So these were not only chelates, right, but this could also be the prosthetic groups, or it could be directly, you know, sort of a -- you know, could be directly labeled onto the B group, right, that gets attached to the L or the A.

So there's a variety of structures that B encompasses, and it doesn't specifically encompass only radio metal chelates, but it encompasses other molecules as well, including the -- as pointed out here, including the optical, so other radioactive isotope molecules, could be a fluorine, could be an iodine, right? So it's not just the radio metals.

Q Just so -- some terminology. When you're

referring to direct labeling, that's basically the radioactive atom -- make it simple, radioactive atom is essentially covalently attached to the remainder of the B-L-A structure, right?

MS. PARTINGTON: Objection, form.

A So in the direct labeling, the radioactive isotope would be bonded to some -- right, to a radio -- to a non-radioactive substance by a molecular bond.

Q Okay.

A Just a broad definition.

Q So for these claims, which require a B-L-A structure, if you put the -- if you directly labeled the B moiety, that would be -- I don't want to say it improperly, but effectively a prosthetic group, right, because you're putting the radionuclide on the -- on the B rather than the A, right?

A So by definition in the claims, right, the B group is the group that has the radioactive isotope, and we -- that could be flourine, could be iodine, could be radio metals, could be other

radioactive isotopes, and as a matter of fact, I mean, if you -- if you take the -- if you take the example of a chelate bound to an L bound to an A, right, and you put a radioactive metal in there, you're doing a direct labeling, and it's just being bonded by the chelate, or if I do an exchange of one isotope for another, could be an isotopologous -- just call it isotope exchange. Isotopologous was the term that I used, that if you do a -- you know, an iodine for an iodine or an iodine for a bromine or a fluorine for a bromine, right, those exchanges, right, are a single -- right, there's a single labeling, and it -- it's direct labeling on the molecule that you have prepared, okay? So that's -- that's defining what -- you know, what we were just describing.

Q And just so I understand this as well as I can, when you're using direct labeling, are you saying that the radionuclide can be bonded to any of the three elements of the B-L-A compound?

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q Or are you saying it's going to be bonded to the B component?

A I'd like to keep it in the context of the patent and say that we're talking about things that are bonded -- that are tagging the B -- the radiolabeling, the B component.

Q Okay. So we talked before about there are different radionuclides, there are metal radionuclides, there are other radionuclides. Earlier, we looked at column --

MS. PARTINGTON: Counsel, we've been going for way over an hour at this point. Does it make sense for us to take lunch?

MR. KUSHAN: Let me ask one -- I think it would make sense to do a break. The question I was going to ask, do you want to do a lunch break now, because it's approaching noon.

MS. PARTINGTON: Noon, yeah, and we have lunch set up.

MR. KUSHAN: All right. Let me -- let me just ask one more -- just one quick --

MS. PARTINGTON: Sure.

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BY MR. KUSHAN:

Q A couple minutes of questions.

A Sure.

Q Then we can break for lunch. So you use certain radionuclides when you're performing radiotherapy, right? Not all of them will have therapeutic effect.

A That is correct, there are isotopes that give off -- that give off emissions that can be used for therapy. These are typically alpha-emitting radioisotopes and beta-emitting radioisotopes.

Q And when we refer to radiotherapy, that's something that's occurring in a -- in a person or an animal, right?

MS. PARTINGTON: Objection, form.

A That's what we think of when we think of radiotherapy, but there is -- these can be obviously used in in vitro cases to -- their emissions can also be therapeutic in an in vitro -- in vitro case, used in research, right, used in development, but the therapy piece we typically

link to a -- a human application, right?

Q Right, because the goal is to have an effect in the human. That's what the therapy is, right?

A The goal is to -- is to -- is to have an effect on whatever tissue it is that you're irradiating with the radioactive isotope.

Q Okay. Do you believe that the B moiety in the B-L-A compound does not have to retain the ability to be suitable for optical imaging, PET imaging, SPECT imaging or radiotherapy after it's incorporated into the B-L-A compound?

A Could -- I might ask you to rephrase the question so I can better understand what you're -- what you're asking.

Q Yeah, so -- so you see that the definition is referring to the B moiety must be suitable for optical imaging, PET imaging, SPECT imaging or radiotherapy, and I'm just asking you to confirm that it has to be suitable for those uses both before it is attached to the B-L-A and after it is attached to the B-L-A compound, right?

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A Well, before it's attached to the B-L-A compound, right, it's still going to be a radioactive isotope in the case of radiolabeling. The optical agent, until you fluoresce it, it doesn't give off any emissions, so it just sits there in the jar or bottle or whatever it is you have, but as prescribed here, building these compounds, right, in order to see the targeting moiety A and where it's going, then this B has to, as indicated, have to be radiolabeled or have optical so you can see where A is going, and again, this is part of the utility of this -- part of the utility of this whole B-L-A compound.

MR. KUSHAN: All right. Why don't we take our lunch break.

(Recessed at 12:02 p.m.)

(Reconvened at 12:40 p.m.)

BY MR. KUSHAN:

Q Give me a description of your experience with the FAP protein and testing for selectivity for binding to it.

A So my experience broadly is close to 40

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years' experience developing radiopharmaceuticals. Many of them are receptor binding radiopharmaceuticals similar to FAP, and we have -- in my laboratory, we have not -- my -- my particular laboratory's not worked directly with the FAP and doing FAP binding, but we are -- obviously this is an area that is a very important area in the radiopharmaceutical field, and so I'm quite well aware of FAP binding, but the procedures to -- and understanding how one would analyze radioligand binding to receptors to proteins and so forth is -- is common to all the different types of radiopharmaceuticals.

So my experience would cover that, and I have written and probably incorporated into review papers or in the papers I've written and grants that -- proposals that -- that I've written.

Q So you don't have any direct -- before you were retained for this project, you had not done any work focused on understanding the FAP protein, its kind of enzymatic mechanisms, things of that nature?

MS. PARTINGTON: Objection, form.

A I was well aware of it in the literature, had read many papers about it, obviously going to meetings, it has become over the last decade a molecule that -- and a target that has been widely evaluated and studied. I have reviewed grants from people who have been working in this field for a long time. I'm a grant reviewer for -- for NIH and for the State of Texas, and so I have reviewed -- reviewed grants, and as I said, my experience in this field I think covers that I can -- can speak to and understand completely the FAP-targeting agents, development of those, and also the applications and also the assays that are necessary to -- to analyze different FAP radiopharmaceuticals or imaging agents or fluorescent agents or whatever.

Q All right, so for -- like you're trying to find a molecule that is going to be a FAP inhibitor, you're going to basically try to exploit the ability of this molecule to behave like a substrate for the FAP enzyme, right?

A It could behave as a substrate for the enzyme. It could behave as an inhibitor for the enzyme. Those are two -- you know, two approaches that one could take if they're looking at enzymes -- enzymes in a -- in a biological system.

Q Based on your review of the literature in this case, testing different FAP inhibitors, they often use a level of inhibition of the FAP enzyme as a measure of affinity of a molecule for FAP, right?

A So affinity is very common in receptor-binding radiotracers, and inhibitor behaves like a -- is -- is a binding relationship with the target, and so that's -- you know, I completely understand how, you know, this interacts and how this works.

Q So you're comfortable using those inhibition measurements when you're assessing the kind of individual molecules for their affinity, selectivity characteristics for FAP, right?

A I am quite familiar with the terminology and methods for evaluating interaction of

molecules with enzymes, molecules with proteins, molecules with receptors, so in general, yes.

Q So one thing we -- I think you've addressed this in some of your declaration testimony. One of the big issues that seems to be addressed in the literature in -- in the patents is the selectivity for a targeting moiety for FAP relative to its affinity for PREP, so there's kind of a comparative engagement of the two different enzymes by the one molecule to evaluate kind of the selectivity in that molecule for one over the other, right? You've seen that?

MS. PARTINGTON: Objection, foundation.

A I've seen that.

Q Okay. In doing the work on this case, did you investigate the mechanism of action of the FAP enzyme and the PREP enzyme?

MS. PARTINGTON: Objection, form.

A In reviewing this, I did read through the literature and understand the interaction of FAP with the enzyme and the assays for -- the assays for characterizing that.

Q Okay, and based on your answer this morning, the literature you would have reviewed is one of those papers that are either in your exhibit list or in Dr. Zeglis' exhibit list. Is that fair?

A That is fair.

Q Okay.

A Yes.

Q Will you -- did you know if there was an experimentally determined structure of the FAP protein before 2017?

A I tried to remember if I'd -- if I'd seen such a structure. I know that's pretty common to have enzyme structures. I mean, I've done it myself for other projects, but --

Q You don't recall if you --

A I don't recall at this moment.

Q Do you -- do you recall if you -- if you looked at any paper describing the structure of the PREP enzyme?

A Excuse me. I don't recall -- I mean, I recall the literature describing the -- the

interaction. I don't recall seeing the literature with the -- with the enzyme structure. I don't recall.

Q Did you attempt to investigate why a molecule that bound with high affinity for FAP did not bind with high affinity to PREP as part of the analysis you did for this case?

MS. PARTINGTON: Objection, form, foundation.

A I'm sorry, I'm going to -- let me just ask if you can repeat the question so I can understand the --

Q Sure.

A -- what you address.

Q In forming your opinions, did you investigate the way that a molecule -- in forming your opinions, did you investigate how a particular molecule was interacting with the FAP enzyme as opposed to how it was interacting with the PREP enzyme other than by the kind of measured activity or affinity?

A So in the descriptions that were -- were

in the -- in some of the publications that I read, that would be the only -- aside from the assays and understanding the assay interaction or the quantitative interaction between FAP and PREP, it -- it's likely that I read through it in the background of the -- of the particular publications that I reviewed, yes.

Q And both PREP and FAP are peptidase enzymes, right?

A They belong to a similar family of enzymes, yes.

Q Do you know if they have similar mechanisms of actions on the peptidases, on the peptides?

A I don't recall their mechanisms of -- well, I can say that I know that they -- they cleave certain residues in the -- in a peptide -- peptide structure, but the exact mechanism for each one I don't recall, or I don't have committed -- I've seen it in the papers, but yeah.

Q They -- they both act on peptides which have a prolene somewhere in them, right?

A Correct.
Q Okay. They're called prolyl oligopeptidases, right?
A Right.
Q Okay. Do you know if anything was known by October of 2017 as to why a particular peptide would be acted on differently by FAP relative to PREP?
MS. PARTINGTON: Objection, form.
A Would you -- would you please repeat the question because I'm --
Q Sure.
A -- trying -- I'm trying to think about this as you --
Q I'm going to -- I'm going to try to give it --
A Maybe to rephrase it or something?
Q Yeah, of course.
A Simplify?
Q What -- so -- so we -- so you've seen papers where a single inhibitor molecule is measured for its interaction, IC-50 values against

FAP and then PREP.

A Yes, yes.

Q And so you see the same molecule causing different IC-50 numbers for the two different enzymes, right, in many instances?

MS. PARTINGTON: Objection, form, foundation.

A So FAP and PREP are two different enzymes, and the molecules that interact with them will inhibit them, will likely, you know, have different interaction between the two, because they're two -- two different enzymes.

Q Right, and there's like a selectivity index in the various papers where they basically divide the IC-50 value of PREP by the IC-50 value of FAP to -- or conversely, to give a rating of the relative IC-50 values of the molecule against those two different enzymes, right?

MS. PARTINGTON: Objection, form, foundation.

A I've seen in the literature and actually have formulated this into some opinions that I

have in my declaration about the interaction of the molecules with FAP, PREP, DPP 4, and there are some other enzymes that are in the same family that are also included in -- in many of the literature that I reviewed.

Q And that index value is used to kind of rate at some level the selectivity of the molecule for FAP over PREP, right?

A It is a measure of how the molecule that you are introducing interacts with the FAP and the PREP, right, how it -- how it interacts with them, the differential interaction between the two.

Q Right, so -- so a number that's larger in this SI, selectivity index, is indicating that the molecule has much higher selectivity for FAP than it does PREP, right?

MS. PARTINGTON: Objection, form.

A So each -- each individual number in this selectivity index that you're describing provides a quantitative value of how much of this material inhibits one enzyme, how much the --

(Interruption)

THE WITNESS: I'm sorry, let me -- so each -- each FAP -- so FAP will interact with -- FAPi will interact with FAP, right, it'll interact with PREP, it'll interact with other enzymes. Each of these has an individual -- will have an -- by the assays that are performed, will give a individual quantitative number, and that -- the difference between those numbers tells you how each one is interacting with their respective enzymes and relative to each other, is it inhibiting one more or one less or so on and so forth, and then you can create indices, which is one measure that is used to develop pharmaceuticals, right, develop drugs, as well as used in development of imaging agents.

BY MR. KUSHAN:

Q Okay. Did you consider any differences in the PREP and FAP enzymes as to the ability of each substrate to access their active sites?

A I considered the assays that are performed to provide the inhibition data to determine the interaction of the FAP with the -- with the

enzymes.

Q But you didn't kind of look at it at a structural level of what that axis looks like and axis of the substrate to the different active sites.

A I reviewed the binding assays and the binding data to give me -- to assess the interaction of the FAP with the FAP and PREP enzymes.

Q In the course of your work in developing radioimaging agents and other imaging agents in your career, do you periodically investigate the kind of structural characteristics of things like enzymes?

A Yes, in my career, I have looked at the structure of enzymes.

MR. KUSHAN: All right. Can I mark this as Exhibit 1064?

(Deposition Exhibit Number 1064 was marked for identification.)

BY MR. KUSHAN:

Q There is a paper by Fulop et al. in Cell

from 1998, and its title is "Prolyl Oligopeptidase: An Unusual Beta Propeller Domain Regulates Proteolysis." I mean, I can ask you to read this whole paper. I -- I want to just direct your attention to a discussion of it. This is a paper that published the structure and discussed the structure of PREP, and I see -- I use the word "PREP," and you'll see a lot of different words in literature. There's prolyl oligopeptide. There's another acronym called POP I think.

I want you to look at paragraph -- or I'm sorry, page 167. There's a section there titled "Access to the Active Site," and if you want to take a few minutes and just read that section, I just want to discuss that a little bit with you.

A Okay, I read the first paragraph. Is that --

Q Sure.

A -- wanted?

Q So that last sentence in that paragraph states, they say, "In this manner, the propeller excludes large structured peptides and proteins

from the central cavity, thus, protecting them from proteolysis in the cytosol," and that's referring back to the discussion about, you know, this tunnel structure that the substrate has to go through to get to the active site, and you see in the middle of the paragraph, in the resting structure, the hole at the bottom of the propeller is not wide enough to permit the diffusion of substrate, and the entrance can be widened by the movements of these flexible side chains.

So there's like this restricted tunnel that the substrate has to get through to get to the active site, and it's just concluding by observing that may explain why PREP might exclude large-structured peptides and proteins from the central cavity, right?

A Yes, I see where this is -- I see where this -- yeah, where this has this, yes.

Q So one of the papers you cited in -- with your declaration is Exhibit 2032. This is a paper by apparently a Dutch guy, Dutch woman, Aertgeerts. I can't pronounce it. It's A-R --

A-E-R-T-G-E-E-R-T-S, again, Exhibit 2032.

A Thank you.

Q And this is a paper about FAP structure.

A Okay.

Q Right?

A Yeah.

Q And if you can go to page 19442, in the right column, at the top, it's a discussion, and it starts with, "The FAP alpha catalytic triad." Why don't you read the -- kind of those two paragraphs and let me know when you're done.

A Okay.

Q Okay. So this is indicating that the FAP -- FAP active site is accessible to substrate through two approaches. One is through this kind of central hole formed by this propeller domain component, and the other is another access point, and they indicate that the propeller dimensions of that kind of tunnel are about 14 angstroms width, and the other access path has a much larger one of 24 angstroms. So this is showing -- or reporting that the active site of the FAP is a bit more

accessible to substrate than the active site of PREP, right?

MS. PARTINGTON: Objection, form.

A Yeah, I mean, it's -- in looking at these -- in looking at these two structures, I mean, and the written description, or the description here of what they're -- of the -- of the structures, I -- I can't say -- and say anything about how, you know, different molecules would interact and whether one is larger than the other or smaller than the other or anything. I mean, this is just a physical description of the openings of both of these enzymes to which molecules could enter and interact, inhibit, bind, and so I'm not able to just on this cursory look describe anything more than the structure of these two molecules.

Q And when you formed your opinion about differential effects of substrates relative to the PREP and FAP enzymes, you didn't consider this information, right?

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q And just to be clear, that's a historical question, in forming your opinions, you didn't consider these comments and explanations of the active site and substrate access to them in forming your opinions, right?

A In forming my opinions, I looked at the assay data, which is the real information that one would -- would look at in order to determine how the FAP and -- the FAP molecule interacts with each -- or the FAP inhibitor, the FAPi, interacts with each of these enzymes. The -- yeah, the structure can -- you know, may -- may allow one to interpret differences in numbers in the -- in the analysis, right, of their inhibition, and you could put, as they do in these structures, put molecules into the structures and actually co-crystallize, right?

There's all kinds of things you can do to analyze, but my opinion remains the same, whether the structure of -- independent of the structures of these molecules, because that's not -- I'm not looking at these molecules structurally. I'm

looking at these molecules on how they -- how they function, not on -- not on their structure, and so this is why, you know, I did not focus my attention relative to this -- to my opinions on the structure of these molecules, but rather, on how the FAPi interacted with these molecules, right, with these -- with these peptides.

Q So you're not trying to suggest that you were explaining why some results may be observed. You were just focusing on the functional data that was generated from the terminal tests and reporting on the conclusions based on those measured inhibition values.

A Right, in developing --

MS. PARTINGTON: Object. Objection, form, foundation.

A I'll just -- I'll just restate that in my analysis of the data for the FAP and PREP interactions of the FAP B molecules, I was looking at how the assay results, right, and not the structural interaction of each of the compounds with the FAP and PREP molecules. My focus was on

and looking at the data coming from the assay -- assays.

Q Got it. Let's -- I'm going to go to Zeglis's report if you could. That's Exhibit 1003. Could you go to paragraph 80 of Dr. Zeglis' report, which is -- which is declaration Exhibit 1003, and paragraph 80 is on -- starts on the bottom of page 51 and goes over to 52. So if you want to take a minute and review paragraph 80, that's fine. Just let me know when you're ready.

A So I'm sorry, just to be clear, which paragraph? Starting on paragraph 80?

Q Paragraph 80 is what I want you to look at.

A Okay, I got to --

Q Hopefully an easy question. Is Dr. Zeglis discussing the low molecular term that was used in the patent claims in this section?

A Dr. Zeglis is -- has connected this paragraph to the phrase a low molecular weight. You know, what it means when it uses -- and he's referring to the '233 patent, what he is referring

to -- what it is referring to as the phrase low molecular weight, so that's how I read this -- read this paragraph.

Q Okay, and there's a footnote 90, which is clipped off of a quote from the '233 which is reproduced in paragraph 80. Do you see that?

A The one at the bottom here, right?

Q Yes, yeah, that's just a citation to the paragraph --

A Yes.

Q -- that is in his paragraph 80, right?

A Yes.

Q And that's the paragraph from the '233 patent just being reproduced here, right? And if you want to look at the patent, you can check. It's the --

A This? Yeah, okay, I see what you're saying.

Q I will say it's a little bit easier to read this text than the patent, but --

A And where is -- I'm sorry, where is that located?

Q You're going to go to column 1.
A Oh, it is column 1.
Q Yeah, lines 60 to 61.
A Okay, yes, I see this comes from the patent.
Q Okay, so does the passage in the '233 patent that Dr. Zeglis reproduces in paragraph 80 identify any problems with using antibodies as molecular imaging agents?
MS. PARTINGTON: Objection, form.
A And antibodies are very commonly used as -- as imaging agents. Sometimes it's some of the first molecules that we have available to us that have affinity or avidity for some of the targets that we're going after. So this -- this describes that some of the -- you know, some of the limitations that there are, but there are also, you know, advantages that we have in terms of imaging that would also be attributed to -- can be attributed to antibodies, including their expert targeting in the -- expert targeting of their antigen.

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Q So what are -- so what are the limitations that the '233 patent identified in using antibodies in imaging agents?

A They describe -- what they described here without details, pharmacokinetic limitations, including slow blood and nontarget tissue clearance and nonspecific organ uptake.

Q And then it continues, the '233 patent continues by identifying some relative advantages of low molecular weight agents relative to the antibody-based agents, right?

A It describes the differences and the pharmacokinetics as -- you know, as described here.

Q And what are some of those advantages that are identified for the low molecular weight agents?

A I said here, they -- they've identified faster pharmacokinetics.

Q Any other advantages?

A They -- they also describe in the next sentence that they -- that they can be synthesized

and made -- may offer a shorter path to regulatory approval, but I can tell you that -- and they've -- they've cited a few citations there, but I can tell you that you can radiolabel antibodies pretty easily and get them approved for regulatory approval as well, so --

Q Are you --

A But this is what it says here.

Q Are you familiar with kind of the regulatory approval processes for biologics versus small molecule therapeutics?

A Yes, I am.

Q Are they the same burden on the developers of those types of products?

A The -- for moving materials forward, there are obviously for both -- for both pathways, for biologics and small molecules, there are different conditions that have to be met, and certainly in our experience with first in human study, not something going all the way to market, that these can be met fairly easily with the appropriate materials.

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Q For biologics, don't they have to regulate the manufacturing process?

A For biologics, the molecules have to be manufactured under good manufacturing practices.

Q But they also have to certify the facilities that are making the product too, right?

A That's part of the GMP manufacturing.

Q And it's -- it's a slightly more burdensome regulatory aspect of that product development as opposed to the small molecule drugs.

MS. PARTINGTON: Objection.

BY MR. KUSHAN:

Q Right?

MS. PARTINGTON: Objection, form.

A If one is starting from scratch, yes, but if there are available materials that have been produced under those manufacturing practices, then the level of burden is almost equivalent.

Q Can you source a biologic from any place as you can a small molecule element of a radioimaging agent?

MS. PARTINGTON: Objection, form.

A One can -- it is possible to source, not for every single target, but it is possible to source antibodies for particular targets and work with them.

Q Let me introduce another exhibit. We're going to mark this as Exhibit 1065. This is a paper, the first author, Ganguly, and you are the second to last author on this paper, so let you take a glance at it.

(Deposition Exhibit Number 1065 was marked for identification.)

BY MR. KUSHAN:

Q Are you the Henry F. VanBrocklin on this paper?

A I am the Henry F. VanBrocklin on this paper.

Q Are you familiar with this paper?

A I am familiar with this paper.

Q Okay. Could I direct your attention to the paragraph under the abstract on the right column of the first page? So this paper was

published in 2015, right?

A That is correct.

Q So it says that the only FDA-approved single photon emission computed tomography diagnostic imaging agent for PCa and 111 indium labeled antibody that recognizes an intracellular epitope of the PSMA transmembrane protein is only accessible in damaged or in necrotic prostate tumor cells. You see that?

A Yes, I see that.

Q Okay, and then it says, "Even though other antibodies targeted to extracellular epitopes of PSMA have been employed successfully to deliver diagnostic and therapeutic radionuclides, the long accumulation and circulation times, the poor tumor penetration and multiple-day imaging procedure result in their suboptimal diagnostic accuracy and reduced clinical use." Is that statement accurate?

A This is a statement that was made referring to the information and data that was known at the time for the antibodies that target

the PSMA in this particular case.

Q So is the long accumulation and circulation times unique to antibodies to PSMA?

A The pharmacokinetics properties, the accumulation time, circulation time, is -- is one of the characteristics or some of the characteristics of antibodies. I would point out that actually, there still are some antibody molecules that are being pursued as imaging and therapy agents for PSMA in spite of the -- in spite of the limitations that were pointed out here. So again, in -- in the field even today, and certainly back in 2017, the availability of sort of all of the different isotope -- sorry, all of the different molecular structures was -- was -- you know, was available to -- and if any, had -- had been made to target specific -- specific proteins or specific targets, enzymes included in there as well that they could be potentially used for imaging.

Q So if you could just look at the sentence that's the first sentence of the next paragraph,

that one states, "In contrast, small-molecule probes possess advantages of drug-like pharmacokinetics, high atom-economy, and reduced production costs." Is that statement accurate?

A That statement does describe some of the attributes of a small molecule.

Q And those are similar to the ones that were identified in the '233 patent, right?

A And so this -- as a class -- as a class of molecules, those on the lower -- you know, the low molecular weight side have properties that are -- make them suitable drugs, make them suitable for radiopharmaceutical labeling.

Q And you're using the word "small molecule probes," and the '233 used the low molecular weight term. Are those interchangeable to you?

A So I have not -- as you know, Dr. Pomper acted as his own lexicographer, and in the prosecution of the '233 patent, put a limit on the molecular weight to 1,500 daltons or less, and so this -- this is a generalization in here, small molecule probes. So I'm not using -- didn't use

it this time, didn't know at this time of the -- of the limitations that Dr. Pomper had put on here, but these are generally the same class of molecule.

Q Okay, and you mentioned antibody-based imaging agents. Do you know -- do you know how many diagnostic antibody-based imaging agents had been approved by the FDA by October of 2017?

A I know that there had been several that have been approved, but I do not have an exact number of the numbers that were approved.

Q Do you know how many antibody-based imaging agents were actually being marketed in October of 2017, notwithstanding their prior approval?

A I don't have that information committed to memory, but I have -- I have -- you know, I've seen that information.

Q Would it surprise you to learn that most of the antibody-based diagnostic imaging agents approved before 2017 were not being marketed in October of 2017?

A I knew that some had been removed from the market, yes.

Q You don't know the proportion of the total?

A I do not know that.

Q All right, and you didn't mention this in your declaration, did you?

A No, that was not something that I was asked to opine on in my declaration.

Q All right. Could I have you go back to Dr. Zeglis' declaration and go to paragraph 83, and this is on -- starts on page 54 and goes over to page 55, and just like the others, just take a look at that paragraph.

A Okay.

Q And I hope this is perhaps the easiest question I'm going to give you today. In paragraph 83, did Dr. Zeglis offer an explanation about what a low molecular weight compound was, and this is his declaration.

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

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Q And to be clear, my question isn't -- I'm not asking you to interpret his -- his statement about whether he offered an opinion. I'm just asking if he did offer an opinion on what the meaning of low molecular weight was.

MS. PARTINGTON: Objection, form.

A I mean, I see here antibodies are separated out from all other -- from all other compounds. That's what I'm seeing here in this paragraph.

Q And -- and that's his --

A So low molecular weight -- sorry.

Q Go ahead.

A Low molecular weight did not include large proteins like antibodies, what it says there.

Q So he explained that in his declaration, right?

A This is his declaration, correct.

Q Could I have you go to paragraph 185 on page 132 of his declaration, and I'd like you to just read paragraphs 185 and 186. Let me know when you're done.

A Okay, I've read the paragraph.

Q Do you see -- turn over to page 186. Do you see that Dr. Zeglis is describing the U.S. '633 patent as referring to certain practical benefits of using PEG-based linkers, including that they're commercially available in a variety of lengths and in functionalized forms that fit the needs one has based on the design of a radiotracer being produced. See that explanation?

A I see that. I also understand from having looked at the '633 patent, that they describe a number of different linkers that are available to incorporate into the structures that they were making.

Q Okay, just keep that up. I'm going to hand you what is the U.S. '633. This is Exhibit 1004.

A Thank you.

Q And you see that Dr. Zeglis has cited paragraph 0133 of the Exhibit 1004 in -- as a footnote in -- to that sentence I just read in paragraph 186. If you could go to 133, paragraph

133 in the '633 patent, let me know when you're there.

A I am here.

Q Okay, great.

A Or there.

Q Got there faster than I did. All right, so does paragraph 133 identify any practical benefits of using PEG molecules as linkers or tethers?

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q Let me refine my question. Earlier today, I think you equated tether with linker, so when they're using "tether" in '633, that's referring to a linker, right?

A Correct, I understand that --

Q Okay.

A -- connection.

Q So let's go back to my question. Does the -- does this paragraph 133 identify any benefits to using a tether with a -- which is incorporating a PEG constituent?

A Well, they describe here modification of a tether by incorporation of heteroatoms into the tether chain, which of course could include things other than -- other than oxygen, and that -- yeah, so it's one of many I think that they describe, and it says a variety of -- of -- you know, of these tethers could be incorporated into the -- into the complexes. So I mean, that's -- I mean, there's many different ones that were described here, other heteroatoms as it says up in the beginning of the paragraph as well.

Q What it says in that third sentence, it says incorporation of heteroatoms into the tether, such as oxygen, can take advantage of the commercially -- commercial -- commercially availability of a variety of short polyethylene glycol, PEG, diamines that can be readily incorporated into the complexes, and then it says one of ordinary skill in the art would readily apply other chelates to prepare functionalized proline-M plus CO3 complexes.

So that third sentence is indicating there

are commercial advantages or advantages from the commercial availability of short poly -- polyethylene glycol diamines for use as forming tethers, right?

A Again, the -- the PEG glycol -- the PEG glycols, the polyethylene glycols are one of many tethers that could be used, and one of many tethers that they showed in their specification that could be used for linking their -- linking their chelate to the -- to the FAP moiety.

Q So the particular type of PEG here mentioned, polyethylene glycol diamines, that's -- that's a PEG that has been functionalized on either end of the PEG, right?

A Again, that functionalization could -- could be for PEGs, it could be for other -- for alkyl chains. It could be for other heteroatom, but it -- so that's not -- you know, again, that's not uncommon, and these types of tethers are quite -- are quite -- are readily available.

Q Right, and -- but just -- I'm just confirming that a three-monomer PEG that's a

diaminal -- basically a three -- three units of the polyethylene with either end of that molecule being functionalized in the form of an amine on either end of the PEG, right?

MS. PARTINGTON: Objection, form, foundation.

A Again, the paragraph describes functionalization of a tether, and this could apply to a variety of different tethers.

Q So literally, a short polyethylene glycol diamine is a bifunctional linker in the meaning of the '233 patent, right?

A Again, these tethers that are -- that are bifunctional, you know, that have bifunctional reactive groups on either end can be -- serve as linkers, tethers, yes.

Q And would you agree that a three-monomer PEG would be a short polyethylene glycol molecule?

A The -- PEG -- PEG is -- is made up of polyethylene glycol units. You've described one where it has three polyethylene glycols. That is the size. I mean, it's -- it could be shorter,

could be longer.

Q You have two options for shorter, right? One and two units, right? Is that correct?

A That is correct.

Q Okay. Could I have you go to paragraph 187, and again, you can read paragraph 187 and let me know when you're done. It's just --

A I'm sorry, they say the results are shown in figure 5. I was looking for figure 5. Do you know where that is in here?

Q I'm sorry, what paragraph are you referring to?

A 187, the last sentence, "Results are shown in figure 5."

Q You're looking at the patent.

A This is '633 patent, yes.

Q Right. I asked you to read paragraph 187 of Dr. Zeglis' declaration.

A Oh, my apologies. I was --

Q No, my -- I should have been clearer, yeah. Just the next -- the next paragraph in Dr. Zeglis' declaration, paragraph 187. Sorry.

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A Okay, I've read the paragraph.

Q So Dr. Zeglis explains that a skilled artisan would have wanted to separate the reporter moiety from the targeting moiety by about ten to 20 bond lengths in order to avoid interactions between two parts of the radiotracer. Setting aside the -- how much you -- how much space you put in between the two, is the general idea of separating the reporter moiety from the targeting moiety something that people of skill in the art in this field try to achieve when they're designing radiotracers?

MS. PARTINGTON: Objection, form.

A It is a method to separate the reporter -- reporter end of the molecule from the binding end, but small molecules where the radioisotope is directly labeled to the -- or molecules, I should say, not characterize them, but molecules where the radioisotope is labeled directly to the -- the backbone itself are also -- make suitable imaging agents.

So this separation is not something that

is -- I would say is -- is -- is common. Modifications to molecules have to be made to accommodate a variety of different situations, so putting this -- putting ten to 20 bond lengths in there or putting a tether in there is just one way of radiolabeling a molecule.

Q Would use of a three-monomer PEG fit the goal that Dr. Zeglis identified that a skilled artisan would have about separating the reporter moiety from the targeting moiety by about ten to 20 bond lengths?

A Again, it's one of many different spacer, tether, linker molecules that one could introduce into radiopharmaceuticals if that was the desired approach.

Q And -- and the three-monomer diamine PEG compound that he discussed would introduce 12 bond lengths in between the two, which is in his range of what you're trying to achieve with his comment, right?

A This was his range that he was trying to achieve, and again, there -- in addition to the --

in addition to the three-monomer diamine type, there are many other compounds that could achieve this particular approach that Dr. Zeglis was talking about in this particular example, not related to the -- you know, to any molecules that we're discussing with the B-L-A, right? That's separate.

Q So in your opinion, the skilled artisans try to vary the distance between the reporter and the targeting moieties in a radioimaging agent using a linker, is that something they do commonly?

MS. PARTINGTON: Objection, form.

A This is not something that is commonly done with every radiopharmaceutical. Again, putting in different groups and adding things on to radiopharmaceuticals to -- to achieve the desired goal with a radiopharmaceutical is something that a person skilled in this area would utilize everything that they have available to them to try and make a better radiopharmaceutical.

MR. KUSHAN: I'm going to introduce and

mark as Exhibit 1066 a paper in J Med Chem, first author, Dannoon. You're the last author on this paper. This will be 1066.

(Deposition Exhibit Number 1066 was marked for identification.)

BY MR. KUSHAN:

Q Do you recognize this paper?

A I do recognize this paper.

Q And this was published in 2016?

A Yes, that is correct.

Q All right, this is a paper describing work that your group did based on inhibitors of PSMA, right?

A That is correct.

Q Okay. Could you go to figure 1 of your paper? In figure 1, is the molecule 1 the targeting moiety?

MS. PARTINGTON: Objection to form.

A Sorry, I'm not looking at figure 1. I'm sorry, I was not looking at the correct figure.

Q Yeah, yeah.

A Could you repeat the question?

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Q Of course, of course. So you got four molecules shown in figure 1, right?

A Yes.

Q What is the molecule on the top left? Is that the PSMA inhibitor?

A The -- sort of the right-hand portion of that molecule is the PSMA inhibitor.

Q Okay, and what's the molecule that's designated Roman 2? Are you looking at figure 1 of J Med Chem?

A Once again, I'm not on the right page.

Q It's on the second -- there it is, right there.

A Right here on the second page.

Q Yes.

A Okay, I'm sorry.

Q So just tell me what -- tell me what 1 and 2 are.

A One is a phosphoramidate molecule that binds to PSMA, and 2 is the fluorobenzamide version of that PSMA molecule, same PSMA molecule.

Q And the fluorobenzamide unit is a

prosthetic group that can be used as your radiolabel, right?

A In this case, we introduced this as a prosthetic group.

Q Okay, and when you make it a radioactive version of it, you use 18F?

A That is correct.

Q Okay, and then directly below that figure 2 are -- is a depiction of that molecule with an insertion of a linker with an N, meaning that there's zero, 1 and 2 units that are repeating of the N designated unit, right?

A That is correct.

Q Okay, and the numbers that are there, the IC-50 values are showing the measured IC-50 inhibitory values for the three variants of -- of this molecule, one where it is literally item 2, which has zero inserts, right?

A Zero, 1 and 2.

Q Yeah.

A N is zero, 1 and 2, yes.

Q So -- so the zero is what is in what's

marked as compound 2, right? Sorry. When N --

A Oh, no.

Q When N is zero, it is that molecule above it, right?

A That is correct.

Q Okay, and then --

A It's Roman 1 -- Roman 1 is number 1 when N equals zero.

Q Got it.

A Yes.

Q And then you've introduced either one or two of these alkyl chains in the other two molecules, right?

A That is correct.

Q Okay, got it. So the N1 and N equal two variants had higher affinity than the molecule with no linker in it, right?

A In the case of the molecule by itself, the PSMA molecule by itself, you can see that the affinity gets better as you increase the N there. It turns out there was little difference -- some difference, little bit difference between the --

when the fluoro -- when the fluorobenzamide was -- or when the fluorobenzyl group was introduced to the terminal chain on all of those molecules.

Q So during the work that led to these -- to this paper, did you work to determine the optimal distance to separate the targeting moiety and the reporter moiety in the molecule?

A So this was really to look at the -- when we did this was to look at the pharmacokinetics, right, of the different molecules, and this was -- we just -- we just looked at these three structures. We didn't do a full -- we didn't do a full-blown synthetic analysis or produce a lot of molecules to -- to get to this -- to get to this point.

Q Could you go to the first page of your paper and look at the abstract? In your abstract, look at the last sentence of your abstract. You state, "Installation of aminohexanoic acid, AH, linkers in the phosphoramidate scaffold improved their PSMA binding and inhibition, and was critical for achieving suitable in vivo imaging

properties, positioning 18F5 and 18F6 as favorable candidates for future prostate cancer imaging trials." That's what you said in your paper in 2016, right?

A That is correct, and as indicated there, I mean, we -- and we do that when we make radiopharmaceuticals all the time, that we alter the structure to try and enhance the ability of these materials to interact with the -- with the target.

Q So you were varying the length of the linker to kind of optimize the properties of the molecule as an imaging agent.

A It -- it was to optimize all of the properties of the molecule for the imaging agent, right? As I pointed out here, all of these had very similar binding affinities, and so we were looking at some of the other properties there as well.

Q Could I ask you to go back to Dr. Zeglis' declaration, the big one, and if you could go to paragraph 153. Like we've done elsewhere, just

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read 153 and let me know when you're done. It's on page 106 and it goes to 107.

A Paragraph 153?

Q Correct.

A Okay, I read 153.

Q So 153 is Dr. Jansen explaining how he went about classifying molecules that were reported in the Jansen paper and other FAP inhibitor compounds?

A Yes, so this is -- the data was from the Jansen paper, yes.

Q And he -- and he provides a -- kind of a classification scheme for affinity and selectivity, and that's what he's discussing in paragraph 153, correct?

A Among other things, yes, but selectivity was the initial basis.

Q So he -- do you see on page 107, there's one table for selectivity ranges and one table for affinity ranges?

A Yes, and this is Dr. Zeglis' classification.

Q Right.

A These were not classified in the patent, not classified in Jansen's paper. These are Dr. Zeglis' classifications.

Q Does Dr. Zeglis identify to you what the parameters are that he's using to classify the molecules as to high, moderate or low selectivity and high, moderate or low affinity?

A I understand Dr. Zeglis' classifications. These were not classifications that were used in any other analysis as part of the -- as part of the patent, but I understand these classifications that Dr. Zeglis had.

Q Okay, and he was -- to be clear, he identified the number -- the numerical ranges that he was using to put things into high, moderate or low selectivity categories, right?

A Again, I understand that he came up with this classification and used this then to analyze the compounds that he had reviewed in Jansen.

Q And you can tell how he classified it because he put the ranges, the values in each

table, right?

A I understand how he classified it based on the values that are in the table that he developed to analyze the data.

Q Do you see that Dr. Zeglis has footnote 163, citing a paper by Mach, which is Exhibit 1033?

A I see that, yes.

Q And do you see that he has attributed his scale to the criteria that is reflected in the Mach paper?

A I see -- I see that he has developed a scale based on the information, as you point out here, from the Mach paper, but again, this was not analysis that was done in any of the other -- you know, any of the other references that I reviewed.

Q And do you see that the Mach paper, like Dr. Zeglis, classifies in this case a PET probe as having a high nanomolar affinity and high selectivity greater than a hundred fold for the target protein versus other proteins? You see that?

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A I see the -- I see that -- I see the numbers that are here that -- that he -- that was used.

Q Do you think it's a reasonable criteria to use a hundred fold, you know, increase to label a molecule as having high selectivity or high affinity relative to one that is a hundred fold less?

MS. PARTINGTON: Objection, form.

A I think it's reasonable to look at all of the data and then look at the molecules itself and look at the -- to look at all the data that one has in order to make the decisions on which one is to bring forward. These are generalizations. We have many of these in the field. These aren't the only ones in terms of affinity and selectivity, but these are very general broad rules for selectivity.

Q But it's fair to say at least he -- Dr. Zeglis is transparent about what the basis of his numbers are in his rating scheme, right?

A It allows you to take the data and put it

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into the buckets that are described here.

Q Okay.

MS. PARTINGTON: Counsel, we've been going for well over an hour. Would this be a good time to take a break?

BY MR. KUSHAN:

Q Let me ask one question, then we can take a break. So based on your experience, would a B-L-A compound that exhibits -- well, sorry. Would you consider a B-L-A compound to exhibit high selectivity if it exhibits hundred fold greater inhibition to FAP relative to PREP?

A I'm sorry, could you --

Q Yeah.

A It's sort of a -- it's a very broad question, and so I -- maybe you can --

Q Right, let me --

A -- help -- rephrase that please.

Q So -- so for these claimed B-L-A compounds, if a B-L-A compound according to these -- to this patent exhibits a hundred fold greater inhibition of FAP than it does PREP, is it fair to

portray that molecule as having high selectivity for FAP -- for PREP?

MS. PARTINGTON: Objection, form.

A I would characterize that it's selectivity, and I think the high is relative to the person who is looking at the data that they have in front of them to characterize high, medium low. Again, these are general rules. These are used by POSAs to make decisions on compounds, but there's no hard and fast rule that says any one given number, just pick a number out and say oh, well, that's high. No, I think it's -- you know, these are -- these are just sort of general guidelines for reviewing the data and understanding the interaction, and this is just one of many characteristics that we have to look at when we're developing molecules.

Q And you -- you have to look at a number of characteristics which are based on experimental characterization of the molecule?

MS. PARTINGTON: Objection, form.

A So one has to look at all data, looks at

data that they have developed in order to determine which molecules to carry forward in their -- in their development.

Q And that will include data where you've experimentally characterized the molecule and also studies of the structure of the molecule and things of that nature?

MS. PARTINGTON: Objection to form.

THE WITNESS: It includes all the data that you have in hand at the time you're making the decision whether to carry your molecule forward or not. That's it, very simple.

MR. KUSHAN: Why don't we go ahead and take our break.

(Recessed at 2:03 p.m.)

(Reconvened at 2:20 p.m.)

BY MR. KUSHAN:

Q Can you go to your declaration and turn to paragraph 52?

A The POR, correct?

Q Yes. Is that your declaration? 2029?

A 2029, thank you, that's what I was asking.

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I should ask by exhibit number, and paragraph again?

Q Fifty-two.

A Fifty -- I'm sorry.

Q Two.

A My hearing is --

Q No, it's my voice, according to my wife. All right, in this paragraph, you make -- you state that Dr. Zeglis agrees that antibodies, antibody fragments, peptides and oligonucleotides are all recognized and used classes of targeting vectors for radiotracers. Do you see that?

A I see that, yes.

Q And then you cite to Exhibit 1003, which is Dr. Zeglis' declaration, and that's at paragraph 50, so if you could just grab Dr. Zeglis' declaration. Put those -- put those within striking distance.

A Yes, yes.

Q I think you just -- and go to paragraph 50.

A I will --

Q And when you -- after you finish reading paragraph 50, just let me know.

A Okay, I finished reading the paragraph.

Q Just generally, what is Dr. Zeglis discussing in paragraph 50 of his declaration?

A So in this -- in this paragraph, he was discussing which isotopes one would pair with molecules that have different properties.

Q It's -- and it's talking about somewhat coordinating the half-life of the molecule with the half-life of the radionuclide with the understanding that those two half-life words mean very different things, right?

A They are different half-lives, and we have obviously a variety of isotopes that we could pair with the radiopharmaceutical to mark the characteristics, specific characteristics of radiopharmaceuticals.

Q So the idea here he's discussing is you want to find a match between the half-life of the radionuclide you're using with kind of the pharmacokinetic half-life of the molecule that is

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being used to deliver it in the subject; is that right?

MS. PARTINGTON: Objection, form.

A As described in the -- in the reference there, right, that's part of that paragraph, what they're stating that the half -- you know, matching the half-life to the physical characteristics of the radiopharmaceutical is a consideration for development of radiopharmaceuticals, one consideration.

Q And that's something you're familiar with in your own development of radiopharmaceuticals, that principle?

A I'm familiar with this principle, among others, for developing radiopharmaceuticals.

Q In paragraph 50, did Dr. Zeglis discuss using small molecule targeting moieties?

MS. PARTINGTON: Objection, form.

A I see all the different molecular classes. They're described in the paragraph.

Q So he did include small molecules as --

A The word "small molecules" appears here in

the paragraph.

Q Okay. Could you go back to your declaration on paragraph 52? When you cite to Exhibit -- sorry, when you cite to Dr. Zeglis' declaration, which is Exhibit 1003, paragraph 50, you didn't include small molecules in the list of the molecules that are in your list. Why did you omit small molecules from your quote of what was in paragraph 50 of Exhibit 1003?

A So in paragraph 51, right, but just above that paragraph 52, the word small molecule FAP-targeting compounds are listed. These are strategies for imaging FAP, among others. I was -- I believe that in this particular paragraph with Dr. Zeglis, I was just referencing that he had also identified antibodies, antibody fragments, peptides and oligonucleotides in that paragraph, and that's -- it was just a reference to that paragraph where he talked about those particular -- where he talked about those particular constructs.

Q So you weren't suggesting -- so you

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weren't suggesting in paragraph 52 that Dr. Zeglis had somehow left small molecules off the list of that list of carriers or target -- targeting moiety types.

A And certainly small molecules were among the many constructs that were being looked at as potential FAP agents, both as drugs and as radiopharmaceuticals at that time.

Q Right.

A Majority of them had been in the antibody, antibody fragments and peptide range and -- but with the Jansen -- Jansen compounds and so forth, there were several also that had the small molecule targeting molecules as well.

Q Okay. Could you go to -- so if you have your declaration in front of you, there's also a citation to Dr. Zeglis' transcript, which is Exhibit 2023, page 68, 8 to 14. Could I get the deposition transcript? This is Exhibit 2023, previously marked. In case you're wondering what happens today, a big piece of paper like this shows up. Big stack of paper.

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All right, if you could go to page 68, so in your declaration in paragraph 52, you cited to lines 8 to 14 of page 68, and just to make it simple, I'm going to read that. 68, 8 to 14, he was asked the -- the question was, "The field of radiopharmaceuticals is not limited to antibodies, correct?" No, and then he answers, "No, there are other vectors that are used in radiopharmaceuticals that are not immunoglobulins or full-length antibodies," right? That's 8.

A Eight, yes.

Q Then it goes on, "One of those is peptides." That was a question. He says, "Yes." "Another is oligonucleotides," correct, and there's a yes, and that's line 14, and then he was asked another -- about another category. What was that? What was that next question and answer?

A "And of course, small molecules is another choice, correct?" The answer is yes.

Q Okay. Do you know why you left lines 15, 16 and 17 off this quote in your declaration?

A Again, I don't -- I don't know why that

was not included there, but I did in the paragraph above include small molecules, and certainly small molecules were -- small molecules, antibodies, antibody fragments were known in the art in 2017 as targeting molecules for -- targeting molecules for FAP.

Q While we have the transcript, could you also go to page 61, and here, the passage that you cited in paragraph 52 of your declaration was 61, 11 to 19, so take a look at 11 to 19. "Your lab uses antibodies because they provide high affinity and high specificity for their targets, correct?" Answer: "That is one of the reasons my lab uses antibodies," right? That's what he said?

A I see that, yes.

Q And then, "What are some other reasons why your lab uses antibodies," and he says, "There are epitopes of biomarkers that are typically found only via antibodies." And then he was asked, "Anything else? Any other reasons were there?" "That's the primary one. They are probably betters, but that's probably the primary one."

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All right. Again, the quote that you use stops at line -- sorry, misquote that one. Line 19, but he's continuing on for other reasons that go out to the next page. I don't know why some of these quotes are being truncated. I just don't -- do you know why some of these quotes are being truncated?

MS. PARTINGTON: Object to the form, foundation.

BY MR. KUSHAN:

Q And one other question, maybe I'll give you a better one. Was Dr. Zeglis at lines 11 to 19 of page 61 saying that his lab only uses antibodies as radioimaging moieties?

A In which -- in which lines again? I'm sorry.

Q Lines 11 to 19 or line 11 to 21.

A On page 60 --

Q Sixty-one.

A One.

Q Yeah.

A And the question again is?

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Q Is this passage of -- on page 61 Dr. Zeglis stating that he only uses antibodies as targeting moieties for imaging agents?

A In this particular --

MS. PARTINGTON: Objection, form.

A In this particular paragraph, it doesn't state one way or the other what -- that only antibodies are -- are used.

Q All right. There's one more if I could. Let's go to page 6. That's not the right -- hold on a second. All right, the next quote I want to just go over is at line -- at page 69. Why don't you look at 3 through 14, so the question, "Your lab does not work with radiopharmaceuticals made using peptides as a targeting moiety, correct?" And the answer is, "I mean, all antibodies are peptides." "They're not proteins?" Answer: "Well, antibodies are proteins are peptides. They're all made of the same thing," but do you mean short peptides?"

"I mean short peptides." "We've worked on those, yeah. We have worked with short peptides

for radiopharmaceutical chemistry." And then he's asked a question, "But your focus is on antibodies over short peptides," and he answers, "We've done more antibody work than we've done short peptide work, but we have short peptide work in the laboratory going on right now," and then about -- he's asked about oligonucleotides in lines 20 to 22. "In terms of oligonucleotides, your focus is -- is on antibodies as opposed to oligonucleotides, correct?" And he says, "We've never done any work on oligonucleotides." And then the same question for small molecules, "Your focus is on antibodies over small molecules. Would you agree with that?"

And then Dr. Zeglis states, "The work we've done in pretargeting involves radiolabeled small molecules and biomolecules. Given the volume of work we've done in that using the radiolabeled small molecules, I can't say right now what the ratio of the papers is, but we've done significant work in both."

A Okay.

Q All right, so I've just read you this long section, and I want you to just look back at your paragraph 52 and what you have cited at line 69. You go -- you go line 69, 2 through line 2 of paragraph -- of page 70, and you omit the question and answer about small molecules that followed it, right, in the quote in paragraph 52 of your declaration.

A Again, the -- what's written here is the section on antibodies, antibody use, peptides, oligonucleotides, and so those were the references that are to those sections specifically, and the -- and so it just -- these -- these do -- these do compare. As I said earlier, small molecules were not out of the realm, as it's shown in the paragraph above and discussed elsewhere in the -- in the declaration. That's just what I know and can see here.

Q All right. Let me do this. Can we go back to Exhibit 1006, which is the Jansen paper?

A 1006, correct?

Q Yeah.

A Thank you.
Q What is the compound that's in the abstract of this paper?
A This is one of the molecules that was part of this -- part of this -- the discovery work, and the number is compound 60.
Q Is it fair to assume that the Jansen authors had some reasons to put this single compound 60 in the abstract of their paper?
MS. PARTINGTON: Objection, form, foundation.
A I have absolutely no reason why Jansen selected this compound to put it into the abstract.
Q The Jansen authors chose to put it in the abstract, right?
A This is their choice. Everybody has a choice when they're publishing papers what they want to put as a graphic into their abstracts. This was what Jansen chose, and I have no idea why they chose this compound versus others that were also in the paper.

Q Do you know which of the compounds that were made by the Jansen group resulted in the most extensive and prolonged inhibition of FAP in the PK studies that were done?

A So there were multiple Jansen references, Jansen -- this Jansen paper, Jansen from 2013, Jansen has also put out a patent, a couple of patents, and so there were multiple compounds that they prepared, and I reviewed these for their -- again, for their inhibition of FAP and PREP relative to the '233 patent that we're talking about.

Q What I was asking was do you know which of the compounds that were made by Jansen resulted in the most extensive and prolonged inhibition of FAP in their PK studies?

A Out of all the compounds that I've looked at, I -- I do not recall which of those compounds had the longest and most prolonged.

Q Would it surprise you that it was compound 60?

A I wouldn't be surprised because he made a

number of different compounds that had very -- had various properties for interacting, and they were developing these as drugs, which is -- you know, may be very different than the parameters that we look at for developing radiopharmaceuticals.

Q Is the behavior of a compound, pharmacokinetic profile and behavior of the compound in the body relevant to development and selection of a radioimaging targeting moiety?

MS. PARTINGTON: Objection, form.

A Among other -- yes, among other parameters, you know, that are -- one needs to assess the pharmacokinetics in the molecule when developing a radiopharmaceutical, just as you do for drugs.

Q Do you think that POSAs who review papers in the field of FAP inhibitors would have found compound 60 to be a promising candidate for the targeting moiety of a targeting radiopharmaceutical?

A As I mentioned a few minutes ago, there were multiple -- multiple reports by Jansen of a

number of different compounds that they prepared and evaluated, and in my declaration, I have definitely shown where there are multiple compounds out of the Jansen -- Jansen compounds, all the different compounds that they made that have suitable properties for developing radiopharmaceuticals, so multiple compounds.

Q Is compound 60 one of them?

A Again, multiple compounds that encompass a range of the FAP and PREP selectivities, and we can look in my declaration and we can see which compounds that includes.

Q Yeah, my question was was compound 60 one of those promising compounds of the multiple compounds you mentioned.

A Of the multiple compounds that I -- that I picked out that also bound to -- that had FAP -- FAP properties, suitable FAP properties for radiopharmaceuticals, I believe that compound 60 was included in those, among the others that also had suitable and maybe even better properties than compound 60 for imaging, for development.

Q All right. Could you do me a favor and go to the '233 patent?

A Yes.

Q And go to column 61 and 62. Do you see this is -- there's a section of the patent called "References." That's referring to publications, patent applications, patents and other references that are mentioned in the specification?

A Yes, I see that.

Q So these are publications that existed before the patent was filed, right?

A These are -- yes, these are all publications that were -- existed before 2017.

Q What is the publication that appears in column 62 lines 31 to 36?

A So that publication is Jansen 2014, Journal of Medicinal Chemistry. Again, it's among many others from Jansen here and other groups that have also produced FAPi targeting molecules.

Q So another one is the Jansen 2013 paper we were just discussing, that's at lines 25 to 30, right?

A Again, this is among many of the papers here that also possess compounds that might have suitable properties for incorporating into the B-L-A structure.

Q So just so I'm clear, lines 25 to 30 in the '233 patent is referencing the 2013 Jansen paper, right?

A There's a 2013 Jansen paper and a 2014 Jansen paper among the references here that also contain compounds that might be suitable FAP-targeting ligands.

Q So the inventor of the '233 patent considered Jansen 2013 to be a paper worth citing to support its patents on B-L-A compounds targeting FAP inhibitors including compound 60, right?

MS. PARTINGTON: Objection, form, foundation.

A Again, there are many other references here which also refer to compounds that had properties that were suitable for the B-L-A that are claims in this patent.

Q Did you find any particular examples of any moieties in the specification of the '233 patent?

A I'm sorry, could you -- I'm sorry, could you just --

Q Sure.

A -- state the question again? I --

Q Sure. When you reviewed the '233 patent specification, did you find any particular examples of specific molecules that could function as A molecules?

MS. PARTINGTON: Object to the form.

A In the specifications, there's many different structures here that are described.

Q Why don't we go to -- could we go to column 12?

MS. PARTINGTON: Wait. I'm sorry, Henry, were you finished with your answer?

A No, I was just going to say that there were many different structures that were described in here that would fit into the -- could be developed into the -- the compounds that are

claimed in -- in the claims.

Q Okay, could we go to column 12, and at the bottom right of column 12, do you see there's a start of a section discussing A moieties, and it continues on to -- through columns 13 and 14?

A Yes.

Q And look at the first two structures, or those two formulas. Those are categories of A moieties because they have options that vary on the pyrrolidine ring substitutions, right? Those are the R groups?

A Yes, this is the -- the A construct, which has different -- different -- that can have different pyrrolidine groups. Putting on different pyrrolidines is another way of -- of modifying the compounds to look for molecules that would have enhanced selectivity.

Q All right, so we go to column 13, there -- 13 and 14, about midway down in the page, it says, "In more particular embodiments, A is selected from the group consisting of," and then there are three iterations of one molecule, and then over on

column 14, there's three iterations of a second molecule. That would be an A molecule, right?

A Yes, there's several -- several compounds on this page that are A molecules.

Q There are two compounds on the page, right? There's --

A Well --

Q The first three are the same, right?

A Under this -- under this banner is what you're saying.

Q Yeah, yeah. So from -- like in column 13 line 35 through column 14 line 15, there are three versions that are the same A molecule with different points of attachment on the quinoline?

A On the quinoline.

Q Right.

A Right, these have different attachment points on the quinoline.

Q But that's one A molecule, right?

A That is one A molecule.

Q And then the next three is a second A molecule, right?

A That is correct, this one -- both -- they have different pyrrolidine structures.

Q All right, so the -- the first A molecule, is that compound 60?

A The first A molecule has the difluoro group, which is consistent with molecules of -- in that class that were developed by Jansen in the 2014 paper.

Q And just -- this is a somewhat narrower question. It is compound 60, right?

A Again, this is one of the molecules, and you can see the others that are on the page that, yes, that are part of the -- you know, that can be incorporated into the B-L-A structure as the FAP-targeting group.

Q It's one of two molecules --

A On this page, one of -- sorry, I'm sorry. Please ask the question.

Q It's one -- it's one of two molecules that are shown as A examples, right?

A On this page, it's one of two molecules that are shown. Also shown here are some other

molecules that have substituents that are not specified on the pyrrolidines. So again, these were -- these were compounds that are referenced from Jansen, and I think it's clear that they incorporated the Jansen compounds into this patent, and I think it's stated as such.

Q So we talked earlier today that the category definition of A type molecules that is, for example, shown at the top left of column 13 translates into about 31,000 -- 31,000 discrete A molecules, right?

A That was what we had -- that's what we had looked at earlier today, that there was a -- a number of molecules, that 31,000 that you state that -- molecules that could be prepared with these different substituents on them.

Q So if I'm reading the patent, I see this figure at the top of column 13, and I see 31,000 possibilities, and then I see two specific molecules following it, right?

A Yes, there are two example molecules that fall into the classes that were described at the

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upper left-hand side of 13, and they have properties that -- along with other molecules that were known at the time from similar classes that could be utilized as FAP-targeting agents.

Q And -- and the '233 patent chose to illustrate those two particular ones, right, compound 60, and then another molecule that followed it?

A So there's two molecules here that they have highlighted in this -- in the patent to show that the -- that they had molecules that had FAP-targeting properties as part of their claims.

Q And one of those was compound 60 --

MS. PARTINGTON: I'm sorry, were you finished, Doctor?

A No, I was going to say that there's -- that the claims also are broader, and that they could also incorporate or add to these molecules here. These are just examples that they chose to put into their patent to exemplify the class of targeting -- A targeting molecules that they had available or could make, that a POSA could make to

satisfy or have -- have the full scope of claims as they have identified in the patent.

Q And one of those two was compound 60 that was highlighted in the abstract of the Jansen 2013 paper, right?

A Again, these are two examples that were chosen by the patent inventors to include into theirs. They're not the only ones that can be utilized to make the -- the B-L-A structure radiopharmaceuticals.

Q All right. Do you recall if there were any specific examples which combined one of the two examples of A moieties with an example of a B moiety and an example of an L moiety in the '233 patent?

A So I'm sorry, are you -- so please just restate the question again so I --

Q Sure.

A -- I understand what all the components are that I'm looking for.

Q Do you recall seeing examples of B-L-A -- B-L-A compounds in the '233 patent which made

specific selections for each of the B, L and A moieties in one molecule?

A So yes, the examples that the inventors actually made as part of the patent and incorporated as data in the patent had all of the components, B, L and A.

Q And there were -- do you know how many -- well, let me take you to them. Could we go to -- you could go to column 31. So if you look at columns 31 and 32 of the patent, there are two examples there of B-L-A compounds where a specific choice has been made for the A, L and B moiety, right?

A 30 -- I'm sorry, 30 --

Q 31 and 32.

A 31 and 32, yes, sorry.

Q So you see the two molecules there?

A Yes, I see those two.

Q One is called XY-FAP-01, and the other one is called XY-FAP-02, right?

A Yes, that is correct.

Q What is the B moiety in XY-FAP-01?

A The B moiety in FAP -- XY-FAP-01 is an optical dye.

Q What is the B moiety in XY-FAP-02?

A In XY-FAP-02, the B group that in this case does not have the radioisotope in it is the -- is a DOTA chelate.

Q Is the same A moiety in both molecules, XY-FAP-01 and XY-FAP-02?

A Yes, the same molecule, the same A moiety is in FAP-01 and FAP-02.

Q And do XY-FAP-01 and XY-FAP-02 have the same linker moiety?

A No, there's some slight differences in the linker moieties here between the two FAP compounds.

Q I'm going to --

A Might be --

Q If I could ask you to do this, I'm going to ask you to just mark where the L -- the L moiety is on XY-FAP-01 and XY-FAP-02. I'm going to hand you the blown-up pictures of XY-FAP-01 and XY-FAP-02. Confirm those are just the same images

and just mark what the A, L and B moieties are in these two molecules. Here is a pen. Do you want to -- they're just blank paper. Okay.

MS. PARTINGTON: I'm not going to draw.

THE WITNESS: I believe I got this -- I believe I got this.

MR. KUSHAN: We're going to mark XY-FAP-02 marked up as Exhibit 1067.

(Deposition Exhibit Number 1067 was marked for identification.)

MR. KUSHAN: And we'll mark marked-up XY-FAP-02 as 1068.

(Deposition Exhibit Number 1068 was marked for identification.)

BY MR. KUSHAN:

Q Actually, could I have that exhibit back? Thank you, and I'm just going to note for the record that the boundary of the L in XY-FAP-01 includes the oxygen and the nitrogen at the end of the aliphatic chain, right? Is that right?

A That's correct, as I circled it there.

Q And then in the same kind of orientation

in XY-FAP-02, it starts before and includes the oxygen on one end and includes the nitrogen and the amidon on the other end, right?

A That is correct.

Q Okay. Just leave that there. So the difference in the linker between XY-FAP-01 and 02 is -- is what? Can you just clarify for me? Are the linkers identical?

A The linkers are the same, yeah.

Q Okay, so the only difference between XY-FAP-01 and XY-FAP-02 is the A moiety then.

A No, that's not correct.

Q Sorry, the B moiety.

A B moiety.

Q Okay, sorry. I'll give you -- I'll give you the question again so we have a clean statement. So the difference between XY-FAP-01 and XY-FAP-02 is limited to the B moiety of each molecule.

A In these examples, the difference is in the B moiety.

Q Okay.

A Yes.

Q Could you go to column 60 line 21 to 32 of the patent, the '233 patent?

A And the line numbers again? I'm sorry.

Q Twenty-nine to 32. That reports the KI, the enzyme inhibitory constant for XY-FAP-01 as being 1.26 nanomolar, right?

A That is correct, it does -- and that was certainly an unexpected result.

Q Is the KI the -- the IC-50 value, is that another name for it?

A The KI is -- can be -- it is -- it is a -- it is a binding -- it is -- yes, it's another name for the IC-50 binding -- inhibitory concept, yes.

Q The '233 patent does not report a measured IC-50 or KI for XY-FAP-02, does it?

A I see where they have done cellular uptake studies with the XY-FAP, but -- again, it was one or two. One or two. I'm not seeing -- reported here, I'm not seeing the value for XY-FAP -- it was XY-FAP-02, correct? Is that what you were asking?

Q Correct, so there's no reported IC value or KI --

A I do not see one reported here in the patent application.

Q Since you were just reviewing, did you see any reported inhibition values for either molecule for PREP?

A I see some -- I see some relating to DPP-IV, which is another family member, but I don't see any other -- I don't see any reference to PREP in here. Again, this is just the data that they had when they -- when they -- when they published the patent, and so it -- it goes -- and it shows that the compounds -- some of these studies show that the compounds have -- have utility, right? They're interacting with FAP as described in the -- in the patent -- in the patent claims. That's the utility of these molecules.

Q To assess the selectivity of the molecules for FAP relative to PREP, you would need to have the measured value of PREP inhibition for each molecule, right?

A For each molecule you make, if are using the --

Q Each -- each of the two molecules.

A Oh, for each -- for each of the molecules here, you would have to assess their binding to PREP and assess their binding to FAP to obtain that selectivity index. Again, that was not done prior to the patent being published, and as the claims are structural, they did show utility in vitro by some of the other cell studies that they did and blocking studies and so on and so forth. So they demonstrated the utility of these molecules. They do have -- they do have FAP-targeting properties, but they just did not report the FAP and PREP data in this -- in this application.

Q And you would need to have the FAP and PREP data to conclude that these molecules are selective or highly selective for FAP over PREP, right?

MS. PARTINGTON: Objection, form.

A In the -- in the context of the patent and

what the patent is about, right, I don't need -- the patent doesn't claim that these molecules have to have a certain selectivity index, right? It just says they have to be a targeting moiety for FAP, which is what has been done in here and what they've demonstrated. That's it.

Q So the patent doesn't describe these B-L-A compounds as having a particular FAP to PREP selectivity profile that would make them good targeting moieties for a FAP-targeting radioimaging agent?

MS. PARTINGTON: Objection.

BY MR. KUSHAN:

Q Right?

MS. PARTINGTON: Form, foundation.

A The patent is -- the claims in the patent are structural claims. The A has to be a targeting moiety. That is, as we established earlier today, the utility for this patent. There is nothing in the claims that says that these molecules have to have a certain biological activity, certain interaction with PREP or FAP in

order to be covered under the claims that are here. These are structural claims, and with the utility for the FAP A structure given. Those data just are -- really go to show the enablement of the molecule in this patent.

Q The patent doesn't enable you to assess whether XY-FAP-02 in a B-L-A form has greater or equivalent or less affinity or selectivity for FAP over PREP, right?

MS. PARTINGTON: Objection, form, foundation.

A Again, what the patent is -- is showing here, right, is that you have utility for the compounds that are structurally claimed in the claims, and this is part of written description as well as -- in the specification on how a POSA could actually make some of these measurements to show the utility of the compounds beyond the -- the utility of the compounds beyond the structural claims that are shown here.

Q Sure. I had asked you if the patent enables you to assess whether the XY-FAP-02

molecule in B-L-A form had greater, equivalent or less affinity or selectivity for FAP over PREP. Because you don't have the data measuring either the FAP or PREP inhibition by XY-FAP-02, you can't make that assessment of that molecule, right?

MS. PARTINGTON: Objection, form.

A So the -- the patent shows, right, it gives you a description of the different analyses that you could do -- perform on the molecules. It does not have the -- it has the information for FAP. It does not give the binding affinity for one of the two molecules for FAP. It has analysis in here. It shows a POSA what they would have to do to gain the information that you're looking for in order to, and it shows that it enables the patent based on these structure claims. I --

Q But it doesn't give you the information you need to know to either assess selectivity for FAP over PREP or -- and assess the performance of the molecule in a B-L-A form relative to the A moiety alone, correct?

MS. PARTINGTON: Objection, form.

A It gives a road map on how to get the data that you would need in order to make that selectivity.

Q So it tells you you could do that, but it didn't actually show you the features of the two molecules.

A It provides a road map --

MS. PARTINGTON: Objection, form.

A It provides a road map to get the data that you would need to make your -- make -- make the assessment.

Q Do you believe that in October of 2017, a POSA would have believed that to be a viable targeting moiety of a FAP-targeting radioimaging agent, the A moiety would have to exhibit greater selectivity for FAP over PREP?

A Again, the patent itself, right, is -- just describes the binding property or the intertargeting property of the FAP, right? The selectivity would be a secondary assessment of the utility of this, and for further utility of the patent claims.

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Q So --
A So --
Q I'm sorry. Go ahead.
A I'm sorry. So what I'm saying is that the patent specifically, you know, in the claims says that A is a targeting group for FAP. That's it. Doesn't say it's a targeting group for -- or not a targeting group for PREP. It's a targeting group for FAP, and so in -- a POSA, right, could take this patent, and they could make B-L-A compounds that target FAP. If they wanted to measure if it bound to PREP, they could certainly do that once they make it, but this patent is explicitly -- does not -- doesn't say anything about necessarily selectivity, right? The utility here is based on the FAP group, or the A group having some targeting property to FAP.
Q So I think my question was asking whether a POSA would have believed that to be a viable radioimaging targeting moiety for FAP, the A moiety would have to exhibit greater selectivity for FAP than PREP, given what was known at the

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time of the ability of these molecules to bind to both FAP and PREP and thereby not discriminate between those two targets. So I'm asking again, do you -- do you differ in the opinions that were being expressed before October 2017, that you -- that a FAP-targeting moiety had to have greater selectivity for FAP than PREP --

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q -- to be useful?

MS. PARTINGTON: Objection, form.

A So not necessarily, because you could use these FAP-targeting agents described in this patent in in vitro applications where the selectivity may not make a difference because you may not have the PREP or other binding groups there that would -- that would interfere. So it really depends on -- it will depend on the use, the ultimate use, but in this particular case, it doesn't -- right, this does not prescribe by this -- the patent -- the patent describes how to make the compounds, right?

It teaches us how to make the compounds, and it teaches on the utility of these compounds as FAP-targeting agents, and in an in vitro case where you don't have any other competing -- any other potential competition from other things, the selectivity wouldn't necessarily matter.

Q I'm trying to understand this point you're making. So you're saying that you can design an experiment where you only present the FAP target to this targeting moiety, and there's value of confirming that this FAP-targeting compound binds to FAP by itself. That has the utility that you're identifying for this class of compounds?

A That -- that is what I am saying. Could -- a potential use of this could be in just a direct FAP-targeting situation where you do not have any PREP around. Could be tissues, could be cancer tissues. It doesn't have PREP. It -- it has FAP, and that you're looking at that tissue, and if you have not looked at the selectivity, that would not preclude you from using -- even if you had looked at the selectivity, it wouldn't

preclude you from using this molecule in that particular case, right, in an in vitro case.

Q So what is the utility that you're describing of finding out that a molecule binds FAP?

A You may be looking for the concentration of FAP in the -- in the tissue that you're interested in.

Q And how would you know that the signal correlates to the amount of FAP if in the tissue, there's also PREP that the molecule binds to?

A Well, what I'm saying is that there may -- there may be certain cases where you don't have PREP as the -- as a -- as another enzyme in -- in this particular tissue, or it's there in such small quantities that it's not going to interfere or cause there to be binding to PREP and FAP. So you could actually have a case where you would only see the FAP binding, right, and that's what -- again, that's what this -- this says, that the utility here is for a FAP-targeting molecule, right, and so that could be one of the -- one of

the use -- one of the uses of this molecule, and you would not have to look at the selectivity.

Q So you -- sorry.

A Sorry.

Q Are you --

A I'm finished, yeah.

Q All right, so you read this patent, and you conclude that this patent is about making compounds that only discover the presence of FAP in some sample, right?

MS. PARTINGTON: Objection, form, foundation.

A I look at this patent and I say the molecules here, right, A is a targeting moiety for FAP. Doesn't say it's a targeting moiety or it could -- could bind to PREP as well. It just says it is a targeting moiety for FAP. It's a structural patent. It has written description that describes how you could use this in interacting with tissues that contain FAP. That's what I'm saying.

Q And if the -- if you're evaluating a

molecule that binds equivalently to both FAP and PREP, and you have a sample which you have not already characterized as to whether it's expressing FAP, PREP or both, the molecule that you're using to probe that sample cannot tell you one way or another whether FAP is present because if you get a positive signal, it may be either there is FAP present in some amount. Second option is there may be PREP present in some amount.

There may be another option where only one of the two is present, and your assay will not differentiate those scenarios, FAP present, PREP present, FAP only present, PREP only present, right? That's what you're telling me, this molecule can't do that differentiation of an uncharacterized sample because it can bind to both PREP and FAP.

MS. PARTINGTON: Objection, form.

BY MR. KUSHAN:

Q Well, let me -- let me try -- let me try my question again, all right? So you're -- you're

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telling me that you read the patent, and you conclude that they're saying that one of the uses of the FAP B-L-A compounds is essentially to confirm the already-known fact that FAP is present in a sample, right?

A These compounds, right, these structure compounds target FAP.

Q Right, and so --

A Yes.

Q So my question is the utility you had been pointing me to that you're reading from this patent --

A Uh-huh.

Q Are you speaking of using the FAP B-L-A compounds to determine the presence of FAP in an uncharacterized sample?

MS. PARTINGTON: Objection, form.

A I think I'm saying you could use this compound to look at any sample, right, that has FAP in it, right? This doesn't -- this patent doesn't say anything about the discriminatory properties of the FAP beyond that molecule binds

to FAP, right?

Q So -- go --

A And I understand the question you're asking, but the patent really relates to the property that this molecule has an interaction with FAP.

Q Have you ever tried to develop an imaging agent that would be incapable of differentiating among known equivalent targets of a -- of your imaging moiety?

A Could --

Q Yeah.

A Maybe --

Q Yeah.

A Slight rephrase? I'm just trying to --

Q Of course, of course. Have you ever tried to develop an imaging agent which would be incapable of differentiating the presence or absence of one of several targets of the targeting moiety in a sample?

A So the development -- developing imaging agents, we really are striving to make molecules

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that bind to the target, right, and that is the primary -- what we see primarily in the assay that we're running.

Q So when you're developing imaging agents, don't you try to find imaging agents that bind to the target you're interested in, and don't bind to other targets that are different targets?

A That is a property of an imaging agent that you would like to have, but that is not what this patent's about, right? This patent is not about that. The patent is about something binding to FAP, which these targets do, right? But I understand, yes, in developing imaging agents, you want to be able to see your target differentiated from other targets, right, but this is -- right, just --

Q So you --

A Putting this into the context of -- sorry, I'm putting this into the context of the patent that we're --

Q So you read this patent as being directed to developing imaging agents that are very bad

imaging agents because they can't differentiate between the types of targets that these molecules are known to interact with.

MS. PARTINGTON: Objection, form.

A I have not characterized the nature of these molecules as good or bad. I've characterized these molecules on their ability to interact with FAP.

Q So the fact that the -- a B-L-A form of one of these A moieties exhibits greater selectivity to -- to the FAP target relative to the A moiety by itself would not be something that's relevant to the merits of this invention?

A It gives -- it goes to show how the molecule could be used, right, and how it can be applied once it's made as -- under this -- under this patent, right, and it has FAP interaction ability, and you would have to look at the other parameters of the molecule to put it to use as a -- an agent for imaging, but the primary -- right, the first thing and what's the focus of this patent is that it has FAP-targeting ability.

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Q How do you know it has FAP-targeting ability if a sample that you're assessing has in it PREP and no FAP, but your molecule will still give you a positive signal for binding to something in that sample?

A So typically when the -- when these molecules are assessed, you are not -- you're using an assay which has only the FAP or the PREP or other proteins that you're interested to see whether or not your molecule interacts with. So you have them separately, so you understand the interaction of your molecule, right, with each of the different proteins, right?

And so it -- in this particular case, you'll take a molecule. First and foremost, we know that -- and that -- the high likelihood that it's -- it has FAP-targeting ability because we have used a FAP-targeting warhead in the molecule, right, and so then we measure first FAP, right? And then if we want to carry this on further and show greater utility, we would measure this against some of the other targets, all right, in

-- in developing the agent.

Q So it's -- it's useful in a -- in a research capacity to characterize molecules for their ability to bind to FAP? That's the utility?

A So the utility is these molecule --

MS. PARTINGTON: Objection --

THE WITNESS: I'm sorry.

MS. PARTINGTON: Objection, form.

THE WITNESS: As I said, as I stated, the utility of these first and foremost is that they bind to FAP, right? That's what -- that's what this says. Then if you want to use them further, right, and we have enablement, written description of how to make the molecules, right, and then you have the enablement in the patent, right, they can be used as imaging agents, but you would have to look at their characteristics further, right, and determine from the molecules that you make that are first and foremost FAP-targeting agents, which of these then would be suitable for downstream uses beyond the FAP-targeting ability that the molecule has as a part of this patent.

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BY MR. KUSHAN:

Q Do you need to put molecules into a B-L-A compound structure to discover that the A moiety binds to FAP?

MS. PARTINGTON: Object to the form.

A No, you don't, and as a matter of fact, there's many examples that we saw prior -- in the prior art prior to 2017, the Jansen papers, the -- the '633 patent, among others, that had developed FAP-targeting A groups, right, of various constructs, and most of them were small molecules that were -- that -- at that time that had FAP-targeting properties. And so -- and they -- as in Jansen and as in '633 patents and others, they looked at various different molecular constructs, right? They looked at different molecules to look -- to look at not only the pharmacophores, right, the binding groups, but also to see what other groups would do to the binding characteristics or the interaction characteristics of the molecules, right, and so in those patents and in those -- and in those papers,

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they also looked at, as they were developing these as drugs, they also looked at its interaction with some of the other -- some of the other enzymes that we've talked about, including PREP, and so they developed the selectivity there, right?

So if you take that A that has binding affinity to -- these are -- in the three that I've -- that I've talked about, these are the Jansen and the '633 patent and some other references that had smaller molecules at the time, they showed that they had very good binding affinity to FAP, and even selectivity, right? And so then if you take that and you put it into the molecules that are of the B-L-A design, you had some reasonable expectation that your molecules were going to bind to FAP, and they might even contain that selectivity that was borne in by the molecules that you used as your A group.

MS. PARTINGTON: Counsel, we've been going for well over an hour.

BY MR. KUSHAN:

Q Stop. Just stop talking please. Thank

you. So I understand what you're asking. I'll take that under consideration. So is your testimony that the affinity and selectivity of A, the targeting moiety, is predictive of the ability of a B-L-A form of that A molecule to bind to FAP?

MS. PARTINGTON: Objection, form.

A The utilization of the A group, right, provides -- that is the targeting group for FAP, right? It has some -- it's selected based on its known interaction with FAP, and may have some selectivity properties, as we've seen, against PREP, and you incorporate that into your B-L-A molecule, and it gives you a high -- a reasonable -- reasonable likelihood that these molecules are going to interact with FAP.

Q So the --

MS. PARTINGTON: Counsel, is this a good time to take a break? Doctor, are you ready for a break?

MR. KUSHAN: Your --

THE WITNESS: I would like to take a break.

MR. KUSHAN: I'm in the midst --

MS. PARTINGTON: The witness needs a break.

BY MR. KUSHAN:

Q We'll take a break in kind of -- in just two more minutes please, all right? So the -- I just want to finish this one point you're making, which is for the -- let's just take these two -- two molecules, compound 60 and the A moiety that is in FY -- XY -- I'm sorry, XY-FAP-01 and 2, right? So those are the two discrete A moieties, right? Before this patent was filed, it was known that both of those molecules bound to FAP, correct?

A I'm sorry, which two molecules are you referring to?

Q Compound 60 -- it was known before this patent was filed that compound 60 binds to FAP, correct?

A Based on the -- based on the Jansen paper, that was one of the molecules that bound to FAP, yes.

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Q And the -- and the form of compound 60 without the difluoro substitution on the pyrrolidinal ring also is known to bound to FAP from prior art, right?

A The --

Q The other molecule.

A The other molecule, yes, that also was -- had been shown to bind to FAP, correct.

Q So what is the added utility of this patent in confirming that those two molecules bind to FAP?

MS. PARTINGTON: Objection, foundation.

A So I'm going to preface this by saying I'm not a lawyer, but I've been provided the legal framework from my counsel about what -- you know, what has to -- you know, what elements constitute a patent, and in there, one of those is utility of the compounds, or the materials that you are producing here.

So it has to have some utility, and the -- as -- in my review of this, the utility here is the ability of the molecule, the B-L-A molecule,

to interact with FAP and have some FAP affinity properties, or have some FAP-binding properties. Targeting -- targeting properties I guess is the word that is used in the patent.

Q And that was not tested or confirmed for the compound 60-based B-L-A compounds, right?

MS. PARTINGTON: Object to the form.

BY MR. KUSHAN:

Q In the patent.

A I'm not sure what you're -- I'm sorry, I don't understand what you're -- the question is.

Q There's no data in the patent that tested the ability of compound 60 in a B-L-A form to bind to FAP, correct?

MS. PARTINGTON: Objection, form.

THE WITNESS: So again, I'm not a lawyer, but it's my understanding that in order for one to get a patent approved, that you do not have to show any examples of the molecules that you are claiming in the claims.

MR. KUSHAN: Okay, we're going to take a break now.

MS. PARTINGTON: Thank you.

(Recessed at 3:40 p.m.)

(Reconvened at 4:08 p.m.)

BY MR. KUSHAN:

Q All right, so before the break, we were going over a few things, and just to kind of wrap up on this point, so -- so it's your testimony that it's not required for this invention that's being claimed that the imaging agent distinguish between FAP and PREP; is that right?

A It's my understanding and my opinion based on my understanding of the -- both the patent and of the claims, that it needs to show utility as a targeting moiety for FAP, which is -- that's -- and so my understanding is that that is the primary -- that is the enabling parameter that is part of this patent.

Q So -- so again, let me try to make it a better question. So your testimony is that it's not required for the claimed B-L-A compounds to be able to distinguish between FAP and PREP to be patentable.

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MS. PARTINGTON: Objection, form, foundation.

A It is my understanding that this patent teaches us how to prepare molecules that have a FAP-targeting group, and linked to that are a group of moiety that would provide the opportunity for this to be developed into an imaging agent. PREP is not -- I don't see PREP in the -- in that description, in the claims, I don't see PREP, I don't see that it has to have a particular selectivity, right, in this -- in this application.

Q So -- so these claimed B-L-A compounds don't have to be able to differentiate between binding to FAP and binding to PREP.

A After making the claimed molecules, which is what this patent teaches us how to do, the -- again, the primary utility is do they target FAP. After that, they can -- you can analyze them for interaction with other -- and binding to other enzymes, look to see whether or not they would be able to give you that ultimate signal when you're

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developing this as an in vitro test, and trying to differentiate between interaction up to -- interaction with two enzymes in a similar family, or if you're going to take it further and develop imaging agents, but again, the -- sort of the first thing is that it has to have FAP-targeting capability, which is -- the utility is FAP-targeting capability.

Q So if a compound like compound 60, which is known to bind to FAP, continues to bind to FAP in the form of a B-L-A compound, then you believe that is all that's required to be patentable, correct?

MS. PARTINGTON: Objection, form, foundation.

A I would go so far as to say that any molecule that has FAP-targeting capabilities for A would be -- could -- could be armed with a linker and put on a imaging group, an imaging moiety, and as -- you know, and as in the claims, it has a FAP group, a FAP-targeting group, it has a linker, it has a B, so therefore, it would fall under the

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claims as stated in the patent.

Q So if a compound in a B-L-A compound -- sorry. If a B-L-A compound could not distinguish between binding FAP and PREP, it would still fall in the scope of the claims because it would report in an assay as binding to FAP, right?

A So again, the claims are structural, right? We're looking at structure compounds, and the A group has to have FAP-targeting -- right, the utility is FAP-targeting capabilities. If we start off with A groups, of which there's a number in the literature prior to 2017, and incorporate those into the B-L-A structure, right, you have a high likelihood of success of having a molecule that has FAP-targeting capabilities under enablement that shows the utility of the molecule as a FAP agent.

Q And is it correct that any amount of binding of the molecule, or the compound to FAP would be sufficient?

MS. PARTINGTON: Objection, form.

A As I read the claims, it's not stated in

the claims to what degree the -- the group would have -- would have FAP-targeting capabilities, but it would still -- there's a high likelihood of success in having a FAP-targeting group if you follow the written description, right, and incorporate your linker and your radio -- or your imaging group, right, as prescribed in the patent.

Q So I think you answered my question in the first part of what you just said, but -- so just to confirm, any -- let me say it this way. Any detectible amount of binding to FAP is all the claims require.

MS. PARTINGTON: Objection, form.

A As I read the claims, right, this is -- it's a targeting moiety, so if A is selected from the examples that were known in 2017 as FAP targeting and were incorporated here, then that actually satisfies the claim that these molecules have a FAP-targeting group bound to a linker and to the targeting -- or -- and to the reporter -- the reporter group, and so again, the utility of these are then ultimately defined by the ability

to bind these molecules to FAP. It's not prescribed in here what quantity of FAP binding it must have. It just says it's a FAP-targeting molecule.

Q All right, could you go to paragraph 20 of your declaration, Exhibit 2029?

A Yes.

Q So you're -- you're explaining in paragraph 20 that even after selecting a particular FAP-targeting moiety as the pharmacophore, a POSA would have faced multiple independent choices regarding how to label that moiety for imaging or therapy -- therapeutic use, right?

A That is what I say there, even after selecting the FAP-targeting moiety as a pharmacophore, a POSA would be faced with multiple independent choices regarding how to label that moiety for imaging and therapeutic use. Sorry.

Q Okay, so -- and then one of those choices would be whether to use a labeling strategy that involved direct halogenation, attachment of metal

binding chelators, and use of prosthetic groups, right?

A Right, so these were the three labeling strategies, or the strategies that we talked about earlier that were known in the prior art prior to 2017 for labeling the -- for labeling these molecules.

Q Right.

A But I can -- I can --

Q So --

A Sorry. I can further say that what was shown in the prior art with these molecules is that putting on larger groups, such as the B-L-A construct, was -- did not necessarily point in the direction of a molecule that would retain high affinity for the -- for a FAP.

Q So you're -- in paragraph 20, you're -- you're facing multiple levels of decisions after you picked your pharmacophore. That's what your paragraph 20 is directed here, right?

A That you have multiple ways that you can label the molecule.

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Q All right, and then you say the literature also described numerous metallic and nonmetallic radionucleotides, a required component of a radiopharmaceutical as it provides the radioactive signal necessary for imaging, right?

MS. PARTINGTON: Objection, form.

MR. KUSHAN: I'm just reading what he wrote --

MS. PARTINGTON: Well, you read wrong. That's why --

MR. KUSHAN: Okay. The --

MS. PARTINGTON: It's a radionuclide, not radionucleotide.

BY MR. KUSHAN:

Q Sorry. Thank you. So the next thing you say is the literature also described numerous metallic and nonmetallic radionuclides, a required component of a radiopharmaceutical, as it provides a -- the radioactive signal necessary for imaging, each associated with different chemical and biological tradeoffs, right?

A That is what I state there in my

declaration.

Q What are the different chemical and biological tradeoffs?

A So you have -- well, each of these is a different element, and so it -- you're talking about whether or not you're making molecules with a single element, just tagged on to the targeting warhead, or you're talking about putting a molecule onto a prosthetic group, which of course is going to add another component, another -- another molecular component to your targeting group, or you're incorporating the radioisotope, such as a radio metal, into a chelate, which of course has got -- you know, it has some structure to it, and you're adding that to your structure, or in the case of what we're talking about here in the -- in the patent, right, you have your radio -- you have your radio -- radiolabel tag, which is then bound to a linker, which is then bound to your molecule.

So you have -- once you start adding, right, as you go from elemental to just having one

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element there, which certainly in the art, it showed that keeping things small was better, and -- and goes back to some of the things we talked earlier today about the structure of the proteins. Small was good for getting into those protein structures, and so these are all the different things that you have to look at when you incorporate the radioactive isotope, or in this case the optical imaging agent, right? That adds another component to your overall molecule, and that can enhance or detract from the binding of your molecule.

Q And so I'm clear, all these choices regarding radionuclide, which chelator you may elect to use, which prosthetic group you may elect to use, every choice that one may make still is within the scope of the claim, right?

A Within the scope of the claim, we would have to have the -- well, B and L and A in a claim scope, and so that's what -- that's one of the things that you would have to have to be in the scope of the claims, but small --

Q I'm sorry, you may have misunderstood --
A Yeah.
Q -- my question. I'm asking -- so in the B group component of the B-L-A molecule --
A Yes.
Q The claims don't exclude any B choice you might make, right?
A The B could be -- B could be picked from any number of different molecules you could have there.
Q The B could be any choice. There's no B excluded from the scope of the claim, right?
A As -- no, as I -- as the claim is, it does not exclude -- right, it doesn't exclude any -- any tagged molecules in the -- in the claim.
Q And it also doesn't exclude any L choices, does it?
A No, the L choices and the B choices can come from what was known in the prior art and then incorporated into the B-L-A structure.
Q And so why does it matter what choice you make if it -- if they're all covered by the claim?

MS. PARTINGTON: Objection, form.

A Well, in this particular context, I was saying that the design choice further demonstrate that the prior art did not point a POSA toward a single predictable path leading to the claimed B-L-A compounds, as it says there at the end of that paragraph, and so that's why I was saying the -- you know, the choices that one has to make, you know, referred to also looking at what the POSA would have been looking at in terms of making molecules, right, and is this -- is it obvious that they are making the B-L-A compounds is the way to go, and in this particular case, it's not because the B-L-A compounds are larger constructs, and it was shown in data from the '633 patent that some of these structures that had larger -- that had linkers actually had poorer binding affinity to -- or poorer interaction with FAP, and so that is what this was in reference to.

Q And just two parts of that question I want to clarify. So the molecule after changes might have poor binding to FAP, but it still is included

in the scope of the claim, right, because it's still binding to FAP.

A If the molecule still binds to FAP, that would be included in the scope of the -- scope of the claim.

Q All right, and then do you recall that Dr. Zeglis showed a number of choices made for -- you know, choices for B and choices for L to go with compound 60 in his declaration?

A If you could point me to -- if there --

Q Yeah, there were like -- he made these six or nine molecules that were specific combinations of like a 3 monomer PEG with DOTA and compound 60. Remember these -- these examples that he had in his -- in his --

A Could you --

Q Sure.

A -- show me where one of those are?

Q Go to page 39 of Exhibit 1003.

A Okay. I'm sorry, what -- paragraph or page?

Q Page 134.

A Okay, thank you. Okay, I see that there, yes.

Q So each of these compounds is a combination of choices that you explained were included as options in the claim, right?

A These are a couple -- I mean, there's multiple choices one could make here. I mean, you could pick one from column A, pick one from column B and pick one from column L and put them together, right? So these are just one or two of the choices that -- yeah, that could be made, yes.

Q So all these are choices from the prior art that could be combined to yield a molecule that is in the scope of the claims of the patent.

A Again, these are two examples of multiple examples that combining the B, L and A combinations would provide and would fall within the scope of the claim.

Q And as long as it retained some ability to bind -- I'm sorry, and as long as the B-L-A compound in these ones I identified here retain some ability to bind to FAP, that would achieve

the utility of the claimed invention, right?

A For any combination of compounds that has the FAP warhead, the B, the L, linker and imaging group, that would fall within the scope of the claims.

Q If you look at compound A3 and A4, do you have any reason to believe that those B-L-A compounds would not bind to FAP, given that they incorporate compound 60?

A Let me be clear. A3 and A4 are page 138.

Q Yes, correct.

A So there is a -- again, these are, you know, just examples of compounds that have the targeting A FAP-targeting group, has a linker, which come from a number of different linkers, not just that one shown here, and the imaging tag, which indicates -- the A3 is a flourine 18 compound, in the case of A4 is a iodine 123 compound, and those are prosthetic groups that are appended on there.

Q And so my question was whether you would expect the A3 and A4 compounds as they are

depicted on page 138 would continue to bind to FAP if they were made, because they incorporate compound 60.

A Given the -- the claims, right, are incorporating the targeting A group, and those claims would then -- as long as the three components are there, then there's a high likelihood that the A group would continue to target.

Q Target FAP?

A Target FAP, yes.

Q Okay. So going back to your declaration, paragraph 20, you -- you paraphrased the last sentence again, but the last sentence of paragraph 20, you state, "These additional layers" -- sorry. "These additional layers of design choice further demonstrate that the prior art did not point a POSA toward a single predictable path leading to the claimed B-L-A compounds." Is it your understanding that the prior art has to lead to a single predictable path to the claimed B-L-A compounds in order for those -- for the -- to make

the claims obvious?

A It is my understanding that in this particular case, the prior art did not point to a path leading to the claimed B-L-A compounds, and -- the molecules that had been made previously in the prior art were small molecules. Larger molecules showed that they didn't fare as well as in terms of FAP targeting, or FAP binding agents, and so it's my understanding that for obviousness, you know, these -- the prior art didn't point towards the B-L-A compounds as being obvious from -- based on the prior art.

Q So I'm trying to understand what you're trying to explain. In paragraph 20, you're pointing to three different categories of B -- B moieties that might be used in conjunction with a linker and a FAP-targeting moiety, right? That's what your discussion is of these choices, direct halogenation, attachment of metal binding chelators and use of prosthetic rings, right?

A Right, so the choices here that we're making would be the linker and the -- or the

target -- the imaging moiety.

Q Are you saying you have to make a decision about which one of the class, or just one in a class?

A No, what I'm saying is that these are the -- right, in putting these together, excuse me, in putting these together, it would pick a linker, you would pick a imaging targeting group from the choices that you had available to you at the time that you were doing this, and I'm saying that picking these, putting them together to make the B-L-A construct, right, was not an obvious choice based on the fact that the molecules that had been made in the prior art showed that as you added more bulk, as you increased the -- as you increased adding more molecules on -- or increasing the structure size, that it reduced the affinity or avidity for -- avidity for targeting FAP.

Q As long as you retain some affinity for FAP, that would be sufficient for what the claims require.

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A So as the claims -- right, as we established, the claims are for targeting FAP, right, and you know, and utility of the molecule is established in this, right, you would want to have B-L-A that retained or had suitable targeting ability to FAP.

Q What is -- what is a suitable targeting ability?

A I'm sorry, that was a -- I'm sorry, that was probably a colloquial term, but to have ability to bind to FAP. Let me clarify that.

Q All right. Did you in your declaration explain that there was an association between bulk of the size of molecule and its ability to bind to FAP?

MS. PARTINGTON: Objection, form, foundation.

BY MR. KUSHAN:

Q To make sure my question was clear, the molecule I was referring to is the B-L-A compound of the claims.

MS. PARTINGTON: Objection, form,

foundation.

A So yes, in paragraph 69 of Exhibit 2029 --

Q Yeah.

A I state here the strategy, like prosthetic group labeling, so here I was talking specifically about metallic radionuclides necessarily introduces structural changes to the apparent molecule, and therefore, must be executed carefully to avoid interfering with target binding, cautioning that conjugated chelator should not interfere with the binding affinity of the peptide, and then it goes on to say that Dr. Zeglis agrees that chelation strategies introduce bulk, charge and rigidity into the molecule, often requiring the use of linkers or altering physiochemical or biological properties. I'm sorry, often requiring the use of linkers, and altering physiochemical and biological properties, including solubility, residence time in blood and biodistribution.

So I was agreeing with Dr. Zeglis here that this introduces -- that adding on an L and a

B, and especially in the case of metallic radionuclides, introduces structural changes, bulk to the molecule, and -- and would potentially have a adverse effect on interaction of the molecule with the intended target.

Q Right. So if I look at paragraph 69 where you're agreeing with Dr. Zeglis, you're agreeing that to solve a potential problem introduced by the inclusion of a molecule that -- B molecule -- sorry, B moiety that introduced size, bulk, you would use a linker to solve that problem, right? You're saying Dr. -- Dr. Zeglis agrees that chelation strategies introduce additional bulk, charge and rigidity into the molecule, comma, often requiring the use of linkers and altering the physicochemical and biological properties, right?

MS. PARTINGTON: Objection.

BY MR. KUSHAN:

Q Sorry. So you're agreeing with Dr. Zeglis that the solution to the bulk problem is to be solved by the use of linkers, which then would

separate the bulk away from the targeting moiety, right?

MS. PARTINGTON: Objection, form.

A I'm agreeing to the statement there that Dr. Zeglis made regarding introducing the bulk into the molecule, and that it would alter some of the properties of the molecule, and it says often requiring. It doesn't say it absolutely requires linkers, and there may be other strategies that one could use to mitigate the interaction or whatever property it was that was introduced by putting the bulk, but a linker is one strategy for doing this, but there may be other strategies. I could think of, you know, using a smaller -- perhaps -- perhaps, you know, looking at the size of the intended -- or the chelate and see if there's a way to reduce the size of the chelate. You know, you may have some other ways of working with these molecules that would -- would or would not require the use of a linker.

Q So using these techniques that would have been known well before October '17, you could

solve whatever problem the bulk issue raised with the ability of the B-L-A molecule to bind to FAP, right?

MS. PARTINGTON: Objection, form.

A So prior to 2017, there would have been methods that could be used to incorporate all the components of this, you know, and to help mitigate some of the issues that might be -- happen with the introduction of bulk into the molecule.

Q And also, to be clear, the claims don't exclude any of these bulkier chelators from their scope, do they?

A There's no -- no, there's no claim on size of the chelators in the scope of B.

Q All right. Can you go to 1 -- paragraph -- to your declaration, paragraph 158. Make sure it's the right paragraph. So in 158, in the middle of the paragraph --

A I'm sorry.

Q I apologize. I apologize. Lot of pages. I'm looking at 123 at the start. So I want to focus on the portion of paragraph 158 that's on

page 124. If you go down to the middle of the paragraph on that page, you say, "Indeed, Dr. Zeglis acknowledges the narrow nature of the claimed A moiety, stating that it encompasses only 30,000 compounds." Could I have you look at paragraph 91 of Dr. Zeglis' declaration, 1003?

A Yes, go ahead.

Q Dr. Zeglis did not portray the set of A moieties encompassed by the claims as having a narrow nature, did he?

A In his -- in Dr. Zeglis' declaration, he actually does a calculation based on the R substituents that were listed in the patent application and came up with a number of 31,752.

Q Right. That wasn't my question. My question was did he portray this as being a narrow nature of A moieties being encompassed by the claims.

A I try to determine the -- the terminology there in my declaration and try to put it into some context, but this is in the -- in fact, the scope of the claims -- title of the section, Scope

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of the Claims, would not have required undue experimentation. This is the 30,000 we concur, we agree, we acknowledge, the 30,000 is equivalent to what Dr. Zeglis said in his application, and then further discussion in this same section talks about looking at the breadth and expanding the breadth of compounds that were not included in the -- in the '233 patent by looking beyond just the scope of certain attachment points for these compounds.

And so this is what -- in the context of this particular section of not requiring undue experimentation, to use the claimed compounds in in vitro applications, this is the context that we had put this narrow nature in the -- in the document.

Q Yeah, my question was did Dr. -- sorry. Were you done?

A Go ahead.

Q Again, my question is whether Dr. Zeglis in his declaration portrayed the scope of the A moiety in the claims as a narrow range of A

moieties, and you cited to paragraph 91 as the basis for your opinion. I'm just asking you where in paragraph 91 did Dr. Zeglis portray that number of A moieties in the claim as being narrow in any -- in any sense.

A I don't see the word "narrow" in Dr. Zeglis' -- in Dr. Zeglis' declaration, and again, in the context of this -- in the context of this -- where this is coming from, the claims are further narrowed of course by the -- the dependent claims in the application, and perhaps that's where we -- again, I don't know the nature of that narrow in the -- in the -- not seeing it here in Dr. Zeglis' declaration.

Q Okay. Could you go to Exhibit 1007, which is Jansen 2013? I'm sorry, I have to give it to you. Actually, do you -- do you want to take a short break?

MS. PARTINGTON: Sure.

(Recessed at 4:53 p.m.)

(Reconvened at 5:13 p.m.)

BY MR. KUSHAN:

Q Could you go to Dr. Zeglis' declaration at paragraph 37 on page 15?

A I'm here.

Q Okay, in paragraph 37, Dr. Zeglis outlines a common or -- common modular design for radioimaging agents that consists of a targeting moiety, a reporter moiety, which can either be a radiolabeling moiety or an optical reporter moiety, and a linker. Do you have any -- do you disagree with Dr. Zeglis' general introduction and observation in paragraph 37?

A So as it's outlined here in modular, right, combining the three components, and I see that -- I see that here, and I don't disagree with what --

Q Okay.

A -- the three components.

Q And on paragraph 38, he's reproduced an image from a paper by Jamous, Exhibit 1009, and this is kind of conceptually what he's discussing in paragraph 37, right?

A Yes, that's a cartoon design of the -- of

B-L-A of A targeting moiety, the linker, and the B in this case radiolabeling, or radioisotope, or radioactive moiety.

Q And all this was known before October of 2017, right?

A In the -- in the prior art, yes, you would have had targeting moieties and linkers, and the radionuclide or in the case of the patent, the optical agents that would be the reporter tags.

Q Okay. Could I have you go to -- let's go over to Jansen 2014. I'm going to give you Exhibit -- sorry, no, I need Jansen 2013. Here, this is Exhibit 1007.

A Okay.

Q This is one of the Jansen papers we've been referencing today. Okay, could you go to page 3061? Is that right?

A No.

Q Table -- can we go to Jansen 2014 please? I apologize. Okay, could you go to table 4, which is at -- on page 3061, and there is a compound on this table, compound 54.

A Okay, I see compound 54.
Q And that has a phenol group on the 7 position, right, of the quinolinol ring.
A I see the -- yes, that's a phenol group on the quinolinol ring, yes.
Q And this is a molecule that's going to be within the scope of claim 1's definition of A, right?
A I mean, this is a -- yes, this is a FAP-targeting -- a FAP-targeting molecule, so this fits into claim 1 definition.
Q Okay.
A Yes.
Q The -- this molecule, 54, shows a high selectivity of binding to FAP over PREP, right?
A I see that, yes.
Q Okay. Go to the next compound, compound 55, and in compound 55, they've introduced an amid bond between the phenol group in the same position on the quinolinol ring as the phenol group was on the quinolinol ring in molecule 54, right?
MS. PARTINGTON: Object to the form.

BY MR. KUSHAN:

Q Sorry. Relative to compound 54, the phenol ring is now on a amid link -- sorry, amine link between the phenol group and the quinolinol ring, right?

A Yes, there's an amine in between the phenol and the quinoline in compound 55.

Q Right, and the -- this molecule has reduced activity despite that.

MS. PARTINGTON: Object to the form.

BY MR. KUSHAN:

Q Sorry. Has reduced selectivity relative to the compound 54.

A So this molecule has retained -- actually, it's a little bit -- may even be a little bit better FAP-targeting properties, but the PREP properties have decreased.

Q All right, so -- so this is showing that there is an impact of the presence of a bulky side group on the quinolinol ring of the A moieties, right?

A So in those two examples, those two

compounds that you have there, there's a difference of the introduction of the nitrogen, and by introducing the nitrogen, you have changed the properties, and I think we established in discussion earlier that adding -- you know, adding different elements to the -- we're not talking about elements necessarily of elemental periodic table elements, but if you're adding elements or molecular elements to the molecule, you can alter their properties, and this is what has happened in this case.

Q All right. Let's go -- now we're going to go over to Jansen 2013 if we can, and what I'd like to do is go to page 493, and look at compound 27.

A Okay, so the chloro quinoline molecule, correct.

Q Correct, so here you have a halogen and chlorine on the 6 position on the quinolinol ring, right?

A That is correct.

Q Okay, and the FAP IC-50 of compound 27 is

point 014 micromolar, right?

A That is correct.

Q All right. The PREP activity is point 84 micromolar, right?

A That is correct.

Q All right, so I did my math right, FAP to PREP here is 60, right? You can calculate it if you want.

A Without -- without pulling a calculator out, that looks -- I think that's -- I think that's close, yes.

Q So the compounds 27 has poor selectivity for FAP over PREP because it's only 60, right?

A So no. It still has selectivity, and it depended on what cutoffs one is using to make the determination is that good, bad, poor, right, or -- yeah, so you know, it still has selectivity. It's greater than one. Still has selectivity for FAP over PREP, and -- but there's no -- I mean, it's still selective. Let's put it that way.

Q All right. Why don't you look at compound 33. Here they've moved the chlorine -- could you

tell me what position on the quinolinol ring chlorine is sitting on compound 33? Seven, eight?

A It's -- I -- I see -- I see that it has moved -- shifted around to right, probably -- that's probably 8?

Q Yeah, I think it's 8, because 6 and 7 are the two on the left edge of the quinolinol ring.

A That's 8, yeah, 8.

Q So here, the calculated selectivity is 1.8 of FAP over PREP based on the measured values for inhibition of FAP and PREP.

A Yes.

Q So that is an instance of a molecule that has poor selectivity for FAP over PREP.

A Again, the molecule still has some selectivity, and compared to compound 27, it is not as good a selectivity as compound 27, but it is not -- it's still above 1, but it's still worse than compound 27.

Q And just almost by definition, 1 is no selectivity right? That means --

A One would be -- 1 would be equivalent

binding to both --

Q And this is --

A -- FAP and PREP.

Q And this is 1.8, so it's very close to no selectivity, right?

A I would agree it's close to no selectivity.

Q All right. Is there a cutoff you would use for good selectivity as a ratio of the two affinities or inhibition?

MS. PARTINGTON: Objection, form, foundation.

A No, I can't say that I would have any definite ratio that I would -- you know, that -- that -- that I would hold myself to if I was making compounds like this, and I certainly wouldn't want them to be 1, but I would need to look at the -- you know, the selectivity as one of the parameters in terms of further developing molecules. So that's important, but certainly I don't have a particular cutoff that I would assign saying oh, I'll take everything above this or take

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everything below that, right? Don't want to get rid of molecules that might actually be very useful.

Q So -- so your view is that -- and this is a view you would associate with a POSA, right? A POSA would not attribute a lot of significance to the selectivity of the molecule, but would instead look at it as one of many criteria of the molecule about whether to advance development.

MS. PARTINGTON: Objection, form.

A But certainly a POSA would look at the selectivity as one of the elements that they would use to move a molecule forward, and if they had in hand data such as this, which has two molecules, which have -- one has low, poor selectivity, and one has better selectivity, they are likely to choose the one with better selectivity to move forward in their -- so I mean, it's a comparison, right? They -- and compared assay, compare the two figures, so the two molecules they had in, and say oh, there's, you know, a clear choice, depending on what it is they're doing.

Q So it's also true that simply attaching a halogen to the quinolinol ring will not always improve selectivity of the A moiety for a fact.

A I'm sorry, could you -- could you state that again?

Q Yeah, it's true that simply attaching a halogen to the quinolinol ring of the A moiety here is not always going to improve selectivity of the A moiety.

A As we just -- you know, as we just showed with the chloro compound, it's the same molecule just by moving that -- the chloro around the ring, that you can have different selectivities for the molecules.

Q And that's also true for the next halogenated version -- look at molecule 34. That's bromine in the same 8 position, again, with poor selectivity, selectivity of 1.

A Yes.

Q So the fact that you put a bromine in one place and saw increased selectivity wouldn't demonstrate that it would always increase

selectivity if you put it in a different position in a quinolinol ring.

MS. PARTINGTON: Objection to form.

A I'm sorry, I think I missed the end of that question again. I'm sorry.

Q It's okay.

A Could you ask -- could you restate --

Q Yeah.

A Restate the question?

Q Yeah, so the fact that you -- the fact that you -- if you saw an increase in selectivity when you put bromine at one position in the quinolinol ring would not lead you to believe that putting it in another position on the quinolinol ring would also always increase selectivity.

MS. PARTINGTON: Objection, form.

A I don't believe -- I don't believe that -- well, certainly moving the halogen around the ring makes a difference. The halogen makes a difference, but in these particular cases, as I see here, they -- the various halogens -- they may have different properties as you move them around

the ring.

As we talked earlier, adding new substituents to a molecule has the ability to both increase or decrease its binding to either FAP or PREP. Sometimes they may go in the same direction. Sometimes they may go in opposite directions, and so I think in -- if I understand the question correctly here, that putting a -- putting the substituent, halogenated substituent on the molecule at the ring will alter the properties.

I don't -- I'd have to sit here and -- and look at all of the numbers to see whether or not there were trends in terms of how that -- trends in terms of how that was -- you know, how that happened, is there a trend, but as we can see here, moving the halogens around the ring, both bromine and chlorine and the fluorine as well does have in part different properties of the molecule in terms of their selectivity.

Q So from your answer before when I asked you what a good selectivity would be, am I right

to understand that your -- your view is that there's no number that you would associate with good, but that you would just consider selectivity with other factors in making a decision about whether to move forward with a particular compound?

MS. PARTINGTON: Objection, form.

A If there was no selectivity, and selectivity was one of the parameters that I wanted to have, then I would not move forward with that molecule, but I do not have a set cutoff for selectivity that I would say above this or below that we -- we should -- should or should not go, and one has to look at the molecule in the totality and the, again, purpose for which you're making it to determine what comfort level there is in making a selection of a molecule with a given selectivity.

Q So based on that explanation, is it fair to think of selectivity as a fabricator that if you want selectivity, it's I won't say binary, but it's present or it's not present as a feature of

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the molecule, and you can tell if it's not present because you're going to be at 1 or less than 1, right?

MS. PARTINGTON: Objection, form.

A If selectivity is one of the features that you would like to have in your molecule, then you would want to in your analysis and assays look for molecules that had selectivity, and if you of course have more than one molecule that shows selectivity, you would then choose the more selective molecule most likely for the application that you're trying to go after.

Q But there's no kind of level or magnitude of selectivity that you are associating as kind of a threshold to --

A I'm not -- I'm sorry, I cut you off.

Q Yeah, threshold -- the threshold for you for selectivity, if that's a factor, is more than 1, right?

MS. PARTINGTON: Object to the form.

A I am not making a determination. Just in this discussion as to what our -- what the cutoff

is for -- for selectivity. It would -- obviously if I want a selective molecule, it would have to be greater than 1.

Q And again, as you understand the claimed invention, there's no requirement for increased selectivity of those compounds, right?

A So in the invention claims, it would still have FAP-targeting ability, and if it has selectivity, that would increase its utility in the case where you would like to have that increased selectivity.

Q But it's not a requirement in the claimed invention?

A Not as I read the claims of the patent.

MR. KUSHAN: I need a short break. We may be able to wrap up.

(Recessed at 5:37 p.m.)

(Reconvened at 5:48 p.m.)

BY MR. KUSHAN:

Q So did -- one housekeeping issue. During the last couple of breaks, did you speak to counsel?

A No, I did not speak to counsel.

MR. KUSHAN: All right. We don't have any further questions.

MS. PARTINGTON: Okay, can we go back -- well, we can just take a break, so let's go back off the record.

(Recessed at 5:49 p.m.)

(Reconvened at 6:01 p.m.)

EXAMINATION BY COUNSEL FOR
THE JOHNS HOPKINS UNIVERSITY

BY MS. PARTINGTON:

Q All right, Dr. VanBrocklin, I'm going to have just a few questions for you today.

A Thank you.

Q So earlier today, you provided testimony related to whether a POSA would have had a reasonable expectation that B-L-A compounds would retain affinity for FAP. Do you recall that testimony?

MR. KUSHAN: Sorry, objection, leading. Objection to foundation.

A I do remember -- I do remember the

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testimony about that.

Q To what extent, if any, would having the specification available impact the POSA's ability to have an expectation that the B-L-A compound would have affinity for FAP?

MR. KUSHAN: Objection to foundation, objection to leading.

A I'm sorry, I'm having some trouble following the -- following the question. I don't know if it's easier -- if it could be broken down into smaller bits or we can -- yeah, or --

Q Let me ask it again.

A Okay, ask it again, yes, that's good.

Q To what extent, if any, would having the specification available to a POSA would impact POSA's ability to have an expectation that the B-L-A compound would have affinity for FAP?

MR. KUSHAN: Objection, foundation, objection, leading.

A So if I understand the question correctly, what expectation would a POSA have if they had the specifications. Other than the -- the

specification contains FAP-targeting molecules and choices for FAP-targeting molecules, that's the only thing I could think that -- and the fact that the claims are -- as stated are, you know, the FAP targets, A is a FAP-targeting group, that in the specifications where the POSA would be told how to put together the molecules that would -- and given specific instructions on how to put together molecules, that there would be then some expectation that the molecules would interact with FAP because of the FAP-targeting group.

Q Now, earlier today, you testified that after you signed your declaration, you reviewed some documents relating to assays from Dr. Pomper's declaration. Do you recall that testimony?

MR. KUSHAN: Objection, leading, objection, foundation, and also outside -- going outside the scope of the direct, so just laying that out.

MS. PARTINGTON: It's not at all outside the scope of the direct. You asked him -- those

documents were discussed. You didn't put --

MR. KUSHAN: No, we didn't --

MS. PARTINGTON: But we did discuss them.

MR. KUSHAN: Sorry. Not have a conversation in front of the witness. You can -- you can answer the question -- that question you asked, but -- whether he recalls that question I asked him, but that's it. Go ahead. Why don't you present the question to him again.

MS. PARTINGTON: Okay. Will you please stop instructing me what to do and what not to do?

MR. KUSHAN: I'm letting you ask --

MS. PARTINGTON: I'm -- I'm going to --

MR. KUSHAN: I'm letting you ask your --

MS. PARTINGTON: I'm going to --

MR. KUSHAN: -- your question.

BY MS. PARTINGTON:

Q -- ask my question. Thank you very much. I'm going to ask it again --

A Okay.

Q -- Dr. VanBrocklin.

A Thank you.

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Q Earlier today, you testified that after you signed your declaration, you reviewed some documents relating to assays from Dr. Pomper's declaration. Do you recall that testimony?

MR. KUSHAN: Objection, leading.

A I recall the testimony, yes.

Q Okay. Now, I will represent that --

MR. KUSHAN: Sorry. Go ahead. I'm sorry, let's take a break because we're going to have -- why don't you step out of the room for a moment.

MS. ELLISON: No, we're in the middle of questioning.

MR. KUSHAN: No, you're -- you're --

MS. ELLISON: Just continue.

MR. KUSHAN: Go ahead.

BY MS. PARTINGTON:

Q I will represent on the record that Dr. VanBrocklin reviewed -- that the documents that Dr. VanBrocklin reviewed were coextensive with the ordered production, and my question for you, Dr. VanBrocklin, is to what extent, if any, do those documents impact your opinions in this

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case.

MR. KUSHAN: Objection, foundation, outside the scope of the direct. That is an improper question. You cannot go into a topic that was not the subject of examination. That's exactly improper, so that is an improper question. You cannot go this.

BY MS. PARTINGTON:

Q Please answer the question, Doctor.

A I believe in my testimony, in response to the questions this morning, that I stated that the data that I reviewed did not have any impact on my -- on the opinions that I had in -- no negative impact on the opinions that I had in the -- in my declaration, signed declarations.

Q Now, over the course of today, you have been shown various documents and asked questions. To what extent, if any, do the documents you were shown today and the discussion you had impact your opinions in this case?

MR. KUSHAN: Objection, leading, objection, foundation.

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THE WITNESS: The documents that I saw, those that were part of my declaration and part of this case as well as the additional documents that were presented today do not change my opinions in this case. As a matter of fact, they -- some of them probably strengthen my opinions in this case.

MS. PARTINGTON: Thank you, Doctor, very much. We don't have any further questions. Let's go off the record please.

MR. KUSHAN: Before we go off, I'm sorry, we'll just make a note that we may move to strike portions of the redirect, and we'll let you know. We don't have any further questions, so we're done.

(Off the record at 6:09 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, Henry F. VanBrocklin, Ph.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Karen Young, court reporter and notary public within and for the District of Columbia, do hereby certify:

That Henry F. VanBrocklin, Ph.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition, and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, The Johns Hopkins University, was represented by counsel at the deposition.

I further certify that the deposition of Henry F. VanBrocklin, Ph.D. occurred at the offices of Sterne, Kessler, Goldstein & Fox, P.L.L.C., 1101 K Street, Northwest, Washington, D.C., commencing at 9:11 a.m. to 6:09 p.m.

I further certify that I am not related to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

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IN WITNESS WHEREOF, I have hereunto set my hand this 1st day of August, 2026.

My commission expires:
September 14, 2029

Karen Young
_____
Karen Young

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