UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE ANDREW J. GUILFORD, JUDGE PRESIDING

HSINGCHING HSU,	)	
	)	
Plaintiff,	)	
	)	
Vs.	)	**No. SACV15-0865-AG**
	)	
PUMA BIOTECHNOLOGY, ET AL,	)	
	)	
Defendants.	)	
	)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL, DAY 3

SANTA ANA, CALIFORNIA

THURSDAY, JANUARY 17, 2019

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SANTA ANA, CALIFORNIA; THURSDAY, JANUARY 17, 2019; 8:45 A.M.

THE COURT: Okay. Are we ready to begin?

MS. JOHNSON: Yes, Your Honor.

MR. GRONBORG: Good morning.

THE COURT: So we might need to go over the 9:00 hour on the deposition issues. Let's first focus on the exhibits referenced by the defense.

My question today is what it was yesterday. Show me where in the exhibits there is a reference to the litigation that would be inappropriate or why the exhibits require you to bring up the litigation.

MS. JOHNSON: Thank you, Your Honor. We're down to two exhibits. Plaintiff has withdrawn one. Let me start with Exhibit 482.

THE COURT: Yes.

MS. JOHNSON: In the second paragraph three lines down, four lines down --

THE COURT: I'm looking at 482. I see one paragraph on the first page. You're looking on the second page?

MS. JOHNSON: Yes. I'm on the attachment.

THE COURT: Okay.

MS. JOHNSON: With the attachment is a letter from Mr. Auerbach to Pfizer. He references in that second

paragraph that Pfizer has sent an extremely detailed list of questions regarding the data. Then he, Mr. Auerbach, says, we e-mailed you stating we would be supplying you with that data, but most of the requested data did not exist.

We understand and expect that plaintiffs will use these documents to say, number one, data he says he had did not exist; and two, data that he provided to Pfizer was different than what he had said in the conference call.

In order to explain why neither of those things is true or nefarious, the entire context of the dispute --

THE COURT: That's what I'm not understanding. You're cutting right to the chase. I'm not understanding why -- and I even suggested yesterday there may be reasons why you have to bring it up, but I'm not understanding why you can't just say this was a demand from someone. You don't need to know why.

You don't even need to tell them you don't need to know why. It could have been their great uncle wanting the information and not providing it. I need to know why your excuse relates to the litigation.

MS. JOHNSON: Because the timing is important.

THE COURT: Keep going. I'm not there yet.

MS. JOHNSON: Right. They are asking for a detailed list of information in the context of a legal dispute with lawyers on the e-mails with lists of information

being requested, with advice of counsel being solicited and provided on both sides regarding --

THE COURT: Where does it say advice of counsel? I mean, let's cut to the chase. If you're telling me litigation counsel said don't give it to them -- I just need to hear something that relates to the case. I'm hearing broad generalities. Time is important.

I need to know why a specific reference to the case is necessary by you, and I'm not getting it. We need to cut this off and move on to the deposition quickly.

MS. JOHNSON: I understand. Can I just say is --

THE COURT: Sure you can.

MS. JOHNSON: -- we are put in the untenable position in this timed trial of listing out the previous correspondence. You need -- they're asking for different data. They're asking for --

THE COURT: I'm not getting the relationship to the motion in limine. If you're now making a different objection from the motion in limine, my brain will shift.

MS. JOHNSON: If they don't have the -- if the jury does not have the context of this dispute, this long --

THE COURT: Why is what I need to know, I keeping asking. Have a conversation there.

MS. JOHNSON: Okay. One second.

(Counsel conferring)

THE COURT: We need to move on to the deposition unless I can get a specific statement about why I'm putting you in the position where you have to bring up the litigation.

MS. JOHNSON: It's prejudicial to say they are asking for this data. We are saying it doesn't exist without explaining the context of the dispute.

THE COURT: I -- Ms. Johnson, you said that a few times. I get it. Tell me why, why you have to bring up the litigation.

MS. JOHNSON: Because if you don't understand the context of what Pfizer is asking for and why -- they've just been embarrassed on a public conference call. Their CEO is on an analyst call and he got a question saying Cougar turned out to be a big success. Pfizer is embarrassed. Pfizer says we're going to pursue all of our legal rights and remedies.

That colors and couches and explains what they're asking for, why there is this dispute, and why this data is different from what he was articulating in the conference call. It they do not have that background of leading up to the dispute and why these things are being asked for, they will get confused or there is a high likelihood about what he is saying in response.

THE COURT: Okay. The objection to the exhibits is overruled. Now let get to the transcript. Again, I

mentioned earlier and perhaps not everyone was here, we might have to go a little bit after 9:00 because I understand why these points are important, and they get a little complicated in the context of a deposition transcript.

Let me just say, my overall view which I think kind of controls various notions is, you know, based on an analysis, the hearsay rule. So let's be clear. This whole deposition is hearsay, yet the parties have decided that the witness is unavailable or whatever, and that provides the first exception to the hearsay rule concerning the deposition.

But within the deposition there are out-of-court statements beyond just the deposition that I find occasionally are subject to granting the hearsay objection. Part of it is, gosh, that's a pretty broad statement that hurts a particular side and the particular side ought to be able to cross-examine the person who made that statement.

Now, you don't get to cross-examine the witness in the deposition because that comes in through an exception. But, gosh, maybe you should get to cross-examine the writer of the memo that gets referenced. That's where it comes down to.

The further complication is questions to this witness like, did you find this ambiguous, well, that's not hearsay. That's just asking the witness, did you find it

ambiguous. If the question is about a word in the e-mail, then it gets a little complicated about referencing what he's talking about.

To that extent the e-mail or the document would be offered just to give context to the later direct statement to the witness, is this a true statement, or, was it ambiguous. So it gets complicated on when I might let a little bit of an e-mail to come in to give context to the direct question like, what do you think of this phrase.

I hope that was somewhat clear. I want us to make sure we're talking about the same thing.

So I think the best way to proceed -- and then I do commend the objections. I didn't get the boilerplate, which I could recite in my sleep -- foundation, relevance, hearsay, privilege. I got hearsay, I think, every time as I recall.

So I appreciate the thought that went into that, but sometimes the hearsay objection applies to, you know, say, 25 lines, some of which are direct questions to the witness. Was it ambiguous? I'm just throwing that as an example -- unrelated to the document or to any other hearsay statement, and I think that comes in.

So on some of these I had to parse the overall hearsay objection down to, say, if there was a specific question within the broad statement, did you find it ambiguous. I think that's an appropriate question and I

allowed it.

So we have to be very careful about what we allow and what we don't allow.

With that, I would like assistance to make sure I don't skip over anything. I believe the first objection appears on -- oh, one other thing. I do not believe the plaintiff ever objected to designating something as rebuttal. I don't think that happened. I didn't rule on whether any of the rebuttals were inappropriate because not part of the rule of completeness or for some other reason.

I'm just saying I didn't rule on that. If you want me to rule on rebuttals, I didn't do so. I'm only ruling on the objections provided by the defense which are uniformly hearsay and I believe start on 126.

Does anyone have -- am I right, starting on 126 where I first see an objection?

MS. CONN: Yes, Your Honor.

THE COURT: Okay. Now, this says Exhibit 316 is an e-mail from you to Gross dated whatever; subject line, major stock upside increasingly dependent on M&A Cowen and Company. That is an out-of-court statement that I would be inclined to sustain.

What is the argument, if any, on that?

MS. CONN: Thank you, Your Honor. I would just like to emphasize that for this objection and also for the

remaining objections, the analyst who's being deposed, his analyst reports have already been admitted into evidence. We agreed to waive our hearsay objection to those reports, but we do think it's important to also give the --

THE COURT: Oh, I thought you were admitting the analyst reports. Did I miss something?

MR. COUGHLIN: No, Your Honor. We're admitting the analyst reports with the limiting instruction.

MS. CONN: Correct.

THE COURT: I thought you were asking that they be admitted.

MS. CONN: That's correct, Your Honor.

THE COURT: Then I'm a little -- you are asking that they be admitted, so I don't understand your argument. Sorry. If you were asking that they were admitted, I don't know how that cuts with this is more evidence.

Go ahead.

MS. CONN: The point I was trying to make is that the analyst reports are coming into evidence. We think it's important to give the context of his state of mind when he was writing those reports. And as --

THE COURT: Okay. That's --

MS. CONN: -- referenced, there's a limiting instruction for the reports. We think the e-mail should also come in with a similar limiting instruction.

THE COURT: Okay. I understand that argument. Give me a moment to think about it.

Okay. You're not offering that to prove the truth or falsity. You're offering it for state of mind. I get that. State of mind is much abused and not as broad as some people would like, but you want this to come in on state of mind.

Just a moment. I understand the argument. Anything further on this first question on page 128? Anything further from the plaintiff -- I'm sorry, 126. Anything further from the plaintiff on that?

MS. CONN: No, Your Honor.

THE COURT: Okay. I am going to sustain the objection to that statement.

Next, page 128. I have myself sustaining up to line 16 but then overruling after line 16. So when it says you go on to say, quote, I think we always knew that Alan is incapable of launching, et cetera, I believe that's an out-of-court statement offered to prove the truth of that point, that Alan is incapable. So I'm sustaining.

But then on line 17 you say: Could you elaborate on that? Did you believe that the M&A excerpt was the primary driver of Puma stock evaluation? I think that can get answered.

MR. CLUBOK: We agree, Your Honor. That's

appropriate.

THE COURT: Okay. Thank you. So that's the issue I always said. And I would look and see, does the plaintiff need the context of what it says to understand this. This question, who asked this question by the way? I mean, it's well asked.

MR. CLUBOK: I'm not certain. Someone --

THE COURT: All right.

MS. CONN: Our counsel in the back.

MR. CLUBOK: Marco asked it.

THE COURT: You asked a good follow-up question which you would ask a witness: Do you believe that the M&A stock was the primary driver? You can ask that.

MR. CLUBOK: And, Your Honor, just to be clear, just because the objection, compound, vague, we have waived that objection.

THE COURT: Oh, I didn't see an objection.

MR. CLUBOK: It's in there, but I just --

THE COURT: Where is it in there? In my version I don't see it.

MR. CLUBOK: Your Honor, it's just in the transcript, if you look at the --

THE COURT: Oh, I see it.

MR. CLUBOK: We're not making that. You are correct to note that we are not trying to claim that here.

THE COURT: Okay. So I would tell the videographer to remove the objection.

MR. CLUBOK: Yes. We have the capability to do that.

THE COURT: So you should remove objections stated on the record.

All right. So on page 128, sustained up to line 17. Overruled from 17 to line 2. That gets us to 130, page 130.

All right. I would overrule the objection through line 10 on the next page. And then I have sustained the objection lines 11 through 19 and overruled the objection for the rest of the input, the rest of the designation.

So stated differently, I am sustaining lines 11 through 19 on page 131, and I am overruling the objection for everything else. So I guess I need to look to the plaintiff to talk me out of allowing everything but lines 11 through 19 on page 131.

Feel free to make your argument.

MS. CONN: I think we're fine with that, Your Honor.

THE COURT: Who said that?

MS. CONN: I did.

THE COURT: Okay. So that's what we'll do.

MR. CLUBOK: I'm sorry, Your Honor. May I just

respond to the part that you're allowing in?

THE COURT: Yes, please.

MR. CLUBOK: So I think, if I have it right, you are sustaining lines 11 through 19 and letting in the previous lines. We agree with that. The problem we have, Your Honor, is when you pick up with line 20, it's really multiple hearsay. It's -- he's basing it on --

THE COURT: I'm sorry. I misspoke when I asked the plaintiff. I should have been asking the defense.

MR. CLUBOK: Oh, excuse me.

THE COURT: My mistake. Go ahead.

MR. CLUBOK: That's okay.

THE COURT: So now let's look at this carefully because -- yes. Okay. So looking at line 20, go ahead.

MR. CLUBOK: Right. So line 20 he's -- this is hearsay within hearsay, I think, or at least double. He's reporting conversations he supposedly had --

THE COURT: Okay. Forgive me for interrupting, but, you know, discussions with investors, consensus appeared to be around four percent. I'm interpreting that as not offered to prove that it's around four percent but offered to prove what the investors were thinking independent of the facts.

So that's a typical hearsay exception. Tell me why I'm wrong on that. I could be wrong on that because I don't

fully grasp all the necessary context. Why is that not offered to prove but just offered to -- you know, if the investors said this is really important to us, four percent, four percent is irrelevant. The fact is that is important to them.

MR. CLUBOK: So, Your Honor, the more hearsay within hearsay you go, the further away you get from being able to cure this by referring to the state of mind or the other exceptions to hearsay.

THE COURT: Not offered to prove.

MR. CLUBOK: Yes. So if this will appear to the jury -- and we do not think a limiting instruction can properly cure it -- as if these other investors actually said it. We can't cross those other investors on what they said, whether it's really true that other investors are saying it and which other investors.

By the way, Your Honor, this exchange is with Mr. Gross, a very -- an investor that has a troubled relationship with Puma. There were some accusations against Mr. Gross.

THE COURT: Is this Bill Gross?

MR. CLUBOK: No, no, not that Gross, Your Honor. I think it's Phil Gross. So it rhymes with Bill. But --

THE COURT: I understand what -- I might change my mind on this. Let me look more carefully. Tell me about

multiple hearsay you see in line 20. Who are the different declarants?

MR. CLUBOK: Unnamed investors that we can't cross-examine who supposedly made these statements out of court that I understand why they would like to say a limiting instruction can cure it, but the jury will surely take this as truth that investors are saying this.

When he's talking to -- and particularly in this conversation he's talking to Phil Gross, an investor who is constantly complaining -- and we could get into an explanation of why Phil Gross's statements are not true.

He's trying to -- whether or not Mr. Schmidt is trying to curvy favor with Phil Gross is another sideshow. But certainly when he tells Phil Gross to sort of placate him that, oh, yes, other investors are saying this, the jury is going to believe that that is true, and there's lots of reasons why it may not be. But we certainly can't cross-examine those other investors and prove that it's not.

So this is where a limiting instruction we just do not believe will sufficiently cure it. The jury will take this as being true. They will not just take it as this is what he thought. They'll take it as he's telling the truth and truthfully reporting the content of these out-of-court, unnamed, untimed discussions with whoever investors we don't know. That's the big problem here.

THE COURT: All right. Anything further on the designations on 131, 132, 133?

MS. CONN: Your Honor, if I may --

THE COURT: Actually I want to hear from the defense here.

MS. CONN: I'm sorry.

MR. CLUBOK: I'll just say one other thing. He reports with what these investors supposedly say, then he reports what they supposedly believed. He goes on to say, well, why did they say that? And he says, oh, it's because of what Alan said.

He's reporting a lot of what supposedly they said and supposedly why they believed it. And all of it is going to seem like he's reporting a truthful report of these unnamed conversations that we can't properly rebut, and a limiting instruction doesn't cure that in this case, we think.

THE COURT: Okay. I think the cross-examination you seek would be cross-examination of Mr. Schmidt: Did the investors think this? Are you sure about that, et cetera? And I am going to stick with my ruling.

So on the designation beginning on page 130 and going through 133, it's all allowed except for 11 through 19 on page 131.

MR. CLUBOK: And may I just add one thing for the

record, Your Honor? I assume Your Honor knows this, but obviously Mr. Schmidt is not being called as a witness here.

THE COURT: Well, yeah, I know that.

MR. CLUBOK: Okay. Thank you.

THE COURT: Then on page 134 I'm sustaining lines 2 through 6. Yeah, you need to cross-examine Mr. Sanayha [phonetic] as to what he meant by that, and you don't get a chance to do that. I'm sustaining lines 2 through 6 on page 134.

Any response?

MS. CONN: No, Your Honor.

THE COURT: And then I'm overruling lines 14 through 17, which may become irrelevant since I am then sustaining through line 6. So 18 through line 6, line 18 through line 6, yeah, I'm sustaining all of that.

So any response to me sustaining that objection through line -- actually through line 5?

MS. CONN: No, Your Honor.

THE COURT: Okay. Then I'm going to overrule the objection 6 through 25, and I invite defense to tell me where I'm wrong on that.

MR. CLUBOK: That's fine, Your Honor. Given the other rulings you've made, we would agree with that.

THE COURT: Okay. Good. All right. Then moving on, page 138, I'm sustaining that. Again it's an exhibit

with a significant subject line, and I'm sustaining that.

Any objection? Any response?

MS. CONN: No, Your Honor.

THE COURT: Okay. On 140, I am overruling as to the statements on 140 and 141. You know, direct question from our friend in the back there: Is there anything else that you can think of that may have been the cause of that drop? That's an appropriate question.

There's a slight reference to a document that the deponent wrote at the beginning, but that's being provided just to give context to what else is said. So that's what I'm ruling on page 140 to 141.

Any response from the defense? Feel free. Take your time, because there's a lot of little statements --

Mr. CLUBOK: I appreciate that, Your Honor.

THE COURT: For example, there's a reference to Mr. Gordon on line 21 that's not a statement offered to prove the truth of the matter. That's a statement that gives context to the response.

Go ahead.

MR. CLUBOK: I guess my only question is, does that mean that you are allowing this statement to be read but not the underlying document to be admitted?

THE COURT: Oh, I'm not allowing the document.

MR. CLUBOK: Okay. In that case, Your Honor, then

I think we won't have an objection. If you just give me one moment.

THE COURT: Feel free. Again, it gets a little dicey in there.

MR. CLUBOK: Yeah. We appreciate that. And it's through line? I apologize, Your Honor.

THE COURT: Say again.

MR. CLUBOK: The whole thing you're allowing in?

THE COURT: Yes.

MR. CLUBOK: Okay.

THE COURT: Anytime there's a reference to another person's statement, I believe that's being offered not to prove the truth of any assertion but to establish context.

MR. CLUBOK: Okay. Your Honor, we understand your ruling.

THE COURT: Okay. Then --

MR. CLUBOK: And we --

THE COURT: By the way, that's a good thing to say. I don't want you to waive your objection on appeal.

MR. CLUBOK: Yes.

THE COURT: Seriously.

MR. CLUBOK: We appreciate that.

THE COURT: Saying you understand -- be careful in these kinds of discussions, also in jury instructions. Sometimes your statement might be deemed a waiver. I like

the notion, we understand, without saying that's okay. You're not saying that's okay.

MR. CLUBOK: That's what meant, Your Honor. Thank you.

THE COURT: I agree with you.

Okay. Page 153, I'm sustaining all of that. It's an exhibit with an interesting subject line. Yeah, the defense ought to be able to cross-examine the guy that wrote that subject line and parse what it means or doesn't mean. So I'm sustaining page 153.

Any response from the plaintiff?

MS. CONN: Just to be clear, Your Honor, this is an e-mail that Mr. Schmidt himself was the author of, so there was the opportunity to cross-examine him on that.

THE COURT: That's a very good point.

MS. CONN: I would also like to, if I could, revisit the issue of the underlying documents. I know you referenced with respect to the last designation that you're not inclined to allow the e-mails in. I would just --

THE COURT: I've not looked at that issue at all.

MS. CONN: Okay. I just want to --

THE COURT: I hope it will come up at a different time. Right now I want to focus on the transcripts so we can get moving along. I wasn't asked anything about the admission of documents.

MS. CONN: Okay.

THE COURT: And I understand of the defense is going to object, and I can't make a ruling on that.

MS. CONN: That's fine, Your Honor.

THE COURT: Okay. You know, here we get into notions of prior consistent statement. Just because the person on the stand has a prior consistent statement doesn't always or necessarily allow it to come in. Here under the record -- under the record made to me, I'm going to sustain that objection.

Moving on to pages 155, I'm overruling all of that on page 155.

MR. CLUBOK: Nothing further from the defense on that objection, Your Honor.

THE COURT: That all comes in. And we move on to 157. I'm overruling everything on 157 and sustaining on 158.

So I'd ask the defense to look carefully at what I'm overruling on 157 and give me a response. He asked a specific question: You believe his credibility was shot after this announcement? The answer is yep. So I'm allowing the first part in for context and the last part in because it's a direct statement from the deponent.

What does the defense say?

MR. CLUBOK: We understand your ruling, Your Honor.

THE COURT: I got it. Okay. I got it.

Then I'm sustaining 158. Any response from the plaintiff?

MS. CONN: No, Your Honor.

THE COURT: Okay. Then 160, I'm sustaining on what he goes on to write here. I'm sustaining up until line 20, and then I'm allowing line 20 on because he is confirming the response. So the response is giving context, and what's being offered to prove is his confirmation of that.

So page 160 to 161, sustained through line 20 and overruled as to line 20 on. You could suggest that him reading his response is a hearsay statement, but it's offered in context and it largely becomes moot, in fact indeed becomes moot because he accepts it there while he is speaking.

So that's my ruling. Any response?

MR. CLUBOK: We understand.

THE COURT: You understand. Good. All right. Moving on. We're getting close here, folks.

Okay. Page 178, sustained. Again it's a re line, Cowen report. I'm sustaining that, but I'm overruling pages 179 through 180. If I'm right on this, that is a statement that defense wants to present since it's in yellow and the plaintiff is objecting.

MR. CLUBOK: This was our provisional rebuttal in case you overruled some of our objections. So we now have it

in here.

MS. CONN: No, Your Honor. Plaintiffs are not objecting.

THE COURT: So actually it was defense's objection to their own rebuttal? You mentioned that yesterday.

MR. CLUBOK: I'm sorry. Maybe I misunderstood.

THE COURT: Let's make sure we're clear here. Pages 179 and 180, in my book it is yellow. It means that the defense is offering it, which would suggest the objection comes from the plaintiff. But maybe the plaintiff is saying you didn't object. The defense objected to their own lines.

The explanation might be that the defense was being careful, et cetera, et cetera, and contingent. So just talk amongst yourselves over there. I'm allowing all of that in, which should be a good thing for the defense.

MR. CLUBOK: There's no objection, Your Honor.

THE COURT: All right. Moving on. Okay. Good. We're getting close. Page 188 -- and the poor videographer, I hope you're making proper notes. I'm trying to be as clear as possible. And I can hand you my version which I think pretty much reflects what I'm saying. All right. 138 [sic], overruled.

MR. CLUBOK: I beg your pardon? What page?

THE COURT: I'm on page 189. Excuse me, 189 says, I'm handing you what's been marked as Exhibit 329. I'm

allowing that in, but I'm sustaining on page 190 beginning at line 10 down to line 19. Here Thomas Reuters is asking, quote: How are you? PBYI is down a bunch for the second day in a row, et cetera, et cetera. I'm sustaining all that. It's what Thomas Reuters is asking. So I'm sustaining down to line 19. Stated again, everything on 189 is acceptable. Objections overruled. On page 190, sustained down to line 20. I'm allowing, so are you aware, et cetera, Puma stock price dropped, on page 190 through 191. I'm allowing that.

You can ask the witness: Are you aware that the stock dropped? That's my ruling there. Any response from anyone?

MR. CLUBOK: No, Your Honor.

THE COURT: Hearing none, we're moving on. And I believe that takes --

MS. CONN: That was the last one.

THE COURT: Excuse me? I think that takes care of all the objections. So there we have it.

Folks, I don't think I altered my rulings here. I don't know if it would be helpful for the videographer to see the notes I took last night.

MR. CLUBOK: May I add one final --

THE COURT: Please.

MR. CLUBOK: In context now, and I appreciate now

that we've seen it all, I'm going to just revisit slightly if I may the one that we had the vigorous exchange about, which is at the bottom of page 131 where he's purporting to report the consensus from discussions with investors and then what those investors supposedly based those discussions on.

At the very least, Your Honor, can we get a limiting instruction?

THE COURT: Oh, you absolutely get a limiting instruction. Remind me to give the limiting instruction. I think at the conclusion of the videotape, the limiting instruction should come if you request it, and I would say this isn't offered to prove -- well, when do you think I should make it?

MR. CLUBOK: This one has to be more there's no proof he had those discussions. There's no truth that they actually said that. He said he's reporting what --

THE COURT: What page are you on?

MR. CLUBOK: This is the bottom of page 131 through page 132.

THE COURT: Okay.

MR. CLUBOK: I think this particular limiting --

THE COURT: I'm going to instruct the videographer to stop at 131, line 19. I will say: We're about to receive information that is not offered to prove the truth of the information but is offered to prove what people thought might

or might not be true.

If you want to expand on that, let me know.

MR. CLUBOK: Your Honor, that is proving the truth of something, to prove he -- he is saying --

THE COURT: Hold on. Now you're switching gears on you. I just want to be clear. Back to the merits and not to what I'm going to say.

MR. CLUBOK: I'm sorry, Your Honor.

THE COURT: It's all right.

MR. CLUBOK: The limiting instruction I think is not going to cure the problem. That's the way I should have phrased it.

THE COURT: Okay. I understand. Okay. On page 131, line 20, the videographer is to stop and I will say something. But my ruling is that it is as it is.

Anything else from anyone before we begin?

MS. CONN: No, Your Honor.

THE COURT: Okay. I hope someone got a hold of Mr. Coughlin's coffee this morning and put in a little decaf.

MR. COUGHLIN: Your Honor, before the jury comes out, maybe I could ask this. When I apologized to the court reporter yesterday, she indicated that it wasn't how fast we were talking but it was that we were talking over each other.

So I will try not to talk over Mr. Auerbach and just maybe try to stop him versus talking over him. And if

we could do the same, it would help.

THE COURT: Was the issue just talking over or speed?

Let me just say, do you know how many pages we got yesterday? In the normal course of the trial, we usually get 225 or so. Yesterday we had 290, which suggests to me it's a speed issue.

MR. COUGHLIN: Understand.

THE COURT: Speed isn't necessarily a problem. As I said, I married someone because she spits it out quickly and I get it and I move on. But here, gosh, I could try and figure out the percentage of 290 to 225. It's a big percentage increase. So it's not just talking over. I think it's also speed, based on the page estimate.

So with that, I think we're ready to go.

MS. CONN: Your Honor, my videographer would like your transcript.

THE COURT: Yes.

(Court and clerk conferring)

THE COURT: If you have any questions -- you know, I'm putting marks. When I put -- actually I put overruled with a down arrow, and it looks like I'm making a male symbol. But it really is overruled, with a down arrow.

(Open court - jury present)

THE COURT: Welcome back, folks. Sorry for the

delay. I really don't like having jurors sit out there. We actually started well before the 9:00 hour to go over some evidentiary issues where both sides are making excellent points on issues about what should be admitted and what shouldn't be admitted.

I was hoping it would last until 9:00. It obviously lasted until 9:25. So I apologize for that.

You may continue, counsel.

MR. COUGHLIN: Thank you, Your Honor.

Alan Auerbach, witness, previously sworn

DIRECT EXAMINATION (RESUMED)

BY MR. COUGHLIN:

Q. Good morning, Mr. Auerbach.

A. Good morning.

Q. If you take a look at the binder and open up to Exhibit 384, I'm going to ask you some questions about that.

MR. COUGHLIN: I'm going to ask that this exhibit with no objection to it be admitted into evidence.

THE COURT: Okay. So for starting off, let me just say that there was in the pretrial conference order reference to objections or non-objections. When counsel tells me there is no objections, I'm accepting that and I will simply say admitted without objection.

That may require the defense to hustle and check and double-check. If I make that statement and all of a

sudden you think there's a mistake, speak up. But if you're not objecting, we'll just move on.

So when I say admitted without objection, I'm assuming there's not an objection. That doesn't mean that three later you might say, Your Honor, wait. There is an objection. It's just a way to move it along.

Go ahead.

Admitted without objection --

(Exhibit 384 received)

MR. COUGHLIN: Thank you, Your Honor.

THE COURT: -- on January 17th. Good.

BY MR. COUGHLIN:

Q. Mr. Auerbach, if you could take a look at this document. It's from Bin Yao. Who is Bin Yao?

A. Bin Yao is the head of biostatistics at Puma.

Q. Okay. And he writes to you on July 24th, 2014; is that correct?

A. Yes. That's correct.

Q. Okay. And first he tells you, I guess he's excited about the increase, the 295 percent increase in the stock, and then he talks about access to the results. Did he have access to the results, can you recall, on July 22, 2014, the date of the conference call?

A. I don't recall if he had access to the unblinded data. I know he had access to the entire data set because he had

confirmed the number of events in the study. I believe that was blinded data.

I don't recall if at this juncture he had access to the unblinded data.

Q. He certainly had access to some data; is that correct?

A. I think that's correct, yes.

Q. Okay. So let's take a look down at what he's asking about some things, some things to do. I'd like to focus basically on the last two bullet points. There he asked that -- some things to do, and he talks about the DFS, DFS-DCIS by interval, the top two lines, by node HR status, region HR2 status, grade of tumor, and other factors.

I assume he's talking about doing analysis of those various subgroups; is that correct?

A. I believe that's correct, yes.

Q. Okay. And then the next he talks about the DF curves beyond the two-year truncation: Granted, it may be biased, but if one believes the information available is random, the curves beyond two years may still be indicative of the truth. We have probably eight events in the past two years that were not included in the primary DFS analysis, and these are not enough to provide much additional information. But at the formal data lock, there may be more.

Do you see that?

A. Yes, I do.

Q. Does that refresh your recollection about how many events that you had going out beyond two years?
A. I believe he's making an estimate of it, I don't know, where he says we probably have eight events past two years. But I don't think he actually has the number.
Q. Okay. Let's flip over of the next -- let's flip over to the next page. Here it's August 13th, and this is Alvin Wong. And who is -- well, wait a second.
MR. COUGHLIN: The next document is 451, and I don't believe there's any objection to this document, Your Honor. I'd move it to be admitted.
THE COURT: Without objection 451 is admitted.
(Exhibit 451 received.)
BY MR. COUGHLIN:
Q. Who is Alvin Wong, if you could tell us?
A. Alvin Wong is the senior vice president of clinical sciences at Puma.
Q. Okay. And he's talking about amendment nine in this document. Can you refresh our recollection about what amendment nine was?
A. Amendment nine was the truncation of the study that was performed by Pfizer prior to Puma licensing the drug.
Q. It was the cutoff at two years, 28 days, right?
A. Correct.
Q. And he says: There's very few patients who we have data

in the clinical database with follow-up for three years. But then he goes on and he charts that data in the next two pages; is that correct?

A. I need to review this document. I do see he says approximately 50 percent did have some exams over the two-year period but fell short of the three. So I'm assuming what that means is we had data out past two years but not out past three years.

Q. Yes. And I think the chart on the next page shows some of that.

A. Okay.

Q. Okay. If you take a look down there, the chart -- let's say past 24 months you start seeing the lines on the chart as they drop down for the data and about the data that you have. And then down below when we talk about randomization and DFS events, it has 73 and 113. And the numbers we looked at yesterday were 70 and 109. Do you recall that?

A. I seem to remember there were roughly 179 in the two-year data, so this would be 186. That would be an increase of seven events.

Q. Right, seven events in the third year?

A. Right.

Q. Okay. So that's about -- does that refresh your recollection now in August about how many dates you had going out into the third year -- events?

A. Yes.
Q. Okay. Now, let's take a look at Exhibit 393 --
MR. COUGHLIN: -- which there is no objection to, Your Honor, and I would like to admit into evidence.
THE COURT: Without objection 393 is admitted.
(Exhibit 393 received.)
BY MR. COUGHLIN:
Q. This is a document dated September 10, 2014, from Bin Yao, the head of your biostatistics. If I could have you take a brief look at this document.
A. (Witness complies.)
Q. And where I want to direct your attention is to page 11 of 23. Do you see this proportional hazard assumption?
A. Yes.
Q. You understand what that is, right?
A. Yes.
Q. Okay. And in the second dash, it says: When the assumption is violated, interpretation of a single hazard ratio may not be adequate. Additional implication of a non-constant hazard ratio over time is the extrapolation beyond two years and will be more tenuous given the current data or truncated at two years. Do you see that?
A. Yes, I do.
Q. If you flip over to the next page, there's an investigation that was done to the hazard estimates over

time. Do you see that?
A. Yes.
Q. And what Mr. Yao has done is he has taken -- at about six-month intervals he has calculated what the hazard ratios are going out for the data that you have. Do you understand that?
A. Yes, I do.
Q. Okay. And do you see in the last six months that the hazard ratios cross; that the neratinib arm crosses the placebo?
A. Correct.
Q. And that indicates that the hazard ratio has been violated; is that correct?
A. I believe that's correct. I know Dr. Yao will be a witness in this. He is much more able to discuss this than I am.
Q. We'll talk more about it with him. Okay.
And if we flip back to the last page I believe of that document, which is page 23 -- well, let's go back to that chart for a second. So that chart basically shows that all of the efficacy for neratinib basically occurs in the first six months; is that correct?
A. Can you explain how you are coming to that conclusion?
Q. I'm looking at the neratinib arm which is up above .003. I'm sorry. It's down at the bottom. And the placebo arm

starts up at .003. And there's a widening right there at those curves, and then they come together in the last six months of the two-year study.

A. Again, the goal of neratinib is to prevent breast cancer recurrence. Right? So if your hazard ratio in the neratinib arm is lower than that in the placebo arm, that can be generally viewed as neratinib having efficacy.

If I look at those two curves, it appears that the hazard rates of the neratinib arm is lower than the placebo arm for the first -- I'm estimating that at 18 months.

Q. I would give it 20 months.

A. And then after of that period is where the hazard changes.

Q. Understand. I just wanted to make sure we were on the same page.

And if we take a look now at next steps at the back of the page -- and that's page 23 of 23 -- Mr. Yao is talking about next steps to be done?

A. Uh-huh.

Q. And he's talking about extrapolating DFS curves beyond two years. Do you see that?

A. Yes.

Q. You hadn't had any curves done before this time frame; is that correct?

A. No, that is incorrect. Claire Sherman, who is our other

statistician -- in the company we had both Bin Yao and we had Claire Sherman. Claire Sherman and Bin were at the same level, if you will. Claire is the one who had done all of the analyses of the ExteNET data. Bin then, I believe, requested access so he could do his own analyses of it. So you have two different statisticians doing analyses.

Claire I believe was the one who did the first three-year analyses, and now Bin is asking that he do them as well.

Q. Right -- the ones that we don't have and can't find?

A. I believe we have been able to recreate those --

Q. In 2018?

A. -- in the exact same data set that was available in July of 2014.

Q. And do you know when Claire was first asked, she said she didn't do it. You know that?

A. I believe she said later in her deposition that she actually may have done it and needed to think about it, something to that extent.

Q. But she would have kept a record of it, right?

A. I -- I don't know the answer to that.

Q. Okay. Let's flip over to the next page -- sorry. I mean Exhibit 394.

MR. COUGHLIN: There's no objection, Your Honor, so I'd move for its admission.

THE COURT: 394 is admitted.

(Exhibit 394 received.)

BY MR. COUGHLIN:

Q. Mr. Auerbach, I'd like you to take a look at this. This is Bin Yao in October 4, 2014, and this is a communication from you to him. Do you see this?

A. Yes, I do.

Q. Okay. If I asked you to take a look at this document, it appears if we go down to the bottom of the document it says: Lastly we discussed trying to simulate a three-year DFS curve using the same trends that we have seen in the data thus far and continuing them. When do you anticipate being able to do this?

Do you see that?

A. Yes, I do.

Q. Now, you said you had already seen the real ones, right?

A. Correct. However, the real ones that we saw were based on a very low number of events. So our curiosity was whether there would be a way to take the recurrence patterns, so, you know, take the patterns we've seen for the breast cancer coming back in these patients, and if there would be a way to perform simulations called Monte Carlo simulation where you kind of look at, you know, assuming the current recurrence rate, assume a lower recurrence rate, assume a higher one, and see what the three-year curves would look like.

Q. Is Monte Carlo the gambling type simulations?
A. I don't know if there is a correlation between these statistical Monte Carlo simulation and the casino. I don't know the answer to that, but it's a statistical term called the Monte Carlo simulation.
Q. Okay. If you take a look at the top, it says -- and you ask him for a timeline, and he tells you, you know, that it should be next Wednesday, and this timeline will work fine with you. When do the three-year simulations you can do for both the DFS -- that's the topline results, right?
A. Correct.
Q. And the other topline DFS-DCIS, right?
A. That's correct.
Q. If we switch over to the next page, 394, you actually sent him a list of things that you want done -- 394, page 3 of 5. And I'd like to direct your attention to the top of that page.
A. Correct.
Q. In those you're asking him to do some curves one, two, and three years out; is that correct?
A. Hang on. Yes, correct.
Q. And down below you're asking him to do some similar analysis on the various subgroups that we were talking about yesterday; is that correct?
A. Can you show me where you're --

Q. I'm talking about subgroup and sensitivity analysis. I'm talking about the third paragraph down, subgroup and sensitivity analysis.
A. Yes.
Q. You're asking him to do some of the same analysis there?
A. That is correct.
Q. Okay. Now, if we switch to the last page of that document, 5 of 5, I'd like to take a look at that chart. That chart comes out of the efficacy analysis that I believe you received on July 17th?
A. Correct.
Q. Okay. And yesterday we were talking about dropouts versus discontinuation, and we had looked at some numbers of discontinuation. We had first looked at discontinuation due to diarrhea. I think it was 16.8. And then discontinuation for all AEs, and that was 27.6.

Here if you take a look at the number of subjects that discontinued before completing part A, we have a 16.6 number. Do you see that there? It's 16.3. I'm sorry.
A. Yes.
Q. So is that the number that discontinued before completing part A?
A. That's discontinued the drug. It's not dropped out of the study.
Q. So this is just -- it's not the dropout number?

A. No.
Q. Okay. You don't know the dropout number; is that what you're saying?
A. No. From the data we discussed yesterday, if you remember, the dropout due to diarrhea I believe was 1.6 percent.
Q. The dropout rate for diarrhea alone -- you're talking about discontinuation due to diarrhea?
A. No. There's two different things.
Q. Yes. The dropout rate is 1.6.
A. There's discontinuation due to diarrhea. The patient discontinues but they continue to go visit their doctor every three months and get checked to see whether or not their cancer has come back. Dropout means they've physically left the study and we get no more data from them.
Q. They didn't ever show back up. That's what you mean?
A. Correct.
Q. And they did that as a result of an adverse event, correct?
A. Their reason stated for why they were dropping out of the study, and we never got any more data past that time period. It is an adverse event, yes.
Q. Right. So we have the discontinuation rate, and that's the 16.8. And then we have the discontinuation rate for diarrhea, discontinuation rate for all adverse events, and

that's 27.6, right?
A. Right.
Q. And then we have a lack of follow-up, and that's 1.6; is that right?
A. Correct.
Q. Okay. And you knew that as of -- those three numbers you knew as of July 17th; is that correct?
A. Yes, correct.
Q. Let's flip to Exhibit 396.
MR. COUGHLIN: I believe 396 has been admitted. I mean, not admitted. I'm moving for its admission. There's no objection.
THE COURT: 396 is admitted without objection.
(Exhibit 396 received.)
BY MR. COUGHLIN:
Q. So in October, a couple months after the call, you're asking him to do these simulations, and he does the simulation for you. Can you take a look through 396 and refresh your recollection?
A. Yes. (Witness complies.)
Q. Let's flip over on the first page. That's 3 of 8 of Exhibit 396. So if we look at the first page of this document, which is 3 of 8, where the charts are, that chart right there is the topline event chart for the KM curves for study; is that right?

A. Correct.
Q. Okay. And that's the 93.9 and the 91.6, which gives us the absolute difference of 2.3 percent, correct?
A. Correct.
Q. And then he's broken it down per six-month intervals. Do you see this down here at the bottom that Mr. Bin Yao has done?
A. Yes. That's correct.
Q. Okay. So you get a 17, hazard ratio of 17 percent in the first six months, right?
A. Correct.
Q. Okay. Then .83. Then it drops back down to .63. Then it goes back up to 1.5. Do you see that?
A. Yes.
Q. And that's what the chart was showing us back before where the hazard ratios were crossing, correct?
A. That's correct.
Q. And then he does it for the 12-month intervals which you had done for the efficacy report that you had seen on July 17th, and he has got a hazard ratio in the second year of .94. Do you see that?
A. That's correct.
Q. So we flip over to the next page. Mr. Yao decides to run out the simulations for the third year into the seventh year using the optimistic, the .67. Now, the optimistic is

your actual hazard ratio, right, that you actually reached in the two years for the overall study? Right?

A. I believe that's correct.

Q. Okay. And then he has a pessimistic number which he says is the same as the hazard ratio of the second year in the 12-month hazard rate table, which is the page before, right, the .947?

A. Uh-huh. Yes.

Q. And then he picks a middle ground to run that, a .80 hazard ratio. Do you see that?

A. Yes.

Q. The lower the hazard ratio, the better, right?

A. That is correct.

Q. Okay. The trend that you were seeing in the second year is that your hazard ratio in the last six months went over one, and in the last year was approaching one at .947, correct?

A. Correct. I seem to remember this was influenced by some censoring that was occurring at the last month.

Q. You can explain it to your counsel --

A. Okay.

Q. -- about why it's happening. I'm just asking, that's what was happening?

A. Correct. But just to make it -- if I can make it clear. Is that okay?

Q. Your counsel can talk to you about that, and then you can make it really crystal clear.
A. Okay.
Q. But that's what was happening. That's what your understanding of the data showed, correct?
A. Yes, with the caveat that there was some noise at the end of the curve that was influencing, making that hazard ratio go higher than the real signal would suggest.
Q. Okay. And he ran those curves for you, is that correct, on those -- well, he actually ran the data for those three scenarios in this document; is that correct?
A. That is correct.
Q. Okay.

If we flip over to the next document, Exhibit 398 --

MR. COUGHLIN: I would move the admission of 398. I don't believe there's any objection.

THE COURT: Without objection 398 is admitted.

(Exhibit 398 received.)

BY MR. COUGHLIN:
Q. This is a document dated a couple days after that last document. It's October 12th. And you're responding to Mr. Bin Yao, and you're asking that the -- can you print out a hazard ratio, would be after three years in the p-value and the DFS and DFS-DCI curves. Do you see that?

A. Yes.
Q. Okay. And you want it for the optimistic scenario; is that correct?
A. Yes, correct.
Q. Okay. So if we flip in to this document, again we start at page 4 of 11. We have your original results, the 2.3; is that correct?
A. That is correct.
Q. Okay. And then we have the optimistic scenario results carrying the charts out, and we have to flip over to page 10 of 11.

If we take a look at that chart on 10 of 11, which goes out to 36 months under the optimistic scenario, we end up with the rates of .916 over .888. Do you see that?
A. Yes, I do.
Q. So that gives you an absolute difference of 2.8 percent. Do you see that?
A. Yes, I do.
Q. Okay. And that's under the optimistic scenario using the .67 carrying out throughout the time period, right?
A. Correct.
Q. Okay. Let's flip over to document 482. I believe it is now --

MR. COUGHLIN: There was an objection, but I believe that we're past that. So I believe it's now admitted

with the objection preserved.

THE COURT: What number?

MR. COUGHLIN: 482.

THE COURT: You stated it correctly. Objections are preserved, but 482 is admitted.

(Exhibit 482 received.)

BY MR. COUGHLIN:

Q. If you could take a look at this, Mr. Auerbach. This document is dated September 19th, so it's a few weeks before those simulations were run. Do you see that?

THE COURT: Before you get too deep into this, on the exhibit list I have this document and other documents near it have an R after it. What does the R mean? Does anyone know?

MR. FORGE: Yes, Your Honor. This is the R document. The black marks on it are the -- is what the R stands for. Redacted.

THE COURT: Revised -- redacted.

MR. FORGE: Yes.

THE COURT: Okay. Good.

BY MR. COUGHLIN:

Q. And this says you're sending some information to your licensor, Pfizer; is that correct?

A. That's correct.

Q. Okay. And if we flip into the second page, 2 of 4, they

had asked you some questions about sending some curves to them, and you respond over on the next page, 3 of 4, you say you're still in the process of fully validating this data; is that correct?

A. That is correct.

Q. Okay. Now, they're asking for efficacy data. Wasn't that validated as of July 17th?

A. Yes. There's a little more context to this discussion. May I discuss that, please?

Q. You can discuss it with your counsel. Let me ask my questions. They can ask you then.

A. This is a different data set they were asking for than what was validated previously.

Q. Okay. Let's take a look. It appears based on our preliminary analysis that the absolute difference in the DFS curves is separating by approximately .5 percent a year; is that correct?

A. Yeah. So again there's more context to this. May I discuss that, please?

Q. I'm going to give you a chance to discuss that. I want to know if that's what you wrote.

A. Yes, but it's a different data set than what was presented and discussed with investors in July of 2014.

Q. And when we actually look at that data set in the curve, then I'll let you explain. How's that?

A. Thank you very much.
Q. Okay. So that's what you were sending to Pfizer, that it was up .5 percent per year for the next year; is that right?
A. Correct.
Q. If we take a look several weeks later, November 5th, 2014 --
MR. COUGHLIN: This Exhibit 475, again an objection is preserved, but this document is now to be admitted.
THE COURT: 475?
MR. COUGHLIN: Yes.
THE COURT: 475 is admitted.
(Exhibit 475 received.)
MS. JOHNSON: Wait. We're noticing that 475 is missing the second to the last two pages of the attachment. So the objection is incomplete.
THE COURT: I don't know what that last sentence means. The objection is incomplete?
MS. JOHNSON: Incompleteness.
THE COURT: I don't know what that means. I just don't know. Where are the last two pages?
MR. COUGHLIN: I'll get them for you, Your Honor. I thought I had them all in my binder.
THE COURT: Okay, which binder? I think this witness now has two binders, three binders, and there's 25

other binders. In which binder can we find the last two pages?

MR. COUGHLIN: Well, I thought I had them all in my binder, but I must have miscopied.

MR. FORGE: Your Honor, just for the record, 475 should be three pages long. Is that what the defense has?

MS. JOHNSON: It's five.

MR. FORGE: Your Honor, may I confer?

THE COURT: I must say, it says plaintiffs' Exhibit 475, page 1 of 3.

MR. FORGE: Correct.

THE COURT: What I admitted was a three-page document. How long a document are you now admitting?

MR. COUGHLIN: A three-page document.

THE COURT: Okay.

MR. COUGHLIN: I don't have another two pages to this document that was produced to us.

THE COURT: All right. So what we argued about and what we're admitting is a three-page document.

Is the defense now wanting the other two pages as part of this?

MS. JOHNSON: Yes, Your Honor.

THE COURT: Is there any objection?

MR. COUGHLIN: No objection.

THE COURT: All right. Then the other two pages

will be a part of this.

Let me just say that there are many, many, many documents. The Court staff and I do our best to be as accurate as possible. On something like this, I don't have the two extra pages. I don't know what we're talking about. That means -- listen carefully. It's up to both sides to make sure that the documents submitted to the jury reflect the Court's ruling. The Court is now ruling that it is a five-page document, but the Court apparently doesn't have the five-page document and the Court won't do the extra effort at the end to figure out and attach it.

It's up to the parties to make sure that happens. If that doesn't happen, it is the fault of the parties. A five-page document, Exhibit 475, is admitted.

Go ahead.

MR. COUGHLIN: Thank you, Your Honor.

MR. FORGE: Your Honor, just for the record, and I apologize. I'm not trying to deflect responsibility. Right now as far as we know, it is only three pages. So I'm going to go step outside and see if I can get it clarified.

THE COURT: All right.

MR. FORGE: In other words, we don't have pages 4 and 5.

MR. CLUBOK: For the record, we have -- we're having copies made very quickly.

THE COURT: Your microphone is not on.

Good. Go ahead. Five-page document, 475.

Go ahead.

BY MR. COUGHLIN:

Q. If you take a look at this document, Mr. Auerbach, 475, which we have as three pages, dated November 5th, 2014; is that correct.

A. Yes, that is correct.

Q. And you're sending Pfizer -- if you look at the bottom of that: Please find attached to this e-mail the Kaplan-Meier curve for the ExteNET trial. Do you see that?

A. That is correct.

Q. The first document shows the curves using a scale of .0 to 1.0. The second document shows the curves with the same -- with the scale from .8 to 1.0?

A. That is correct.

Q. Okay. And if you flip over to the first page, to the first curve that you're sending, what you're showing is a 36-month curve; is that correct?

A. Yes, that's correct.

Q. Okay. And that is -- and that shows a 2.8 absolute difference, doing the math we just did in the previous document?

A. Correct.

Q. And those are the documents you sent Pfizer for the

going out to three years?
A. That is correct.
Q. You didn't send them the document that Claire Sherman created showing the actual data you had; is that correct?
A. That was not what they had requested.
Q. They hadn't requested a simulation from you?
A. May I -- as I mentioned earlier, there's more context to this. May I please go into that now?
Q. You can go into it some.
A. Thank you very much. We received the ExteNET data in July of 2014. Pfizer is the company who we licensed this drug from, and we've had a wonderful relationship with them. They're really great people, and we're very pleased that they allowed us to license this asset.

In August of 2014 I flew to New York and we discussed the ExteNET data with them, and we also went through a, you know, an update on the company as a whole. We had discussed with them that, you know, we were obviously eager to look at the longer-term curves, three years, four years, five years, et cetera.

Our goal with this drug is to reduce a woman's risk of the breast cancer coming back. Being able to do that at two years is wonderful, but these are young women. These are women who were 40 years old. They don't want to have their cancer come back. They're very young women. They have

babies, and their dream is to watch those babies grow up and produce babies of their own.

Reducing their breast cancer recurrence at two years is wonderful. Obviously we want to look at the longer term as well. So we had discussed with them that we were performing simulations where we were taking the existing hazard ratio and assuming that that would apply to the future events as well.

And that was what they had requested of a gentleman by the name of Vatnak Vat-Ho, I believe, who I believe was included in this e-mail as well. So they had requested that we provide them with these simulations because they found them very interesting. And specifically Vatnak had asked that we produce the simulations because he found them very intriguing and he wanted to see where they went. That is the reason we supplied these.

Q. Okay. So he didn't ask for the real data that you had left, the data you said you saw and the data that you relied on on the conference call?

A. I believe we had shown that to them. As a recall, we had actually shown them the data with the caveat of the patient numbers were dropping off very dramatically. My recollection of this is we had our face-to-face meeting. We should them the data where the patient numbers were dropping off quite dramatically as we went out two years, three years,

et cetera.

Then we had mentioned to them that we were doing the simulations as well, and this is what they had requested.

Q. Okay. They wanted simulations. They didn't want to see the real data?

A. We had already shown them the real data.

Q. You have no record of showing them the real data. That chart does not exist anywhere.

A. We had a face-to-face meeting with them, and it was produced to them in a PowerPoint slide show. How that was, you know, why there is no record of that being done, I'm not quite sure how there could be of that record.

Q. And you flew out there in August to do this?

A. That would have been August right after we got the data, August 2014.

Q. Okay. And you flew out there and showed them this, but there's no electronic record anywhere, not from the person who sent it to you, not to you showing it to them. Did Claire Sherman go with you?

A. No. She was not there.

Q. So you had it on your computer?

A. In some way, shape, or form. I remember showing it to them. I don't know if we showed it to them as a piece of paper, if it was shown to them on a slide. At some point it was definitely shared with them.

Q. And who else was with you at that meeting?
A. My attorneys.
Q. From Latham?
A. I don't remember which attorneys we had with us.
Q. Well, who was with you?
A. One of the attorneys for the company.
Q. What's the name of the attorney?
A. I don't remember who was with me.
Q. Okay. So you can't remember if it was a Latham attorney or not?
A. It may have been a Latham attorney or it may not have been. I don't remember.
Q. So you took an attorney to this meeting and you showed them the actual data, and they said, we'd like to see simulations out for three years?
A. They had specifically requested the work we were doing with the simulations.
Q. Okay. So when you show them -- when you sent them the simulations, you say in the note that you sent them: Please find attached the Kaplan-Meier curves for the ExteNET trial. Do you see that?
A. Yes.
Q. Okay. You don't say, please find the simulations attached for the original intent-to-treat population; is that correct?

A. You know, again, this is what they had requested, and this is what we had sent to them.
Q. Okay. So nowhere on this document do you say that these are simulations.
A. It was discussed not with Kathy but with Vatnak.
Q. Okay. And you some removed the patient populations from these documents before you sent them, too; is that correct?
A. When you say removed had the patient populations, what do you refer to?
Q. When Daniell first did the simulations for you, you asked him to remove the patient populations at the bottom. Do you remember that?
A. Oh, the patients at risk.
Q. Yes.
A. The patients at risk was meaningless because they weren't real patients. They were simulations.
Q. So you took them off?
A. We had taken them out because it was misleading. It was difficult to see the patients at risk because you were making assumptions you didn't have.
Q. And did Pfizer ask you about that and say, hey, we want to see the patient populations?
A. We never got a request from Pfizer asking for the patients at risk.
Q. They never followed up and said, hey, we can't figure

out these curves?
A. I don't remember getting any type of communication from Pfizer where they said that they wanted to see the number of patients at risk on the X axis.
Q. Okay. And nowhere on this document where you say it's the original intent-to-treat population do you label these as simulations; is that correct?
A. As I recall the meeting in August, this was what they had requested.
Q. So that's what you sent them?
A. Correct.
Q. Let's take a look at Exhibit 1067. Do you recognize what 1067 is?
A. I apologize. I need to refresh my memory.
Q. Okay.
MR. COUGHLIN: Your Honor, I don't believe there's any objection to Exhibit 1067, so I'd like to move for its admission.
THE COURT: 1067 is admitted without objection.
(Exhibit 1067 received.)
THE WITNESS: Yes, I remember this.
BY MR. COUGHLIN:
Q. Okay. And this is an October 13, 2014, document, and you're writing Claire Sherman who we've just been talking about?

A. That is correct.
Q. And you're asking for the HR positive and HR negative subgroups to be broken out into KM curves; is that correct?
A. Correct. So I believe, if you look at the bottom of this e-mail, please.
Q. That's where I was looking at. Yes: I apologize if I I've already asked for this information --
A. So you will notice I say the words, I apologize if I have already asked for this information, but do you have -- it is quite common that I will ask for things multiple times --
Q. Understood.
A. -- even if they've been shown to me in the past, because sometimes they're not shown to me in a manner where I can, you know -- may be on a piece of paper, may be on a computer where I visually see it, but I don't have a tangible copy of it.
Q. Now, she says -- she replies to that, that forest plots were produced to examine the hormone-receptor subgroups. Do you see that?
A. Yes.
Q. Okay. And she can modify the programs to produce the Kaplan-Meier plots you are asking for. Do you see that -- you are requesting?
A. Correct.

Q. Okay. So she hadn't done that before?
A. She may not have. Someone else may have.
Q. Somebody else had done these Kaplan-Meier curves you're now asking her to do?
A. Yeah. After -- I mean, before July 2014 Claire had access to the data, and I believe someone else did as well, perhaps Judy Bebchuk. There were other statisticians who had access to the database.
Q. Okay. So Claire wouldn't have known that those had already been done?
A. You know, Claire is up in our San Francisco office. We have an entire team down in Los Angeles as well. I don't know if they communicate on a minutely basis as to what analyses are being gone. So I don't know the answer to that.
Q. Okay. So she says she will create the two-year -- create the tables with the two-year DFS, DFS-DCI rates. Do you see that?
A. Yes. Yes, I do.
Q. And if we take a look at the next document dated October 17, 2014 --

MR. COUGHLIN: I'd move for the admission of document 1068. I don't believe there's any objection to it, Your Honor.

THE COURT: 1068 is admitted without objection.

(Exhibit 1068 received.)

BY MR. COUGHLIN:

Q. So it appears these are the materials that she creates, the KM curves for you for the HR negative and HR positive; is that correct?

A. That appears to be correct. Please let me review.

Yes, that is indeed correct.

Q. And this is the estrogen, progesterone, the HR negative and HR positive; is that correct?

A. Yes. The estrogen receptor or progesterone receptor, if the tumor has that, that is known as hormone-receptor positive.

Q. And in the first table we get a .2 absolute difference -- if we flip over to the next page, I'm sorry. First chart inside that document is 6594, the table?

A. Yes. That is correct.

Q. And then the curve is drawn on the next page, 6595?

A. That is correct.

Q. Okay. Then we -- if we flip to the next, we have HR positive? And this was where neratinib had a high statistical significance, is that correct, in the HR positive?

A. Correct. It was where we saw the majority of the efficacy. If you looked at those two subgroups, there was more efficacy in the hormone-receptor positive.

Q. And that's a subgroup of your intent-to-treat

population; is that correct?
A. Correct. It made up about between 65 to 70 percent of the patients that I remember.
Q. Okay. And it has an absolute difference of 4.1 percent; is that correct?
A. That is correct.
Q. Okay. And we flip over to the last page where we -- I'm sorry. Before we go from that previous one, the hazard ratio for that was .51; is that correct?
A. Yes, that is correct.
Q. So it had a better hazard ratio than the overall population of .67?
A. That is correct.
Q. And finally, if we flip to the back page that I said, 6600, that's the ER PR plus. So that's both plus; is that correct?
A. No. That is the same analysis that you just referenced previously. However, this time it's --
Q. Oh, it's the ductal?
A. The DFS-DCIS, as we discussed yesterday, includes the premalignant tumors but not the noncancerous tumors.
Q. And they had an improved rate of 4.7, correct?
A. That's correct.
Q. And to your knowledge that was the first time that Claire had produced those curves; is that correct?

A. I don't know if Claire -- someone in the company had produced them. I don't remember if it was Claire or another statistician.
Q. Well, she said she had never produced them. She said she had only done forest plots?
A. As I said Claire, may not have done them. Other statisticians may have done them.
Q. But those other reports were not produced to us?
A. I'm -- I'm not aware of what was produced to you and not produced to you. I do know that back in July of 2014, someone had produced those curves because I remember seeing them.
Q. Let's take a look at the next exhibit, Exhibit 494. It might not be the next exhibit but next in line.
THE COURT: Is it admitted?
MR. COUGHLIN: It's admitted without objection, Your Honor.
THE COURT: Oh, that means it hasn't been admitted?
MR. COUGHLIN: No, it hasn't been admitted.
THE COURT: You move its admission?
MR. COUGHLIN: I'd move its admission.
THE COURT: Admitted without objection, 494.
(Exhibit 494 received.)
BY MR. COUGHLIN:
Q. This is in March of 2015?

A. That is correct.
Q. And you're asking Mr. Bin Yao to produce a chart on the centrally confirmed; is that correct?
A. Yes.
Q. And it's a KM curve?
A. Correct. This had been -- so we have two different statistical team, if you will. At the time one was headed up by Bin and one was headed up by Claire. I was asking Bin to produce this for me. I believe Claire or someone on her team had produced it previously.
Q. Previously to when she was doing these other ones in October -- September and October?
A. No. It had been produced in July of 2014.
Q. It had been produced -- so these are reports that had been produced in July? You're saying --
A. When we -- I'm sorry. Please go ahead. I didn't mean to interrupt you.
Q. These same curves had been producing to you in July?
A. I remember seeing these curves in July of 2014, and it was part of the presentation that had been done. I don't remember who did the presentation, and I didn't ask on every slide that was shown to me who was the statistician who did this.
Q. And there's no record. You haven't seen it in preparation of this litigation. You haven't seen those

curves in July; have you?
A. I am not aware of what has been produced regarding this topic in this litigation, so I don't know that I can answer that.
Q. Well, none of those curves have been produced to us. You've been involved in the litigation. You've been asked to produce those documents, your company has. But we haven't seen any of those curves that were -- back in July. This is like the fourth thing that you said existed. Did you have a computer shutdown or something and the documents just disappeared?
A. I'm not aware of a computer shutdown where documents disappear, but we are a small company and we are an entrepreneurial company. Oftentimes we don't save everything or files get deleted or people leave and take their computers with them and we don't have access to them. Again, we're a small company. These things happen.
Q. So you're saying --
THE COURT: I must say, counsel keeps saying the documents aren't there. The documents aren't there. The documents disappeared. That may be true. It may not be true. But you're not the witness and you're not sworn.
I am just reminding folks.
MR. COUGHLIN: I understand, Your Honor.
THE COURT: The issue of missing documents always

presents a challenge in proving it. But, go ahead.

MR. COUGHLIN: It's tough to prove the negative.

THE COURT: Yes, indeed. I understand your position.

BY MR. COUGHLIN:

Q. So this centrally confirmed, you understood at this time even at this late date that you were missing 60 percent of the data?

A. I believe, if I remember this correctly -- hang on one second. I don't remember -- hang on. I thought I saw this in one of your earlier -- I don't remember. I remember that we had centrally confirmed testing that was still being done from the samples from the patients back in July, but I thought this analysis was, for lack of a better word, complete enough that we felt confident in it.

Q. Even if you were missing 40 percent of the overall data?

A. I don't know that the number was that high. I need to refresh my memory on how high that number was. I remember it was enough that we felt confident in it. And again, you know, we had data, so it was, you know, worth reporting.

Q. You would agree that if you were missing 40 percent of data at this time, in March, that would be a problem?

A. It could be a problem or it could not be a problem. The 40 percent of the data was similar in its results to what we has seen -- I mean, 60 percent is a lot of data.

If it was 10 percent, I would agree with you that the results had a high potential for error. If you're talking about 60 percent of the date, you know, the next 40 percent might agree with your 60 percent or it might not. So I can't answer that.

Q. But this is because you had quit collecting the data two years before; is that correct? We saw that document off the safety?

A. I don't know that we quit collecting the centrally confirmed. The bio marker data, which has nothing to do with this where we're looking for, you know, genetic mutations and things like that, if that work had been stopped, yes.

The centrally confirmed, I don't remember that that was actually specifically stopped. I seem to remember that we had it and it was still being processed.

Q. Well, that's what the slide deck said, is that you had quit collecting it. The slide deck that you got on the safety data before the conference call said you had quit collecting that data with amendment number nine.

A. I don't remember that.

Q. Okay. Let's take a look at the next exhibit, Exhibit 179 -- sorry, 175.

MR. COUGHLIN: There's no objection to this document, Your Honor, so I would move for its admission.

THE COURT: 975?

MR. COUGHLIN: 175.

THE COURT: I misheard. 175 is admitted.

(Exhibit 175 received.)

BY MR. COUGHLIN:

Q. So this is about two months later, May 27th, 2015?

A. Yes.

Q. Okay. And here you are talking to Al Lalani; is that correct?

A. Yes.

Q. Again if we flip in to page 3 of 6, it says: Am I correct that to date the central HER2 testing has been done on 60 percent of the patients?

A. Correct, 1,704 out of 2,840.

Q. Does that refresh your recollection that it was 60 percent?

A. Yes.

Q. Let's take a look at our next in line exhibit, Exhibit 1012. I'm going to step back in time, Mr. Auerbach, back to August 25th, 2014, if that's all right.

A. Sure.

MR. COUGHLIN: There's been no objection to this document, Your Honor, so I would move for its admission.

MS. JOHNSON: We just preserve our objections under MIL four. Otherwise, no objection.

THE COURT: Give me the document again.

MR. COUGHLIN: The document is 1012, Exhibit 1012. I understand the preservation of their objection, Your Honor, but now there's no objections to its admission. They've preserved their objection to what it does.

THE COURT: Yes. Okay. Now I'm understanding. 1012 is admitted over objection.

(Exhibit 1012 received)

BY MR. COUGHLIN:

Q. Can you take a look at this document, Mr. Auerbach?

A. Yes.

Q. After you got your results, you wanted to get what they call a breakthrough designation from the FDA; is that correct?

A. That is correct. We discussed it with them.

Q. And that's what this document deals with, this document that you're editing; is that correct?

A. I believe that's correct, yes.

Q. Okay. And it says here -- and you're writing to Christine Woods; is that right?

A. Yes.

Q. You're saying that you would like to -- you made a few edits onto that document. Let's turn to those edits if we could, to page 4 of 7. At the top of the page we see an edit by you, node positive or node negative. You added that?

A. That's correct.

Q. Okay. And down below we have the actual tables and the results for the DFS topline, and that's done in the reverse this time of 6.1, which gives you the 93.9, and the 8.4, which gives you the 91.6, for the absolute difference of 2.3. Do you see that?

A. Yes, I do.

Q. So these are the actual results of the ExteNET study going to the FDA?

A. That is correct.

Q. Okay. And these are the KM curves on the next page, page 5 of 7?

A. That is correct.

Q. And you were involved in that process trying to get the breakthrough designation?

A. Yes. I was involved in the call that we had with the FDA to discuss this.

Q. Okay. And that -- that breakthrough designation allows you certain benefits of speeding up the approval process; is that correct?

A. There's a little more context than that. May I discuss that, please?

Q. Yes. You can discuss it in all the detail you want with your counsel. But it does give you an advantage as you're trying to seek approval, right?

A. I believe on the FDA website it states that the

breakthrough designation is meant for -- is ideally meant for drugs that have not yet started a phase III trial. So as you know, with ExteNET, ExteNET was a phase III trial. So to answer your question, it is meant to expedite phase II drugs that would like to get approval before doing their phase IIIs because they achieve efficacy that is, you know, so much greater than what the current standard of care would.

Q. Right. And you had completed phase III, so you were a step beyond?

A. Yeah. Late, yeah.

Q. And it still gives you benefits to expedite things, and that's why you sought it, right?

A. I don't know that that was the case. As I remember this, the breakthrough designation came out from FDA. They first introduced this sometime in 2012, 2013. And it wasn't quite clear what it was, but our regulatory group had said that, you know, they felt it would be good if we attempt -- if we discussed it with them.

I don't know that it would have given us any advantages over the path, otherwise we would have taken it.

THE COURT: We're at a good breaking time. Okay?

MR. COUGHLIN: Yes, Your Honor.

THE COURT: We're going to break now, and we will come back in 15 minutes. Thank you.

THE CLERK: All rise.

(Recess taken from 10:28 a.m. until 10:45 a.m.)

THE CLERK: All rise.

(Open court - jury present)

THE COURT: All right.

Please continue, Mr. Coughlin.

BY MR. COUGHLIN:

Q. Mr. Auerbach, if you could turn to Exhibit 1014.

MR. COUGHLIN: Your Honor, I believe there's an objection, but they're preserving the objection and this document can be admitted.

THE COURT: 1014 is admitted over objection.

(Exhibit 1014 received.)

BY MR. COUGHLIN:

Q. If you take a look at this document, this is Ms. Woods sending on the request for breakthrough, the breakthrough request to the FDA. Do you see that?

A. That is correct.

Q. If we just flip in to the document to page 6 of 7, we see that document contains your edit from node positive or node negative --

A. Correct.

Q. -- at the top? And it has the absolute difference charts down at the bottom?

A. Yep.

Q. And the KM curves on the next page, correct?

A. That is correct.
Q. If we can flip to Exhibit 460, we're going to flip in to this exhibit page 78 of 128.
MR. COUGHLIN: I don't believe there's any objection to this.
THE COURT: Without objection 460 is admitted.
(Exhibit 460 received.)
BY MR. COUGHLIN:
Q. If we turn to page 78 of 128.
A. (Witness complies.)
Q. Mr. Auerbach, who is Judith Bebchuk Segal?
A. Judy Bebchuk is a statistician in my company.
Q. And you had mentioned her name before, somebody possibly doing some of the curves and things like that?
A. That's correct. She was involved in the ExteNET trial.
Q. Okay. And she's got her notes dated September 23rd, 2014, and it's the breakthrough request meeting with the FDA. Do you see that?
A. Yes, I do.
Q. Okay. And we talked a little bit about what the breakthrough would do. Correct me if I'm wrong. My understanding is that the breakthrough -- the breakthrough drug is intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition. Was that your understanding?

A. That's the indication, yes. As I mentioned earlier, the FDA on their website also says that the time they would like you to meet with them is before you have started your phase III trials.

Q. And it says preliminary clinical evidence indicates that the drug may demonstrate substantial improvement. Is that your understanding of what they -- what they're considering, if it may demonstrate substantial improvement?

A. I don't have the FDA definition in front of me, so I can't answer that.

Q. But does it sound like what it was?

A. It may be what it is.

Q. We'll look at it.

A. Okay.

Q. So this is a meeting September 23rd, 2014, and it lists the attendees, or I guess it's probably a phone call. Do you remember this meeting?

A. Yes, I do.

Q. Okay. And it talks about the different questions that were asked --

A. Uh-huh.

Q. -- and different people that were asking questions and responding. And if we go down to the bottom, her final notes are: 2.3 percent improvement in DFS not enough for breakthrough. Need safety. Worried about censoring.

Do you see that?

A. I'm sorry. That cuts off there. If we can continue on to the next page so we can see that, please.

Q. Yes.

A. Thank you. That's perfect. Yes. So as I read -- may I read this?

Q. Yes.

A. Thank you very much. As I read this, it says, 2.3 percent improvement in DFS not enough for breakthrough. Need safety. Worry about censoring. Does not have implication on NDA.

So just to clarify, an NDA is the formal FDA filing where you apply for approval of your drug.

Q. The new drug?

A. New drug application is what it stands for, yes. So in the part below there which is not being highlighted, I believe it says: Does not have implications on NDA. Only afflicts breakthrough.

And that is mentioned by someone named Patricia. Patricia is Patricia Cortazar, who was the heard of the breast cancer group at the FDA. So we were quite encouraged in this meeting because they were essentially telling us, encouraging us to file our NDA, which would be the application for the FDA approval of the drug.

Q. Right. But they denied you breakthrough designation at

this time?

A. As I recall this meeting, when we discussed the concept of breakthrough designation, they reiterated to us that it is meant for drugs -- you have three phases of clinical trials, phase I, phase II, and phase III. Phase I is where you look for your initial safety. Phase II is where you look for your initial efficacy. Phase III is either a very large study where you compare the efficacy of your drug to whatever the standard of care is.

What they had mentioned to us, as I remember this, was that this breakthrough designation was a way for a phase II drug that was very promising to leapfrog phase III and get approval while still running the phase III trials. It was an early window for approval for earlier drugs.

So I remember them telling us that we were a little bit late. Then I also seem to remember that they had mentioned to us that if someone did do a large phase II trial -- so let's say they did a smaller version of ExteNET but it was a phase II study, the bogie, if you will, the number they would look for, would be a hazard ratio of 0.5, I remember them telling us, and we were at 0.67. So we just kind of barely missed it.

Q. I see. So you're saying you were further along. You had done a big clinical trial that had covered years and years, and they denied you breakthrough because you were too

far along?
A. So the -- as I understand --
Q. Mr. Auerbach, could you just answer that question? That's really your testimony, right?
A. That was --
Q. You were too far along?
A. My recollection was --
MS. JOHNSON: Objection, Your Honor, to the compound question. He has to be allowed to finish his testimony.
BY MR. COUGHLIN:
Q. Were you too far along?
THE COURT: When there's an objection, it's my job. I gotta respond. You said, like, three things. You said compound. You said he has to be allowed to finish. I'm not sure where we are.
MS. JOHNSON: It was --
THE COURT: What's your objection?
MS. JOHNSON: That the question was compound.
THE COURT: All right.
Rephrase your question. Proceed.
BY MR. COUGHLIN:
Q. Ms. Bebchuk doesn't write anything in here about you being too far along; is that correct?
A. These are Judy's notes. This is actually the first time

I've seen them. So I would probably venture to guess that this is not a direct transcript of every word that was said at the meeting.

Q. Thank you, Mr. Auerbach.

If we go to the next exhibit, Exhibit 1008.

MR. COUGHLIN: Your Honor, there was an objection here. The objection is preserved. But with that caveat, we'd move 1008 in.

THE COURT: Admitted as described. 1008, right?

MR. COUGHLIN: Yes.

(Exhibit 1008 received.)

BY MR. COUGHLIN:

Q. Mr. Auerbach, this is September 24th, or one day later. Maybe even the same, later that day: We do not intend to submit a formal breakthrough therapy designation request for this neratinib indication. Do you see that?

A. Yes. That is correct.

Q. And in this document you're asking for a nonclinical type C meeting request and briefing package, is what you're submitting; is that correct?

A. That is indeed correct.

Q. Okay. And this was for more -- you could probably explain it better -- follow-up studies on the cancer risks; is that correct?

A. No, not exactly. May I describe that?

Q. Yes.

A. Thank you very much.

So when it comes to applying for FDA approval of a drug, they ask you to do clinical studies which is where in actual patients you're testing that your drug is safe and effective. But there's also nonclinical studies. Nonclinical studies are studies done on animals, so rats and things like that, where you're testing various things that you couldn't really test in humans very easily.

Specifically the ones we're testing here is what is called carcinogenicity. What carcinogenicity is, is does your drug cause cancer. So, for example, here we have a drug which has shown efficacy in preventing breast cancer, but what if it causes lung cancer or it causes brain cancer or it causes non-Hodgkins lymphoma or something?

THE COURT: Causes what?

THE WITNESS: Non-Hodgkins lymphoma. So this is what you're testing in these studies. The way you do these studies is that you give your drug to rats because rats are known to develop spontaneous tumors much quicker than humans.

So you usually do very long studies for a period of two years where you'll take a number of rats, give them a large quantity of your drug at various doses and then a large quantity of a placebo, so just a dummy pill. And you'll see whether or not there's a difference in between the number of

cancers caused in the rats who get your drug versus the ones who get the placebo.

You're usually looking for large differences, doubling, tripling, things like that. If you see that, it would imply your drug has the risk of causing cancer in humans. If you don't see that and the two are basically the same, then you can feel quite comfortable that your drug likely does not cause other cancers.

BY MR. COUGHLIN:

Q. You were quite comfortable with neratinib at this time because of all the studies that had been done before that you wouldn't have a problem in that area; is that correct?

A. We -- well, until you do the testing, you can't be certain of that. Some of the initial studies that we had done -- not these two-year rat studies. Some of the initial studies that we had done certainly did not give us any concerns that neratinib would indeed cause other cancers.

Q. So you were asking that some of these longer studies with the rats and the other animals, that they would be allowed to be submitted after you had made your NDA application, your new drug application; is that correct?

A. So that is correct. The two-year rat studies had not been completed at the time we were hoping to file for FDA approval of this drug. So the purpose of this meeting was to request of the FDA that we could be allowed to apply for FDA

approval and then submit that data afterwards.
Q. Okay. And in this application you include the topline results of the ExteNET study; is that correct?
A. Let me --
Q. Flip to page 27 of 47.
A. Yes, that is correct.
Q. Page 27 of 47. And again we have the topline DFS of 2.3 percent in the reverse; is that correct?
A. That is correct.
Q. And on the next page, 28 of 47, we have the Kaplan-Meier curves; is that correct?
A. That is correct.
Q. Okay. Now, if we flip to the next exhibit, Exhibit 1048, dated November 24th, 2014, this appears to be the teleconference setting up the teleconference meeting for the call the next day with the FDA at the end of November 2014; is that correct?
A. Correct.
MR. COUGHLIN: I should move this in with the same caveat. The objection is preserved. And other than that, the document can come in.
THE COURT: State the document.
MR. COUGHLIN: 1048.
THE COURT: 1048 is admitted.
(Exhibit 1048 received.)

BY MR. COUGHLIN:

Q. And if we flip in to this document and first go to page 7 of 21, this document has some of the FDA's preliminary comments to Puma; is that correct?

A. I believe that's correct, yes.

Q. Okay. And it has this table with the top line there of neoplasms, malignant, and has some rates?

A. Correct.

Q. And the next page has the topline results from the ExteNET study if we go to page 8 of 21; is that correct?

A. That is correct.

Q. Okay. And then it has the forest chart, the next page, 9 of 21?

A. That is correct.

Q. And here's where you ask the FDA whether you can submit those studies after you submit -- if we look at question number two, page 7 of 10 --

A. Uh-huh.

Q. -- they ask -- you ask if you could admit those studies later, and the FDA's response to you is, no, you've got to submit them with your application; is that correct?

A. Yes. That was the initial response, correct.

Q. Let's take a look at Exhibit 773.

MR. COUGHLIN: I'd move for the admission of this document 773, with the objection preserved.

THE COURT: 773 is so admitted.

(Exhibit 773 received.)

BY MR. COUGHLIN:

Q. And Christine Woods on December 15th, 2014, appears to be distributing the FDA's -- the minutes from the meeting from Jeannette O'Donnell from the FDA; is that correct?

A. Yes, that is correct.

Q. Okay. And you received a copy of these?

A. Yes. I'm on the e-mail list. I did.

Q. Turn to page 6 of 15. It has that same chart that had been part of the discussion, the telephonic discussion, right?

A. That is correct.

Q. Okay. And 7 of 15 are the ExteNET topline results; is that correct?

A. That is correct.

Q. Okay. Then if we take a look at page 10 of 15, we now have the FDA's response. Again, no study reports from the carcinogenicity studies should be included in an NDA submission. Do you see that?

A. Yes, I do.

Q. You received this on 12/15; is that correct?

A. That is correct.

Q. Okay.

Let's turn to Exhibit 569 [sic].

MR. COUGHLIN: There's no objection to this exhibit, I believe, 567. I'd move to admit, Your Honor.

THE WITNESS: You said earlier 569.

MR. COUGHLIN: No, it's 567. Thank you.

THE COURT: 567 is admitted.

(Exhibit 567 received.)

BY MR. COUGHLIN:

Q. Who is Bradley Wolff?

A. Bradley Wolff is the managing director of healthcare investment banking for the investment banking firm of Bank of America Merrill Lynch.

Q. Okay. And they were going to do an offering for Puma; is that correct?

A. That is correct.

Q. Okay. So they were starting to undertake their due diligence here in October; is that correct?

A. Yes, that is correct.

Q. And they had asked you for recent FDA correspondence, if any; revised license agreement; and an IP update, if any. Do you see that?

A. Yep. That is correct.

Q. Okay. And did you provide them with those materials?

A. Yes, I did.

Q. Okay. Let's turn to Exhibit 491.

MR. COUGHLIN: I'd like to move for the admission

of 491. I don't believe -- well, there's an objection. So subject to the objection.

THE COURT: Can we hear the objection?

MR. COUGHLIN: No. It's on the record, Your Honor.

THE COURT: Well, when you say it's on the record and I admit it, if it's a viable objection, we could get reversed.

MR. COUGHLIN: No. It's an objection to a whole line of questioning. So they're preserving their objection.

THE COURT: Have I had a chance to rule on the merits of the objection?

MR. COUGHLIN: Yes.

THE COURT: I want to make sure I have the chance to rule on the merits of any objection made by a party.

All right. So 491 is admitted.

MR. COUGHLIN: Thank you, Your Honor.

(Exhibit 491 received)

BY MR. COUGHLIN:

Q. Who is William Hicks?

A. William Hicks or Bill Hicks is the attorney who was acting as what's called underwriter's counsel, which means that he acts as the lawyer for the underwriters, which here would be Bank of America Merrill Lynch.

Q. He was --

A. Sorry.

Q. He was mentioned in the previous document, that he would be reaching out to you to do the due diligence; is that correct?
A. Yes, that is correct.
Q. Okay. And here you are providing him with some materials that he requested; is that correct?
A. Yes, that is correct.
Q. Okay. And this is January 7th, 2015; is that right?
A. Yes, that is correct.
Q. Okay. And you wish him Happy New Year. Then, please find attached the minutes from our recent meeting with the FDA for neratinib which is being provided to you for regulatory diligence in advance of our update call on Friday; is that right?
A. That is correct.
Q. Okay. And then you talk about there is no other legal or IP diligence items; is that correct?
A. Correct.
Q. And then you provide him with the FDA report that is attached to this e-mail; is that correct?
A. That is correct.
Q. Now, you understand today that this FDA report that you're providing him that was supposedly sent by Jeannette O'Donnell in 2015 is different than the report that you received from Christine Woods back in December of 2014,

right?
A. Yes. I became aware of this at my deposition, which was in January of 2018.
Q. Okay. Let's compare these two reports. If we could compare Exhibit 773 with Exhibit 491. Exhibit 773 with the exhibit number at the bottom is on the left. Exhibit 491 is on the right. Okay.
The one you sent to Mr. Hicks is the one on the right. The one that is on the left is the one you received from Ms. Woods; is that correct?
A. Yes, correct.
Q. Okay. If we flip in to the first page, we see that both these reports are the same; is that correct?
A. Yes.
Q. And the second page, they are the same, correct?
A. That appears to be correct.
Q. Okay. On the third page they are the same?
A. That appears to be correct, yes.
Q. Okay. On the fourth page, still seem to be the same, right?
A. That is correct.
Q. Let's go to the fifth page. Let's go to the top two columns on the fifth page. The one on the top is from the report that you received on 12/15, and the one on the bottom is the report you sent Mr. Hicks on January 7th. Do you see

that?
A. Yes, I do.
Q. Do you see how the numbers are changed so that the neratinib arm no longer goes above the placebo arm?
A. Yes.
Q. It's your testimony you didn't make that change?
A. I have no recollection of making that change. I have no recollection of asking anyone to make that change.
Q. Okay. Let's go to the next page in each document. I'm sorry, let's go back to page 6. On the bottom of that page, there's also a missing sentence on the original, the sentence that begins, the placebo group. Do you see that, right on the right on the original document? That sentence is no longer in the document that Mr. Hicks received. Do you see that?
A. Yes, I do.
Q. Let's flip to the next page of both documents. Do you see that the next page of the document on the right that you sent Mr. Hicks no longer contains the ExteNET results?
A. Yes, I see that.
Q. Somebody has removed those results. Do you see that?
A. Yes, I see that.
Q. Okay. Let's go to the next page. Do you see that also the forest chart has been removed?
A. Yes, I see that.

Q. It's your testimony you didn't remove that chart?
A. I have no recollection of removing that chart, and I have no recollection of asking anyone to remove that chart.
Q. I'd like to go to question number two in the document, in the original document 10 of 15. Here the question -- let me get them both up there first. Question number two from the one, the document that you sent Mr. Hicks on January 7th, the question seems to have been changed. Did you change that?
A. I have no recollection of changing that, and I have no recollection of asking anyone to change that.
Q. Okay. Are you denying that you made these changes?
A. I have no recollection of making any of these modifications.
Q. Okay. Now, you understand that -- let's go to 491. The metadata of that document shows that it was created on January 6, 2015, at 11:15 at night, page 12 of 12?
A. I'm sorry. Where are you looking?
Q. At the end of that document, of 491. You can just flip to it.
A. Yes. Correct.
Q. That document was created on January 6, 2015; do you see that?
A. Yes.
Q. And that you're listed as the author of that document,

correct?
A. Correct.
MR. FORGE: Hold on.
BY MR. COUGHLIN:
Q. So are you denying that you created this document?
MR. FORGE: Hold on one second. We've got to get this up on the screen.
MR. COUGHLIN: It was easier when I could use the elmo.
MR. FORGE: Why don't you use the elmo?
MR. COUGHLIN: It's all right.
BY MR. COUGHLIN:
Q. You can see that document; is that correct?
THE COURT: By the way, you can still use the elmo. I tell everyone that. The elmo is that document just to its left. You slap a document on and it goes on the screen and you can point to it and you can have fun with it.
But most of the time counsel these days put all their documents on computers, which has its advantage. They quickly hit a button and it shows. But you can't point to things. Old timers like the elmo. That would be me but not necessarily Mr. Coughlin.
MR. COUGHLIN: I like the elmo.
THE COURT: Go ahead.

BY MR. COUGHLIN:

Q. So you understand the metadata shows you were the author of that document, correct?

A. Yes. My understanding of this is that the metadata shows I am the author of the pdf, but it is not showing that I am the author of the Microsoft Word document that is located toward the bottom there.

Q. And you understand that we were informed by your counsel that Alan's flash drive, that this came from your flash drive? And then it supports the metadata that this is the e-mail that was sent and that the actual document itself was not on any Puma drive and that it was only provided by you in this e-mail on Puma's system and that it comes from your flash drive?

A. That is incorrect information. There was a version of this document that was found on my flash drives. It was saved on February -- early February 2018. At my deposition this is the first time I was shown that there was a difference between these two documents, the one that was sent to Mr. Hicks and the one that we received from the FDA.

And I was asked to go investigate where this -- how this was caused, et cetera, et cetera. I opened the e-mail to Mr. Hicks to get the version that had been sent to him, and I saved it on my flash drive.

My deposition, if I remember correctly, was

January 28-29, 2018. And I believe the date the document was saved on my flash drive was somewhere around February 1st or 2nd of 2018. So the document that you're referring to on my flash drive was saved after my deposition. It would not be a diversion that would apparently have been sent back in January of 2015.

Q. So you're not denying that you sent this to Mr. Hicks?

A. This document was indeed sent to Mr. Hicks, but the one that you're referring to which was on my flash drive is the same document. I believe actually on the flash drive it actually denotes that it's a copy of this file.

Q. So you think somebody got in and changed this document and took all the important information out of it that would have indicated that you had a 2.3 absolutely difference and altered the document, and that's the document you sent Mr. Hicks for his due diligence?

A. So I first became aware that the document that was sent to Mr. Hicks was different from the version that had been sent to the FDA at my deposition in January of 2018.

We then went back to look for reasons, et cetera. I don't know. I certainly did not alter this document and I did ask anyone to alter this document.

Q. Mr. Auerbach, actually I thought you said you don't recall altering it. At every juncture you said: I don't recall --

A. I don't have any recollection of altering this document. I don't have any recollection of asking anyone to alter this document.

Q. You'd certainly remember if you had altered the document, right?

A. I certainly would've remembered. I assume that I would have remembered if I had altered this document, and I assume I would have remembered if I had asked someone to alter it.

Q. So your testimony is you didn't alter this document?

A. I have no recollection of having altered this document. What I can say is that my recollection of this was that I had asked my team to give me copies of all recent FDA correspondence so I could send them to Mr. Hicks.

I have a team. I trust that team. Does that team make mistakes? That team does make mistakes.

Q. So somebody else at Puma took all the important information out and sent it to you, the CEO, to send on for a $200 million offering for the due diligence?

A. Well, when I requested from my team that they send me copies of all of our recent FDA correspondence, I did not mention to them that it was for a financing. It was -- I just asked them for copies of our recent communications with the FDA.

Now, it is common practice in the company that after we have meetings with the FDA, we will oftentimes edit

those notes, edit those meeting notes to reflect any changes that may have occurred since that meeting or to also discuss anything that may have been different from our perception of what happened at that meeting versus what they're writing in writing.

So we typically will maintain an internal version of the meeting notes that includes our own annotations, et cetera. In terms of the content of the meeting notes that were sent to Mr. Hicks, all of the information in there is indeed accurate. It reflects exactly what was discussed at the meeting with the FDA.

If you would like, I would be more than happy to go through each page if you'd like --

Q. You're going to get a chance to do that, Mr. Auerbach.

A. Okay.

Q. All of the tables, though, from your ExteNET study that show how efficacious neratinib was have been taken out of this document.

A. Can we go back to the meeting notes, please?

Q. You can go back with your counsel.

Are any of those -- have those tables been taken out of this document?

A. They were -- out of the internal version of the notes, we took them out because when we attempted to discuss with the FDA the clinical data, they made it clear to us that this

was a nonclinical meeting, which, that was the reason I wanted to go back to the notes. If you'll notice, it says at the top nonclinical meeting.

So the reason for us doing this is that it was a nonclinical meeting. When we tried to discuss the clinical data with them -- again, what we were trying to do is get them to allow us to not use the carcinogenicity studies, not have to file them, and file them after because we didn't want to delay applying for FDA approval by two years.

So we were attempting to use the clinical data to sway that opinion, and we --

Q. That's no reason to take out --

MS. JOHNSON: Your Honor, I would just object that he's asking him complicated questions and not letting the witness finish his answer.

MR. COUGHLIN: I've let him --

THE COURT: We are timing this matter, and to some extent his further responses and review of further documents and such is best timed against his defense team. And it is cross-examination.

I'm going to allow counsel to ask the next question, please.

BY MR. COUGHLIN:

Q. Actually, Mr. Auerbach, I'm going to ask you to go to Exhibit 492.

A. Correct.
Q. Do you have that?
A. Yes, I do.
MR. COUGHLIN: I'm going to move for the admission of 492.
THE COURT: Any objection to 492?
MR. COUGHLIN: No objection.
THE COURT: Who said that?
MR. COUGHLIN: It's the same caveat.
MS. JOHNSON: With the same --
THE COURT: Okay.
MR. COUGHLIN: I should have said that, with the same caveat as to these documents.
THE COURT: All right. 492 is admitted.
Proceed.
(Exhibit 492 received.)
BY MR. COUGHLIN:
Q. And this is Mr. Hicks following up on January 9th to ask you if there's been anything more, any other correspondence with the FDA; is that correct?
A. That is correct.
Q. Okay. And you say: Hi, Bill. And he actually says -- I think it says that he has -- he didn't get any FDA correspondence update in November; is that correct?
A. Correct.

Q. Had you sent him any update for the breakthrough denial?
A. No, we did not. That was the -- first of all, the meeting we had with the FDA on the breakthrough was what they termed a not-formal meeting. There was no meeting minutes. It was just a call to discuss whether or not we should or should not apply for it.

Second, it had no relevance to what investors cared about, which was the potential FDA approval of neratinib. I mean, if anything, as you saw in the notes, the FDA actually encouraged us to file the NDA.
Q. You're saying that the investors would not have had an interest in an expedited approval of neratinib?
A. There is nothing to state that a breakthrough designation would have been an expedited approval or any quicker than the path we took.
Q. Isn't that the whole purpose of the breakthrough designation, is to get a quicker approval?
A. For phase II drugs, yes. We were not a phase II drug.
Q. But you had gone already through phase III, so it would be that much quicker, right?
A. The FDA always prioritizes drugs that are post phase III. You have thousands of companies trying to request meetings with the FDA, and the biggest problem you have is them trying to schedule this because they're very busy and unfortunately quite under-resourced.

So one of the reasons for the breakthrough is through all of those earlier stage drugs -- this is an industry that has a very, very high rate of failure.

Q. Mr. Auerbach --

A. Can you please let me continue?

Q. No. I would like to ask you a question. You wanted to get this drug expedited --

MS. JOHNSON: I'll object for the record.

THE COURT: You may continue, counsel.

BY MR. COUGHLIN:

Q. You wanted to get this drug expedited with the FDA, right?

A. Our goal was to get this to patients as quickly as possible, yes.

Q. So even though you had gone through phase III, you went to the FDA and sought breakthrough because you wanted to get it expedited, right?

A. No. The breakthrough designation does not have impact on your timing of FDA approval or the quickness of the review. What you're referring to is the difference between priority review, accelerated approval, and things like that. The breakthrough designation is a completely different entity.

Q. So the -- off the website, the FDA will expedite the development of the review, is incorrect?

A. There is no statistics that show that the breakthrough designated drugs go through quicker than others.
Q. Why apply then? Why did you apply?
A. It was an early program. They had just come out within 2012. We didn't -- our regulatory group wasn't even clear what the benefit would be, but we figured we would apply.
Q. Okay.
A. There was absolutely no guarantee of anything that would make it quicker.
Q. So you didn't notify Mr. Hicks of the denial of the breakthrough?
A. There was no formal denial. There's no -- there's no meeting minutes from that meeting.
Q. But they had told you that you wouldn't get breakthrough, and you didn't tell Mr. Hicks, right?
A. I believe we told him that we had a meeting with the FDA. I don't remember if we said it was on the breakthrough, but we did mention that in our informal meeting with the FDA, that they had encouraged the NDA submission.
Q. Okay.

Let's go to Exhibit Number 108, please.

THE COURT: Do you move its admission?

MR. COUGHLIN: I do. I don't believe there's any objection.

MS. JOHNSON: Wait --

MR. COUGHLIN: Oh, wait. There is an objection. I'll pass 108.

THE COURT: Okay. 108 is not admitted.

MR. COUGHLIN: I'm going to Exhibit 528.

THE COURT: Any objection?

MS. JOHNSON: No, Your Honor.

THE COURT: 528 is admitted.

(Exhibit 528 received.)

BY MR. COUGHLIN:

Q. Mr. Auerbach, do you recognize what this document is?

A. Yes, I do.

Q. Okay. And this project Panthera, that was your follow-on offering; is that right?

A. That is correct.

Q. If we flip in to page 6 of 62, if we look at the bottom, of the key issues for commitments, committee consideration. It says: Puma has not disclosed details of new data that they recently discovered. While the company plans to disclose this information in the near future, possibly at an upcoming conference, they have decided not to reveal the data with any of the banks involved in this transaction.

Do you see that?

A. Yes, I do.

Q. And Mr. Hicks was supposed to do the due diligence for the banks; is that correct?

A. Yes, and he did do that due diligence.
Q. Okay.
MR. COUGHLIN: Let's turn to the next exhibit, Exhibit Number 753.
There's no objection to 753, Your Honor. We'd move for its admission.
THE COURT: 753 is admitted without objection.
(Exhibit 753 received.)
BY MR. COUGHLIN:
Q. This is the release January 27th for the offering, the $218 million public offering; is that correct?
A. Yes, that is correct.
Q. And that went out at, I think, $190 a share; is that right?
A. Yes, that is correct.
Q. Okay. Now, you had a meeting with Mr. Hicks following that exchange of the FDA minutes; is that correct?
A. We had a meeting face to face in January of 2015. That's correct.
Q. Okay. And did you send Mr. Hicks the materials before the meeting?
A. No. We -- it was a face-to-face meeting, so I just gave -- presented -- it was to present him the ExteNET data, and I presented him the data at that meeting.
Q. And that was off your computer; is that right?

A. That is correct.
Q. A slide deck?
A. Yeah. It was the -- so this meeting took place in January of 2015. In December of 2014, the prior month, there's a medical conference which is called the San Antonio Breast Cancer Symposium. At that meeting we had shared the ExteNET data with a number of breast cancer physicians. So we shared that same data slide deck with Mr. Hicks.
Q. And that was the academic steering committee that you were talking about?
A. No. It was larger than that. So it was important to us to, you know, get feedback from the breast cancer community as to what they thought of the ExteNET data. So we put -- I'm ball-parking here, but it was tens if not a hundred -- we probably put tens of doctors under a confidentiality agreement and then showed them the ExteNET data.

So, yes, you're correct. We showed it to the academic steering committee, but we also showed it to a number of other breast cancer doctors as well.
Q. So you didn't provide Mr. Hicks a hard copy of what you showed him?
A. He did not request one. I had the meeting with him, and afterwards I believe I asked him, do you want me to e-mail you this? He was, no, I'm good.
Q. So he didn't bring anything to the meeting either? He

didn't bring any documents or anything like that to share with you and talk to you about?

A. The purpose of the meeting was that the banks had put together a system so we could protect the confidentiality of the ExteNET data where Mr. Hicks signed a confidentiality agreement, and then I shared the data with Mr. Hicks.

In terms of him bringing, yes, he brought, you know, obviously a large notepad and pen, and he took, you know, copious notes as I was presenting the data to him.

Q. And you knew Mr. Hicks had no background to understand some of the technical terms in the ExteNET date; is that correct? That he had a partner that he was sending on the reports to review that you sent him?

A. I don't agree with that statement. Mr. Hicks has been in this industry a long time. He did work with my prior company 10 to 15 years prior. He knows this industry very well.

In terms of him, as you said, not qualified, I would disagree with that statement.

Q. Maybe I misspoke about qualification. He was sending it on to somebody he was working with that had expertise in this area to review the FDA stuff that you had sent him. Did he inform you of that?

A. I was not aware of that.

Q. He didn't tell you that?

A. No.
Q. Okay. Let's take a look at the next exhibit, Exhibit 503. I believe this is the copy we've agreed on. Good. Take a look at 503, please.
MR. COUGHLIN: And I don't believe there's any objection to this, so we'd move for its admission.
THE COURT: I believe it was admitted yesterday.
MR. COUGHLIN: Okay. Thank you, Your Honor.
BY MR. COUGHLIN:
Q. Can you tell us what this is, Mr. Auerbach?
A. Yes. So when you apply to have your data presented at a medical conference -- and this was ASCO, which stands for the American Society of Clinical Oncology meeting -- you will usually --
THE COURT: Hold on. The American Society of Clinical Oncology meeting, did you say?
THE WITNESS: Yes. That is correct.
THE COURT: One at a time. Continue.
THE WITNESS: So you will usually submit an abstract. What an abstract is, is a short summary, kind of a preview, if you will, of the data that you're going to be presenting. It's usually a one-page summary, and that's what gets submitted to the conference.
This would be the submission we made. I believe this was made in either January or February of 2015 to the

ASCO meeting. They receive thousands of these abstracts because this is a very large medical conference and everyone would like to present at it. They will usually categorize them in three generic categories. One is that you're not allowed to physically present the data at the meeting, but they'll publish it in the book they put out, which, the book, I used to use the analogy it's the size of a phone book, but I don't think they put those out anymore. But if you have remember the old Yellow Pages --

THE COURT: Hold on. Hold on.

MR. COUGHLIN: I didn't want to interrupt.

THE COURT: You're going way too fast.

THE WITNESS: I'm sorry.

BY MR. COUGHLIN:

Q. If we could look at Exhibit 503.

THE COURT: I do have to ask since I interrupted. Did you finish your answer?

THE WITNESS: Yes.

BY MR. COUGHLIN:

Q. If we take a look at the bottom of 503 and take a look at some of the results you reported, if we take a look at the last sentence, efficacy results are shown below, do you see that sentence?

A. Yes, I do.

Q. And it goes over to the next page and it talks about

hazard ratios for the centrally confirmed group.
A. Uh-huh. Yes.
Q. And there's another group that is being presented for; is that correct? You're adding two different subgroups here; is that right?
A. Yes. That is correct. So we are adding the hormone-receptor positive patients, which would be referred to as ER/PR positives. And then we are adding the centrally confirmed HER2.
Q. And the hazard ratio for the first group ER/PR positive is .51; is that correct?
A. That is correct.
Q. And for the centrally confirmed it's .52?
A. That's correct.
Q. Now, you don't disclose in the abstract here the absolute difference for those two subgroups; do you?
A. No, we do not. You're unfortunately leaving out --
Q. No, Mr. Auerbach. I just asked you if you disclose.
A. No, we do not.
Q. Okay. But you do disclose the absolute difference for the intent-to-treat population, the topline results; is that correct?
A. Correct. We were limited for space.
Q. Okay. If we take a look at the next exhibit, 506.
MR. COUGHLIN: There's no objection to 506, Your

Honor, so we would move for its admission.

THE COURT: Without objection 506 is admitted.

(Exhibit 506 received.)

BY MR. COUGHLIN:

Q. Do you recognize what this document is, Mr. Auerbach?

A. Yes, I do.

Q. Okay. And we saw some of these names the other day. Howard Liang, do you remember Mr. Liang? He's an analyst?

A. That's correct.

Q. And you're actually giving him over this e-mail the absolute differences between the HR-plus population as well as the centrally confirmed population; is that correct?

A. My recollection of this is that -- if we can go down in the e-mail, please.

Q. Certainly.

A. No. Can you go to what's listed as page 2 of 3, please.

Q. Yes.

A. Okay. So I believe this was after the abstract had been made public information --

Q. Correct.

A. -- and I had spoken to them on the phone. These Wall Street analyst groups have quite a sophisticated ability to do analyses. They have statisticians in-house. They have software packages that, you know, are extremely robust.

So while I was on the phone with them, they were

recreating the KM curves, which apparently there's an ability to do that based on the data we gave and the hazard ratios we gave. And as I was speaking to them, they were coming up with the differences.

Q. And you wanted to make sure they got the right numbers, so you reported exactly what the numbers were, right?

A. No. Those were the numbers they told me on the phone, because I remember I had written them down as they were doing them because I was actually quite impressed that they were able to do these curves so quickly. So I had written them down. This was the back and forth of that conversation.

Q. I'm looking at the top where you write back 4.2 percent at the top of one of three. 4.2 percent is for HR-plus population, right?

A. So they were -- when I was on the phone with them, they were both talking over each other, and they were getting the HR positive -- again, they were doing the calculations and they were getting the HR positive DFS magnitude and centrally confirmed mixed.

So when they e-mailed me -- and again, they were doing the calculations. I had just written them down. They were then e-mailing me back because obviously they were trying to write a report and they each had different numbers written.

Q. And you wanted to make sure they got the right numbers?

A. Based on their analyses, not based on anything we had done.
Q. So you corrected them or made sure they had the right analyses and the right numbers --
A. Based on their analyses.
Q. Let's turn to Exhibit 505.
MR. COUGHLIN: I'd move for the admission of 505. There's no objection.
THE COURT: 505 is admitted.
(Exhibit 505 received.)
BY MR. COUGHLIN:
Q. So those absolute difference numbers that you were conferring with those analysts about, they were not in the abstract. And then you received this Adam Feuerstein note; is that correct?
A. I received this e-mail, correct.
Q. All right. And he's a columnist for the The Street; is that correct?
A. Yeah. I believe that's a website of some sort.
Q. Okay. And he is asking you if you did talk to these analysts. He said: Did you speak with Leerink and UBS analysts last night? And if yes, did you provide the analyst with the DFS percentage point difference in the subset of patients with central lab determination of HR-2 status? Do you see that?

A. Yes, I do.
Q. Those Leerink and UBS notes say that the difference between neratinib and placebo for the central lab cohort of patients was approximately four percentage points. That data is not contained in the ASCO abstract released last night. And he asked: Did you provide the analyst with that data?
Do see that?
A. Yes, I do.
Q. It's your testimony you didn't provide it. You were just correcting them?
A. My recollection of this is as I was on the phone with both here Leerink and UBS analysts, that they had their statisticians on the phone as well and they were using a software program -- I thought it was SAS. I could be wrong -- where they were somehow able to calculate these numbers based on what we had already made public.
Q. Okay. Let's take a look at the next exhibit, Exhibit 739.
MR. COUGHLIN: I'd move for the admission of this exhibit. There's no objection.
THE COURT: Number again?
MR. COUGHLIN: 739.
THE COURT: 739 is admitted.
(Exhibit 739 received.)

BY MR. COUGHLIN:

Q. So this is after the abstract went out and you received this from -- who is Benjamin M. Matone?

A. Ben Matone works for NASDAQ.

Q. And he's letting you know that after the abstract went out and that the placebo was -- that absolute difference was different, that that's the reason that at least the market has a selloff?

A. I believe what he said and you've very nicely highlighted there is that there's a comment on Twitter which says -- may I read this?

Q. Yes.

A. Thank you. There's a comment on Twitter that says that investor expectations for absolute neratinib DFS improvement over --

THE COURT: Hold on. Slow down. When you read, people read fast, and there's some difficult words.

THE WITNESS: I'll restate this.

The Twitter comment is investor expectations for absolute neratinib DFS improvement over PLO was three to four percent, actual delta, 2.3 percent, hence tonight's selloff. So I believe he's referring to a comment on Twitter.

BY MR. COUGHLIN:

Q. That's right, and that difference is the difference

we've been talking about this whole trial, the difference that you had led the market to believe three to four percent versus 2.3 percent, right?

A. We did not lead the market to believe it was three to four percent. We gave the guidance of a range between one and six percent, and both the intent-to-treat population and the centrally confirmed population, both fell within that range.

Q. And the stock was hit with a 32 percent decline; is that correct? Do you remember that, your stock going down 32 percent that night?

A. I don't remember what -- it was -- I'm sorry. It was after-hours trading. So, yeah, I don't remember what it was doing.

MR. COUGHLIN: Now, I'd like to turn to Exhibit 701. There's an objection to this exhibit, Your Honor. I'd like to lay the foundation to have it moved in.

MS. JOHNSON: The objection is hearsay, Your Honor.

MR. COUGHLIN: This is a document in the ordinary course of business that Phil Gross sent to Mr. Auerbach who received this document. Phil Gross's company, Adage Capital, is the second largest shareholder and --

THE COURT: Just a moment. Let's get the document.

MR. COUGHLIN: 701.

THE COURT: Okay. I'm looking at Auerbach exhibit

book. The numbers aren't in order. They start at Exhibit 1034. Shall I go to the 16 volumes, or what else shall I do?

MR. COUGHLIN: That's the -- 1043 is your first exhibit. It's right at the back.

THE COURT: 1034 is my first exhibit.

THE WITNESS: The numbers don't line up.

THE COURT: Are there two volumes of Auerbach?

MR. COUGHLIN: Yes.

THE COURT: Okay. I'm looking in the wrong volume. It's a little difficult because, again, the numbers are not in order. Now I'm looking at the second volume.

MR. FORGE: Your Honor, may I approach with 741?

THE COURT: I'm sorry. I didn't hear you. Would you say that again near a microphone.

MR. FORGE: May I approach to provide you with a copy of 701?

THE COURT: Not if you've given it to me in one of the two books you've provided.

MR. FORGE: I'm sorry. I was just trying to expedite things.

THE COURT: I'm looking in Volume 2 for this witness, and I'm looking for 701?

MR. COUGHLIN: I would go all the way near the back, Your Honor.

THE COURT: All right. I now have 701.

You move its admission. The defense says hearsay. Give me a chance to look at it for a moment.

MR. COUGHLIN: I will, Your Honor.

THE COURT: All right. So I see in the first line a hearsay statement by the declarant, Mr. Gross. Is Mr. Gross going to be a witness subject to cross-examination?

MR. COUGHLIN: No, Your Honor. He was a large shareholder.

THE COURT: Let's just start, then, with that first line and tell me why that's not hearsay and why I shouldn't sustain the objection on hearsay without repeating what it says.

MR. COUGHLIN: Because Mr. Gross was writing in the ordinary course of business to Mr. Alan Auerbach, who received this --

THE COURT: Stop. Step. Let's just break it down. When you say in the ordinary course of business, you're saying this is a business record?

MR. COUGHLIN: I am.

THE COURT: It's not a business record.

MR. COUGHLIN: Okay. Your Honor, I'm not offering it for the truth of the matter asserted because you raised a hearsay objection. I'm offering it for the state of mind that between the largest -- the second largest shareholder in

Puma communicating with the largest shareholder in Puma, both at about 20 percent, okay, talking to them about the market reaction as a result of the release of this ASCO thing and the market selloff.

So these are two of the biggest owners of this company talking about what's happening and why. So it is very relevant. And if Your Honor considers it not a business record, which I think it is and it might even be, you know, an adoption, then it's at least for state of mind.

THE COURT: Hold on. Okay. I want to break it down. You can't just give me an aside and say adoption.

MR. COUGHLIN: Okay.

THE COURT: What is your adoption argument?

MR. COUGHLIN: My adoption argument is that Mr. Auerbach receives this and does not respond to this e-mail. And therefore --

THE COURT: Well, why don't we begin by you just asking this live witness the information you want from this document.

MR. COUGHLIN: Okay.

THE COURT: And we'll see where it goes. It might turn into an impeachment document.

MR. COUGHLIN: Okay.

THE COURT: So for now the objection to the exhibit is sustained.

MR. COUGHLIN: Okay.

BY MR. COUGHLIN:

Q. Mr. Auerbach, did you receive this exhibit from Mr. Gross?

A. Yes, I did.

Q. Okay. And the information contained in it, you read the this e-mail; is that correct?

A. I believe I did, yes.

Q. Okay. And in this e-mail certain of your quotes are quoted; is that correct?

A. Yes. It appears to.

Q. Okay. And the first quote is: We would anticipate --

THE COURT: Hold on. No.

MR. COUGHLIN: Okay. I'll step back.

THE COURT: Just ask him that information.

MR. COUGHLIN: Okay.

BY MR. COUGHLIN:

Q. Did you say at any --

THE COURT: Nope.

BY MR. COUGHLIN:

Q. Okay. Was the diarrhea rate in line of 29 to 30 percent that has been seen in prior studies of neratinib as a mono therapy?

A. We were referring to the first cycle effect. And, yes, in this trial the first cycle effect was roughly 28 percent.

Q. And is the response from Mr. Gross is that diarrhea rate was actually 40 percent?

MS. JOHNSON: Objection, Your Honor.

THE COURT: Sustained.

BY MR. COUGHLIN:

Q. And what was the actual diarrhea rate at this time in August in --

A. In the trial --

THE COURT: Hold on. Don't talk over each other.

BY MR. COUGHLIN:

Q. What was the diarrhea rate that you reported in the ASCO release?

A. It was 39.9 percent.

Q. And then there's some questions about DFS.

THE COURT: Don't refer to the document. Just ask this witness questions.

BY MR. COUGHLIN:

Q. Were you comfortable with the number 86 percent in the placebo arm?

A. I believe the conversation was mid to high 80s, around 86 percent or so.

Q. And the actual rate in the control arm, it was 91.6; is that correct?

A. That is correct.

Q. And as far as the neratinib arm, did you believe that

you could get to that number of 90 to 91 with a 33 percent improvement?

A. Again, the range we were endorsing was mid to high 80s for the placebo arm and 90 to 91 for the neratinib arm. That would be endorsing a range of between one and six percent.

Q. In fact, neratinib was only 2.3 percent; is that correct?

A. That's correct, and that would be within the one to six percent range.

Q. And the actual range for that was 93.9 percent versus 91.6 percent, right?

A. That is correct.

MR. COUGHLIN: I'd still move for the admission for this document.

THE COURT: Any objection?

MS. JOHNSON: Yes, Your Honor. Hearsay.

THE COURT: Sustained.

BY MR. COUGHLIN:

Q. Did you talk to Mr. Gross about the falloff, the dropoff in the stock that night?

A. I believe I spoke with Mr. Gross when the abstract first became public that evening, and I also met with him at the actual ASCO conference.

Q. And he was upset that he felt he had been misled; isn't that correct?

A. That was not the context of our conversation.
Q. But he was upset because he had been misled, and he told you that, right?
A. I do not remember him saying that he was upset because he had been misled. May I expand on that, please?
Q. You can expand on it with your counsel.
You don't remember him being upset?
A. I remember him being upset. I do not remember him being upset about being misled.
Q. Okay. If we flip to the next document, Exhibit Number 221.
MR. COUGHLIN: There's no objection to Exhibit 221, Your Honor.
MS. JOHNSON: No objection.
THE COURT: 221 is admitted.
(Exhibit 221 received.)
BY MR. COUGHLIN:
Q. Do you recognize this as the news release on June 1st for the neratinib study to be presented at the ASCO conference?
A. Yes. That is correct.
Q. And it actually contains the actual numbers to be presented; is that correct?
A. I'm sorry. Can you clarify that question?
Q. It actually contains the absolute differences to be

presented for all of the arms at the ASCO conference; is that correct?

A. Yeah. There's a detailed description of the trial and of both the safety and the efficacy results.

Q. Okay. And that was to be presented on June 1st at ASCO, too; is that correct?

A. As I remember this, this release went out at the exact same time that the data was actually presented at the ASCO meeting in Chicago. So, yes, it was the data that was being presented as this came out.

Q. If we flip over to the next page, Exhibit 1007.

MR. COUGHLIN: I'd move for the admission of 1007, Your Honor.

THE COURT: Any objection?

MS. JOHNSON: No objection.

THE COURT: 1007 is admitted.

(Exhibit 1007 received.)

BY MR. COUGHLIN:

Q. This is an e-mail dated May 18th, 2015, from you to Arlene Chan. I think we already talked about who Dr. Chan was, how she was going to present it. She was the head of the committee presenting ExteNET; is that correct?

A. Yes, that is correct. She was the head of the academic steering committee.

Q. And in the first paragraph, in the middle of the

paragraph, you were talking to her about what slides she was going to present; is that correct?

A. No, that is not correct.

Q. Okay. Well, let's talk about it. It says: Also remember that the grade-three diarrhea rate in ExteNET is extraordinarily high at 40 percent. Do you see that?

A. Yes. There's more context to this. May I discuss that?

Q. Not yet. You can do it with your counsel. I just want to ask you: And you wanted to adjust the slide and put in ongoing studies suggest loperamide prophylaxis significantly reduces incidence in severity, grade-three diarrhea 0 to 17 percent with intensive prophylaxis be put back into the slides. Isn't that what you said?

A. She had originally had that statement in the slides because we wanted -- again, it was important for us to communicate that we had a drug that had efficacy; however, in the ExteNET trial nothing was done to prevent the diarrhea. There was no Imodium prophylaxis as we've been discussing.

Q. Stop there for a second. If I might --

A. Sure.

Q. -- ask you. We know that 84 percent of the patients were on Imodium?

A. After the diarrhea occurred.

Q. From day one?

A. The diarrhea occurs -- it could occur on day one.

Q. So you want to put back into the slides this statement that she had taken out?

A. So initially that statement was in the slides, and Arlene's comment which I respected was that the results of those studies that showed that we could reduce the grade-three diarrhea to 0 to 17 percent was not part of the ExteNET study. She felt she should be more of a purist, if you will, and just present ExteNET data and not present data from other trials in this presentation.

My comment to her was that, you know, the reason that we present these studies at medical conferences is so that doctors can get comfortable using this drug in their patients and know that this drug has efficacy that can prevent this deadly disease from coming back.

But since we knew that there was a way to deliver this to patients in a safer manner, we should be communicating that to doctors to protect the safety of the patients. That was the point I was a hinting to get across here.

Q. And she didn't want to include it because it was not part of the ExteNET study, and she also didn't want to include it because of the size of the patient population in those studies; isn't that correct?

A. I don't remember her being concerned about the size of the studies. I remember that the conversation was she said

she would not put it in the slides but she would just mention it orally in her talk.

My comment to her, which I'm going through in the first few lines up there, is that, number one, often people are distracted, so it's helpful to have it on the screen. But also a lot of times people don't attend the presentation and instead they download the slides later. And if they download the slides later, they wouldn't see that.

Q. And you knew that the population of these different studies was six people, 41 people, 14 people, and 13 people of the four different studies that you're referring to; is that correct?

A. I don't remember if that was the numbers at that time.

Q. Okay.

MR. COUGHLIN: Your Honor, I think this might be a good time to break. I don't have much more, but it would be shorter if we take the break now.

THE COURT: Good timing, sir. It is almost straight up noon. We'll be back at 1:30.

Thank you for your attention. Remember, don't discuss the case. Don't research the case. Keep an open mind. We'll see you at 1:30. Stay dry.

THE CLERK: All rise.

(Open court - jury not present)

THE COURT: All right. See you all at 1:30.

(Recess taken from 12:02 p.m. until 1:33 p.m.)

THE COURT: Let's go on the record.

MR. COUGHLIN: There are four documents that I'd like to use for impeachment. They were in dispute earlier.

THE COURT: Let's cut this short. What do you want me to do right now?

MR. COUGHLIN: I'd like you to look at four documents, and I'd like to use them for impeachment of Mr. Auerbach.

THE COURT: Why don't you just -- why don't we just rule on them as they come in?

MR. COUGHLIN: Okay.

THE COURT: Tell me what the documents are. I'll take a look.

MR. COUGHLIN: I'll hand you a copy because they're not in the book. They're impeachment.

THE COURT: Well, I'm not crazy about that, but we'll have to --

MR. COUGHLIN: I didn't know he was going to say what he said.

THE COURT: All right. Give me the four documents you intend to use for impeachment. Just come around this way. Thank you. Okay.

Actually, let's just have a brief discussion of impeachment. Do you know what these documents are?

MS. JOHNSON: No, Your Honor.

THE COURT: They're not on the exhibit list?

MR. COUGHLIN: Yes, Your Honor. They were in dispute in the Pfizer matter, and they do not reference the dispute. But Mr. Auerbach testified --

THE COURT: I'm not interested in that. They're on the exhibit list I have in front of me?

MR. COUGHLIN: Yes.

THE COURT: And the defense objects to them?

MS. JOHNSON: They were excluded by your motion in limine. I will check specifically, but your motion in limine regarding Pfizer listed out the Pfizer documents and you excluded them.

MR. COUGHLIN: And these four documents have to deal with -- Mr. Auerbach said he had gone in August of 2014 and provided the information to Pfizer, and these four documents indicate that that was not correct, that he had not provided that. They were still asking for that information in September and October.

And in -- actually on the last document, Exhibit 486, Mr. Auerbach states in an e-mail to himself that he prepared to send out if Pfizer had commented that Pfizer has not seen the disease-free survival data.

THE COURT: When do you think you'll get to these?

MR. COUGHLIN: Right now. I'm not going to do any

more. I'm just going to do the impeachment and be done.

THE COURT: Well, then, that's different.

MR. COUGHLIN: Your Honor, I can even do this after. I didn't want to sit down --

THE COURT: After what?

MR. COUGHLIN: After they go. I didn't want to sit down and not have brought this up. Because this is impeachment material, I thought I should bring it up while I'm standing up.

THE COURT: Let's make a ruling on them right now. So it's 480, 481, and --

MR. COUGHLIN: 795 and 486. And I can go over them briefly.

THE COURT: Hold on just a moment. Okay. We're looking at 480.

Now, Ms. Johnson, you said something about these were referenced in the motion in limine?

MS. JOHNSON: I believe that they were, Your Honor.

THE COURT: Okay. What is your objection to 480?

MS. JOHNSON: That it is subject to motion in limine number two.

THE COURT: It references the Pfizer litigation?

MR. COUGHLIN: No.

THE COURT: Where does it -- I'm asking her what her argument is.

MS. JOHNSON: Your Honor, they've redacted specific references to the dispute resolution, but this was my worry earlier when they -- they cannot open the door by asking questions of the witness and back-door in documents around your --

THE COURT: Maybe this has information they're entitled to get in that could be completely independent of Pfizer. You can't exclude harmful information that doesn't reference Pfizer or that you say you will have to reference Pfizer on your own.

I get back to my previous question to you. Why do you have to mention Pfizer? What in 480 are you going to refer to?

MR. COUGHLIN: I'm going to refer to the fact that there was request in September for the tables summarizing the data that was presented, you know, in the ExteNET conference call. They -- Mr. Auerbach testifies earlier this morning that in August 2014, that he had gone to New York and he --

THE COURT: I don't need to get into that much detail.

MR. COUGHLIN: It does not mention --

THE COURT: Where about 480 implicates the motion in limine concerning the Pfizer litigation?

MS. JOHNSON: First of all, it was referenced in the motion. Second of all, it -- you're not -- this is what

I was trying to explain earlier.

THE COURT: No. It's like you didn't get a chance to explain it earlier. I fully understood what you were saying, and I kept asking why you have to implicate Pfizer, and I just never got an answer on that.

So I don't know what more I can say, then. You need to tell me how it implicates Pfizer.

MS. JOHNSON: It's not persuading --

THE COURT: The Pfizer litigation, I should say. Excuse me.

Go ahead.

MS. JOHNSON: At the risk of repeating the arguments, this is such a long story if you don't have context for it. He says they asked for this --

THE COURT: You've said that before, and I keep asking: Why do you need the context of the litigation? I have asked you. Was it withheld because it was privilege? Was it withheld as part of litigation strategy? Was it -- you haven't said any of that.

MS. JOHNSON: Because they were asking for -- within the context of the litigation, they were asking for different types of data, different runs.

THE COURT: But they could have been asking for that for investment purposes or whatever else. Okay. Anything else on 480? I just need something that ties it in

to the Pfizer litigation.

MS. JOHNSON: The context informs what they were asking for, why, when they asked for it, what the resolution was. Mr. Auerbach testified there were lawyers at that meeting. It's all -- to understand what they were asking for and why, and what he provided and why, it necessarily implicates the litigation.

THE COURT: Yeah. I'm not -- that's what I keep asking, and then I don't see that. Would your argument be the same on 481, 486, and 795? Or can you show me specific things that implicates the litigation?

MS. JOHNSON: If you can give us one minute since we just received these.

THE COURT: Sure.

MR. COUGHLIN: I don't believe 481 does have anything about the litigation. I know it doesn't. What it does have is a table stuck to the back with the absolute delta, the key data removed from the middle of the chart on the fourth page.

He says he'd gone in August -- and this is dated September 16th. He says he'd gone in August and shown them that data and even shown them the Bin Yao separating curves data.

THE COURT: Go ahead.

MS. JOHNSON: That is exactly why you need the full

context in order to understand.

THE COURT: I'm not understanding right now. Tell me why you need the full context.

MS. JOHNSON: He's misleading the jury by simplifying the story. He's misleading the jury by --

THE COURT: Let me ask you again. Why do you need to reference the Pfizer litigation to give this context? I've thrown out five different options, and I'm not hearing any of them coming back at me.

MS. JOHNSON: No. That's correct. But if you are in a business negotiation or a request for information and you're under a CDA, that is one context for providing information.

If you're in litigation and there are lawyers on every e-mail, lawyers in every meeting, that is a different context for understanding.

THE COURT: Can't you ask him: Did this request for information have anything to do with investors? No.

You can even ask if you want: Does it have to do with unrelated litigation where there was contentions going on? I think you could ask that if you wanted, and we wouldn't get into the concerns I have about the Pfizer motion in limine.

It wouldn't be accusations against you. It would just be other litigation where lawyers are involved. I would

allow you to get into that if you wanted to explain perhaps he had a level of caution you shouldn't have in responding to investors.

What about that?

MS. JOHNSON: The concern about doing that, it would bring up the exact -- well, one of the issues that we had in bringing the motion in limine in the first place, that there was a dispute. The jury may misunderstand, and Pfizer is not here.

THE COURT: Well, I can only do so much. I bought the trial within a trial, but whenever you have a motion in limine, there's evidence that doesn't go to the trial. It goes to another significant point here.

When I excluded it, it was out of concern about a trial within a trial, and it's not fair to say you are getting -- were you sued by Pfizer?

MS. JOHNSON: No.

THE COURT: Well, then, maybe that motion in limine was wrong. But instead of getting into all of that lawsuit -- that's why I granted the motion in limine, but that has nothing to do with whether he withheld documents that were requested. I think that's an important point that plaintiff should be able to show.

MS. JOHNSON: And I --

THE COURT: And you can't protect your client from

that by saying, oh, it mentions Pfizer.

MS. JOHNSON: I'm actually concerned by Your Honor's question because that is the implication that counsel is trying to raise, that --

THE COURT: What is the implication?

MS. JOHNSON: That Puma withheld information --

THE COURT: Is there any doubt about that?

MS. JOHNSON: There is absolutely doubt.

THE COURT: No, no. Is there any doubt that that's what he wants to do?

MS. JOHNSON: No.

THE COURT: Okay. So my raising the obvious point of why he wants it in, you shouldn't be concerned about that. We all know that's why he wants it in.

MS. JOHNSON: And I'm concerned that the jury will get the misimpression that there was something wrong with what Puma did vis-à-vis Pfizer. That is the subject of the litigation. We would have to litigate that it was an arbitration.

THE COURT: I've been asking over and over and over again, what is your explanation for this that necessarily requires you to get into the litigation?

MS. JOHNSON: If you are -- so this was a dispute resolution process pre-arbitration under the licensing agreement. If a person -- if parties are in a dispute

resolution process, which is basically litigation or pre-litigation, that context explains their interaction. It explains why there might be certain timing of information requests, which this exhibit is, and information provided.

There might explain why you have meetings with lawyers to discuss the exchange of information rather than just providing what one has. That explains the sequence here and the timing, and it explains that there in fact was not any withholding of information, at least not any improper holding of information, which is the implication counsel seeks to bring out.

THE COURT: I think you can do all of that without asking questions that implicate the concerns I had in granting your motion in limine. Were you in litigation? Yes. Were there lawyers involved? Yes. You can ask those questions. The concerns I had about the motion in limine are just not implicated.

I mean, I suggested what plaintiff is trying to do. It's possible defense wants to say Pfizer and let bad stuff out that aren't going to implicate Pfizer or the Pfizer arbitration.

MS. JOHNSON: And I guess my concern is if I don't explain what was going on in the litigation, documents will be taken out of context by the jury to suggest that something was withheld or going on or wrong.

THE COURT: Tell me why it wasn't wrong? I mean, that's the core issue. Why wasn't it wrong?

MS. JOHNSON: Because it wasn't wrongfully withheld.

THE COURT: Tell me why it wasn't wrongfully withheld.

MS. JOHNSON: Because it was part of the dispute resolution process provided for by the licensing agreement that they would go through this process --

THE COURT: And that allowed them to withhold documents in response to requests? I don't understand.

MS. JOHNSON: That's what I would I have to --

THE COURT: That's what I'm asking you.

MS. JOHNSON: I would have to put on witnesses to say no.

THE COURT: Well, you haven't even told me that yet. I mean, if you told -- I suggested to you five different arguments, and you haven't taken up any of them.

MS. JOHNSON: Correct.

THE COURT: What would you say? I'm still asking. Why weren't these documents produced?

MS. JOHNSON: There were many documents produced. What was produced was what was required.

THE COURT: You're staying these documents weren't required?

MS. JOHNSON: Correct.

THE COURT: What do you say to that?

MR. COUGHLIN: That's absolute hogwash.

THE COURT: I'm not -- why weren't they required?

MS. JOHNSON: Of course he would say hogwash because we --

THE COURT: Why weren't they required?

MS. JOHNSON: Because the license agreement required certain things. Those certain things were provided. Then Pfizer asked for different things. There was a dispute about whether they were entitled to those things under the license agreement.

If I could lay out that whole story, the jury would see, hear at the end when Pfizer is asking for things that under the license agreement, those things were not required to be provided to Pfizer.

THE COURT: This is the closest you've come to answering the question I've been asking since this morning.

Go ahead. Did you want to have a conversation, or what did you want to do?

MR. CLUBOK: I'm sorry, Your Honor.

THE COURT: You can speak.

MR. CLUBOK: I appreciate it. I think the trouble here is that there is no duty to provide Pfizer any documents except what they're entitled to under the contract. If we

are -- if we are able to provide the whole story if we're required to to rebut the false implication that they withheld something improperly, we would show that everything that was required to be produced under the agreement was produced.

There was a dispute over what they were entitled to. That dispute gets resolved. Pfizer doesn't sue. So we can tell them, you know, that Pfizer originally complained that they weren't getting what they were entitled to, but here they ended up getting it.

Mr. Coughlin will say, oh, that's hogwash. Pfizer didn't get what they were entitled to. Now we will put on a witness from Pfizer to show that they did get what they were entitled to.

And by the way, there was Ropes & Gray involved. There was Latham & Watkins --

THE COURT: I don't know how that helps.

MR. CLUBOK: Because there's lots of lawyers involved. So which of the witnesses will we be induced to call to prove that at the end of the day -- I mean, the proof is in the pudding that Pfizer did not sue. You could argue that.

But to tell the whole story -- and by the way, to explain why there's some negative comments in these documents, it's not because they're true. It's because Pfizer started this off by having an aggressive position

because their CEO was surprised at a conference call about how good the results were, not about how bad they were.

So Pfizer then says, well, gee, we want to see this data. And they threatened litigation. That's why the lawyers get involved. That's why people are super careful about what's provided.

They ultimately do provide everything that's required, but misleadingly. A snippet of this makes it seem like they're not because they take this document that Pfizer is writing in a litigation context like lawyers often do when they say you're not giving me what I'm entitled to.

Then the two sides either, you know, go to a judge or an arbitrator to prove that they're not, or they resolve it. So this whole story we're being sucked into responding to, that's the trial within the trial.

Ultimately there is no lawsuit. Pfizer doesn't make a claim --

THE COURT: I got it. I'm not there.

What's your response to what we just heard?

MR. COUGHLIN: This has nothing to do with what Pfizer was required to give over or get or anything else like that, or what Mr. Auerbach was required to send over or not. Okay?

Our assertion here is that he didn't send Pfizer the true data. He sent them simulations because he didn't

want anybody to know that he had lied on that conference call. He says here -- wholly apart from any Pfizer dispute, he says here this morning that: In August of 2014, I flew to New York and I provided them two things. I provided them the real data. He says that. He also provided them with the curves going out that we talked about Bin Yao. These documents show that Pfizer a month later had not gotten that data and were asking for it.

So it shows that what he said this morning, wholly apart from any Pfizer litigation or any long, lengthy explanation, that what he did was he deleted key tables. He said he showed them the real data.

Why would you delete the key efficacy table if you had shown them the real data in August when you flew to New York? Why in September would you do that? Just the same reason he did it with the FDA stuff. He's hiding it -- could I finish? He's hiding it from the market.

Okay. He's hiding it from other people like Pfizer. He's keeping this data only to himself because he doesn't want it out there. And this -- and he lied about it this morning, okay, because he didn't show them this data, and they kept asking for it. He said he did it in August.

That's ripe -- that's all ripe for us to impeach him now with this document -- wholly and apart from anything else that might have happened with Pfizer.

THE COURT: Response?

MR. CLUBOK: If I may, Your Honor, he didn't say that. What he said was they agreed at that meeting that they would get -- they agreed either at that meeting -- I can't remember if it was at that meeting or as a follow-up call -- that they would get the simulation curves, which they sent.

I'm sorry, Your Honor.

MR. COUGHLIN: I have it right here, Your Honor. In August of 2014, he says he flew to New York to share with them this data. Okay. And they requested had requested certain things. Okay.

I asked: Okay. Did you show them the real data that you had left, the data that you had seen, you know, in the July snapshot, the data relying on the conference call, that you relied on in the conference call? I brought it back to the conference call.

And he says: I believe we had shown that to him. Okay. As I recall, we had shown them the data with the caveat that the patient numbers were dropping off. Now he's talking about the three-year Bin Yao curve. Okay. Very dramatically, my recollection of this is we were in a face-to-face meeting. We showed them the data where the patient numbers were dropping off quite dramatically. We went out two years, three years, et cetera.

Then had mentioned to them we were doing the

simulations as well, and this is what they requested. They wanted simulations. They didn't want to see the real data? Answer: We had shown them the real data. And that is absolutely false in these request documents, because they -- they attached the data he shows them. He sends them back the false data and he cuts out the key data.

MR. CLUBOK: Your Honor, the questions were incredibly confusing. But cut through all of that, what Mr. Auerbach would testify to is that the data set that he had available to him in July of 2012 [sic] was the data from which he talked on the conference call about the preliminary data. That's what he was talking about. Point one.

Point two, the data from which these simulated curves that were sent to Pfizer comes from is that same data set informed by a few additional months.

Point three -- can you turn that off for one second?

THE COURT: That's not going to help.

MR. CLUBOK: It's okay. Your Honor, I'm sorry. The flashing light distracted me from the most important point. If you would give me a second -- but that's a good technique.

Let me think for one second where I was in the middle of it. Plaintiffs' counsel in the midst of all this has repeatedly represented that they don't have this same

data set. All of this is an ultimate sideshow because this exact data set that both what Mr. Auerbach told the people in the conference call on July 22nd about and that these simulated curves were from and the curves we've done now, it all comes from the exact same data set that was provided to plaintiffs over a year ago.

So this whole thing has become impossibly incomprehensible on an issue that is designed to confuse the jury as --

THE COURT: You have not -- I didn't hear you mention the Pfizer litigation.

MR. CLUBOK: Oh, sorry. I apologize.

THE COURT: Hold on. I thought you were finished. Now you seem to be making other arguments, and I just have a compartmentalizing mind here. So I'm going to give you a little more time to make any additional arguments and then I'm going to rule.

Go ahead.

MR. CLUBOK: There was a dispute resolution pre-litigation -- at least they called it litigation process -- where Pfizer suggested that they -- they had suggested and in the course of that exchange were suggesting that they were not getting information, as if Mr. Auerbach was hiding.

There was a dispute resolution process that Puma

successfully demonstrated to Pfizer that it had given it all of the data that it was entitled to under the license agreement. By the way, the claim in that litigation was that the data was so good and that's why it was being, quote, hidden. So they're claiming it's being hidden inappropriately. It's not.

THE COURT: That's why we have --

MR. CLUBOK: Understood, but --

THE COURT: Let me finish. Gosh, I'm listening a lot and I'm only talking a very little bit here. That's why you get a chance to ask questions on direct or whatever we call it.

MR. CLUBOK: That's right.

THE COURT: You get to clear it up that way. They get to raise implications on the evidence before them and you get to refute the implications.

MR. CLUBOK: You're right. But Your Honor had previously said when they raised these implications, don't you think that we're going to have to respond? And once we start telling the story, we tell a little bit more about the story, like a meeting, that then causes them to say, well, now we have to rebut what he said about that. Then we have to rebut what they said about that.

Now we're litigating over what was happening in the Pfizer litigation, exactly what Your Honor was worried or

anticipated would happen.

THE COURT: No.

All right. I'm ready to rule. You don't have to implicate the Pfizer litigation. You can talk about -- let me start from the beginning.

I think plaintiff obviously is making a case about withheld documents, not surprisingly. It's not earth shaking. Is that what you're doing?

MR. COUGHLIN: I am, Your Honor.

THE COURT: Yeah. I think that is part of your theory of the case, and I think there's been a lot of mourning on that. I think you're allowed to present evidence that supports that theory. I think the defense is allowed to refute that evidence. And I believe the defense can do all their refuting without mentioning the fact of this Pfizer litigation.

I've suggested to you you can say, and the witness is here and he's listening, you can say that was part of a dispute and everyone came away from that dispute happy. You can say that.

MR. CLUBOK: And may I just ask about one -- we've talked about several of the documents. Can I raise a specific issue?

THE COURT: Well, it's a little late to be raising a specific issue because we've been at this for 25 minutes.

You'll note my modus operandi is to identify the issues and address them, not let the issues move on to others.

Go ahead.

MR. CLUBOK: I appreciate that. Exhibit 486 is a draft e-mail that Mr. Auerbach is writing to himself in the course of this litigation to explain what he's doing here would require -- he's at the time working with attorneys. He's preparing drafts internally, and --

THE COURT: Your objection?

MR. CLUBOK: -- this never gets publicly disclosed to anyone. This certainly is the kind of thing that to explain it, I do think we would have to explain why he's writing it and what it means. And it's going to seem suspicious when it's not, particularly since it never goes anywhere outside of his draft folder.

THE COURT: Okay. So your objection to 486 is on what grounds?

MR. CLUBOK: On the grounds that -- first of all, this was specific --

THE COURT: Let me ask again. Your objection to 486 on what grounds?

MR. CLUBOK: 403, 402, relevance, the prejudicial value.

THE COURT: You said 402.

MR. CLUBOK: Relevance, and that it would require

us to bring in issues unrelated to the case in order to have a chance to properly rebut the false implication that they want to use this document for.

THE COURT: Okay. Let me read it to myself.

(Court reading document)

THE COURT: We have four documents in front of us. I do think 486 from what has been presented to me gets the closest to the concerns that have been presented. I think I said to Ms. Johnson this is an issue of strategy for the litigation, et cetera. This e-mail sort of looks like issues of strategy and what they're doing.

MR. COUGHLIN: I would -- I would propose, Your Honor, if you feel that way, because this goes right to the heart of it, he says Pfizer has not seen the disease-free survival data, nor has Pfizer seen the Kaplan-Meier curves for the ExteNET trial. I would take off the next two sentences and delete anything about legal. It just has to do with that he made a representation --

THE COURT: Very good point. Thank you. That sentence doesn't necessarily -- in fact, it doesn't seem to implicate what I had concerns about.

So 486 as presently stated is the objection is sustained. If you want to ask the witness: As of October 27th, 2014, had Pfizer seen the disease-free survival rate? You know, just ask that question without even

referencing this document.

MR. COUGHLIN: Got it, Your Honor.

THE COURT: And if he disagrees with that, I think you've got some effective impeachment with that sentence.

MR. COUGHLIN: Got it.

THE COURT: That's what we need to do. So 486, for now the objection is sustained.

MR. CLUBOK: Your Honor, because I knew you were reading and I didn't want to say anything, but let me add. This was created definitely in anticipation of litigation.

THE COURT: Say again.

MR. CLUBOK: This was also -- it's part of the litigation process. He's anticipating what they're going to say and helping form his legal strategy, even the first two sentences. I wanted to say that for the record.

THE COURT: Yes. Understood. That's why 486 is excluded. Perhaps it could come up as an impeachment.

Are we then prepared to proceed?

Let's call the jury in, Ms. Bredahl.

THE CLERK: All rise.

(Open court - jury present)

THE COURT: Welcome back, folks.

Again, we've been dealing with some issues outside your presence so this will proceed more smoothly.

You may continue with your examination.

MR. COUGHLIN: Thank you.

BY MR. COUGHLIN:

Q. Good afternoon, Mr. Auerbach.

A. Good afternoon.

Q. This morning we were talking about some documents that you had sent to licensor, Pfizer; is that correct?

A. That is correct.

Q. You said you had gone in August of 2014 to meet with Pfizer in New York, Mr. Vatnak; is that correct?

A. Correct.

Q. And that you provided Mr. Vatnak with the real data that you had presented on June 22nd, 2014, on the analyst call. And that you had also provided him with the curves going out, the Bin Yao simulation -- the Ben Yao curves going out, not the simulation curves; is that correct?

A. That is what I said this morning, yes.

Q. Okay. Let me show you what has been marked as document, Exhibit 480. Do you see that document?

A. Yes, I do.

Q. Do you see that it is referencing a discussion in August -- I mean, in September 12, 2014?

A. Correct.

Q. And there's a request. There's a request for documents; is that correct?

A. Yes, a very extensive request.

MR. COUGHLIN: I'd move for Exhibit 480 to come in, Your Honor.

THE COURT: Over objection 480 is admitted.

(Exhibit 480 received.)

BY MR. COUGHLIN:

Q. And in that request Pfizer is requesting table -- if you go down to the baseline data and the primary efficacy analysis, do you see that on the second page, page 2 of 4?

A. Yes.

Q. Pfizer is requesting that information; is that correct?

A. That would be correct.

Q. And that's -- and earlier you testified that you had already provided that information in August of 2014; is that correct?

A. We had shown -- my recollection of this is that in the August 2014 meeting, we had shown this to them, but we didn't leave them with any formal copy of it. We didn't give them any hard copy of it. This appears to be a very extensive list of requests from them for data analyses that includes what we had shown to them but more than that.

Q. Okay. You said -- and you believe you had shown them the efficacy tables; is that correct?

A. That was my recollection, yes.

Q. Okay. I'd ask you to turn to Exhibit 481, and I'd ask you to flip in to page 6 of 7. Now, this is an efficacy end

point summary chart. Do you recognize it?
A. Yes, I do.
Q. And it takes out the Kaplan-Meier rates. Do you see that?
A. I don't remember if they had -- in between all of these e-mails documentations, I seem to remember calls with them because, as I recollect, they had sent us this huge list of things they wanted.

We had asked them -- which were kind of the high points they wanted because this was, you know, quite a lot of work to get done. I seem to remember them kind of triaging this, if you will, in terms of here's what we really need right now and you can get us the rest later.

I seem to remember this table was high on that list, which is why it's likely being provided.
Q. Let's take a look at Exhibit, I believe it's, 123. It's already been admitted into evidence. Let's go into the table. Find 123. Let's go into the efficacy charts.

Let's go in to page, if we might, page 8 of 35.
A. I apologize. I don't have that exhibit in front of me. Can you please provide it?
Q. We're going to show it on the screen.
A. Okay.
Q. Do you see that table there?
A. Yes.

Q. Okay. That is the table that you were given on July 17, 2014; is that correct?
A. Correct.
Q. Okay. And now let's go back to -- and that has -- that has the KM rates where you can figure out the absolute delta of 2.3 percent; is that correct?
A. That's correct.
Q. Okay. Let's go back to Exhibit 481, page 6.
In this document those -- that -- those KM rates, those rates in the absolute delta table are cut out. Do you see that?
A. Yes, correct.
Q. You're saying that's what Pfizer wanted?
A. In between these calls -- so you'll notice on the e-mail from --
Q. Could you just answer that question, Mr. Auerbach. Then you can explain with your counsel if you want to go through this document. I just asked that question. Is that what Pfizer wanted? Yes or no?
A. So what was communicated to me when we had said to them, you sent us this long list, can we triage this so we can kind of get to the stuff you want right now, right away, this was what they had said they wanted.
Q. They wanted you to cut a table out --
A. Communications were between the various parties, as you

can see on the screen, including our attorneys at Latham, and this is how it was communicated to me. So this is what we sent.

Q. Okay. Let's go to the next, document 795.

Mr. Auerbach, before get to that document, if you presented all this documentation to them in August 2014, why are you cutting out certain information in September and October?

A. Again, what we presented to them was a presentation, right, where we showed it to them. We didn't leave them an actual physical copy of it. When they sent us this list, my assumption was they wanted an actual physical copy of it, which, I understand that request.

The list was extremely long, and obviously we had just gotten phase III data, so we were excited to go start moving this toward FDA approval. So we had just asked them, listen, we're short-staffed. What do you -- can we triage this? Can you tell me what is the highest propriety things you want and what are the lower priority things so we can get this to you in a timely fashion.

Q. And let me stop you. So it was quicker to cut a table, to have somebody actually cut a table out of results, topline results that you received, and send it to Pfizer? That was more efficient?

A. That is what was communicated to me that they wanted to

see.
Q. Weren't you keeping it from them because you couldn't tell anybody outside your company what the real results were? Isn't that the reason you cut that table out?
A. That is absolutely not the reason that that table is not in that document. We were more than happy to provide that data --
Q. Mr. Auerbach, let's go on --
THE COURT: Just a moment. Here under the circumstances I'm going to let you finish your answer.
Go ahead.
THE WITNESS: We were more than happy to provide that data to numerous breast cancer physicians, to the FDA, and to other parties who asked for it. There is -- I'm not aware of anyone who asked for that data who was under confidentiality agreement that we did not show that data to.
BY MR. COUGHLIN:
Q. Well, you didn't show it to Mr. Hicks when you sent him the FDA data; did you?
A. We did show it to him in a meeting in January of 2015, which I believe he has testified he saw. And I believe the underwriters have also said, testified that he saw.
Q. I think that you're misquoting that testimony, but we're going to hear that testimony about what he remembers seeing then. Okay? Let's go next to Exhibit Number 795.

Mr. Auerbach, you testified this morning that you had shown them curves, the Bin Yao curve simulation, the real data, going out from two to three years. Do you remember that testimony this morning?

A. We had shown them the preliminary curves.

Q. Okay. And then this is a document dated September 17, 2014. Okay. And they have three bullet point requests. It says: In response to a question from Mr. Werber, Dr. Werber, that we heard on the conference call regarding DFS rates, Alan implied that he knew the DFS rates of the active and control arms.

You said you had given them that data in August, and here they are wondering about that data in September; is that correct?

A. We had shown them the data. We did not leave them a physical copy. I interpreted this when we got this that they just wanted to have a physical copy of it.

Q. Okay. Next question. In response to a question by Howard Liang regarding long-term follow-up, Alan implied knowledge of DFS rates beyond two years and alluded to continued separation of curves; is that correct?

A. Again, this had been shown to them. My interpretation of this is they were asking for a physical copy of it.

Q. And you say you already had shown them a copy, and they were just asking -- this is them asking for a physical copy

saying that you had implied knowledge of this beyond.
A. Well --
Q. Doesn't this indicate that they had never seen anything like that?
A. I don't think that implies that at all. The people who we met with were only two of the members of Pfizer on this list. You have, it looks like, five or six, so this may be one of the five or six who were not at that meeting requesting that.
Q. You can explain with your counsel. In the final bullet point in response to a follow-up question by Howard Liang regarding subgroup analysis, something we went over extensive this morning, Alan implied knowledge of efficacy in prospectively defined subgroups and that a number of those subgroups were extremely differentiating.

Is it your testimony that you had already shown them that and they wanted a hard copy?
A. My recollection of this is that we had shown them this but they were asking for more information on it.
Q. Thank you. No more further questions, Your Honor.

THE COURT: All right. Thank you, counsel.

MS. JOHNSON: Thank you, Your Honor.

MR. COUGHLIN: I meant to move all these into evidence, Your Honor, those three documents.

THE COURT: I'm afraid you can't just say all these

three.

MR. COUGHLIN: I'm Sorry?

THE COURT: I think you did move them into evidence.

MR. COUGHLIN: I thought I had.

THE COURT: Let's just confirm it. Document what?

MR. COUGHLIN: 480 I know I did.

THE COURT: That's in.

MR. COUGHLIN: Exhibit 795.

THE COURT: I think you might not have done that.

MR. COUGHLIN: And Exhibit --

THE COURT: Just a moment. It's also good to let the jury know that they're going to see it.

MR. COUGHLIN: Yes.

THE COURT: All right. Next was what?

MR. COUGHLIN: 481.

THE COURT: No. You said seven something.

MR. COUGHLIN: 795.

THE COURT: 795 you didn't mention. Now you did. And what's last?

MR. COUGHLIN: 481.

THE COURT: Okay. That's in. Go ahead.

(Exhibits 481 and 795 received.)

MR. COUGHLIN: Thank you.

MS. JOHNSON: Can we approach with the witness

binder?

THE COURT: Please.

Ms. Johnson, looking at various estimates, I believe you will take this witness to the end of the day?

MS. JOHNSON: I expect so, yes.

THE COURT: Yes, I think so. Just letting the jury know and the others know. And he'll be back with us on Tuesday, correct?

MS. JOHNSON: Correct.

THE COURT: Okay.

CROSS-EXAMINATION

BY MS. JOHNSON:

Q. Good afternoon, Mr. Auerbach.

A. Good afternoon.

Q. You were asked quite a few questions that you wanted to expound on and follow up on, and we'll do that and I'll ask you about those.

I wanted to start by perhaps asking you to back up and introduce a bit about yourself, starting with what did you found Puma in order to accomplish?

A. The goal of Puma when I founded it is the same as the goal of my prior company, Cougar, that it's very simply to help cancer patients.

Q. Why was that mission important to you?

A. So I don't know if we discussed this earlier, but I'm

actually a former Wall Street analyst. I was a biotech analyst on Wall Street for six years specifically dealing with small and mid-size companies who develop drugs for the treatment of cancer.

Unfortunately in 2002 my father was diagnosed with terminal cancer, and I made the conscious decision to stop being an analyst and to do something to help cancer patients, and more specifically to help their families. It was devastating what occurred in my family with the loss of my father, and I wanted to do everything I could to help the cancer patients and to help their families.

So in 2003 I founded my first company, Cougar Biotechnology. We developed the drug Abiraterone, now known as Zytiga, which ended up being the drug in prostate cancer showing the greatest survival benefit ever in the history of prostate cancer.

When that was done, I wanted to relive that experience, and so Puma was founded immediately after the completion of Cougar.

Q. All right. A couple of questions leading up to Cougar. Where did you grow up?

A. I'm born and raised in Chicago.

Q. Did you go to college?

A. Yeah. I have an undergraduate degree from Boston University.

Q. How did you pay for Boston University?
A. I was fortunate to receive many scholarships, fellowships, grants, et cetera.
Q. Did you go to graduate school?
A. Yes. I received a -- my bachelor's degree was in biomedical engineering. USC gave me a fellowship which was full tuition, et cetera, where I received my master's degree in biomedical engineering.
Q. And what was your first job after you graduated?
A. I worked for a company in Los Angeles known as Diagnostic Products Corporation, also known as DPC. They're a diagnostics company. More specifically, they make blood tests for the treatment of cancer. And I ran the clinical trials of all of those cancer diagnostics.
Q. And then what was your next job after that?
A. I then went to Wall Street and became a Wall Street analyst where I worked with small and mid-size companies developing treatments for cancer.
Q. And through those two work experiences, did you gain experience with clinical trials for oncology products?
A. Yes, absolutely. We were running clinical trials when I was at DPC. Then when I was a Wall Street analyst, all of the companies that I dealt with were developing drugs for the treatment of cancer. So were analyzing those trials, and I was there working with the companies that did.

Q. Then you've explained a little bit about this already. Can you please slowly explain to the jury how you came to found Cougar.

A. So when my father was diagnosed with cancer in 2002, it was unfortunately extremely advanced, and unfortunately my family and I recognized we were going to lose him. And I started to realize that there was a lot of companies that were developing drugs that for whatever reason they either internally determined that they didn't have the money for, perhaps they had changed their priorities. But for whatever reason, they abandoned these programs.

I became very angry with that because I realized that these were drugs that possibly could keep my dad alive, and they weren't being developed. So they were just sitting on the shelves.

So I had the idea to go to these companies and see if they would sell the rights to them or license the rights to them to an entrepreneur like myself where we could then take the drugs, take them off the shelves and start to develop them and help the cancer patients and their families.

That was how Cougar was founded, and the first drug that we actually bought, which was Abiraterone, as I mentioned, had previously been developed by a company in the United Kingdom. The company is called BTG -- B as in boy, T as in Tom, G as in Gail. And that stands for British

Technology Group.

They had developed the drug Abiraterone, and it was sitting on a shelf for about three and a half years. I found it through the medical literature and through talking to doctors. I bought the rights to it. I was in the UK, so we brought it here to Los Angeles.

We built the company from there, and I'm very, very proud of the fact that it has had a pronounced effect in the lives of prostate cancer patients.

Q. Briefly on Cougar, did you raise money to start Cougar for the purposes that you've told us about?

A. Yes, we did. When I decided to leave my career as an analyst, I went to all the investors who I had built relationships with and told them exactly what I was going to do.

They liked the idea. They thought it was a very innovative idea. And when I bought the drug, they found the technology to be very intriguing. So when I first acquired the asset, we raised money around that, and then we raised money over the course of the company as well.

Q. And what did you do with that money? What did you do to develop Abiraterone?

A. All the money we raised was put forward just for running the clinical trials and doing the research to bring the drug to the market for cancer patients. So in the history of the

company I think we raised somewhere in the neighborhood of $200 million, I believe, and all of that was put forward just for developing that drug for cancer patients.

Q. And then what happened with Cougar and its drug product?

A. While we were in the middle of doing clinical trials, we got approached by the large pharmaceutical company Johnson & Johnson. Johnson & Johnson had an interest in building out their cancer portfolio. They did not have very much at the time, but they were interested in doing so.

And we as a small company, at that point we were in phase III, and I believe we had two very large phase IIIs that were running, and we had to start moving toward building up our manufacturing facilities, building out our sales and marketing force, and the costs were starting to get, you know, quite large.

Also the amount of, you know, people we would have to hire would get quite large as well. So when Johnson & Johnson approached us, they had approached us with the idea of them acquiring the company. They obviously have a lot more resources. They have huge manufacturing facilities, so it was very easy for them to do this.

Again, my goal was do what is best for the cancer patients and to put the drug in the hands of someone who is much more experienced, has much more capital, and can certainly guarantee that this drug gets to the patients as

quick as possible. It made a lot of sense. So Johnson & Johnson ended up acquiring the company in, I believe it was, somewhere around July of 2009.

Q. Did you stay on with Cougar after the acquisition by Johnson & Johnson?

A. Yes. After Johnson & Johnson acquired Cougar, they had asked me to stay on because, you know, these people are my family. My employees are my family, and I wanted to make sure they were all taken care of.

In the contract with Johnson & Johnson, I put a stipulation in there that they could not terminate any Cougar employee I believe it was somewhere in the range of two to three years.

And I stayed with the company for six months to make sure the employees were okay. I wanted to make sure they all saw me there every day and that nobody was negatively impacted. So I ended up staying until January of 2010.

I left on a Friday, and by that next Monday I was already talking to investors about starting Puma.

Q. Did Abiraterone end up getting FDA approval?

A. Yes, it did. It is now called Zytiga, and it is spelled Z-y-t-i-g-a. It has been available to prostate cancer patients since approximately 2011.

MR. COUGHLIN: Your Honor, I think we're going

pretty far afield here for relevance.

THE COURT: Yes. I -- it's a timed trial, so I provide some leeway. How much more on -- before we get to the merits?

MS. JOHNSON: That was my last question on Cougar.

THE COURT: Well, not just Cougar.

MS. JOHNSON: And on Puma, now we're going to turn to the development of neratinib.

THE COURT: Proceed.

BY MS. JOHNSON:

Q. After you sold Cougar, you came to found Puma. Did you raise money from investors to start trials on neratinib?

A. Yes, we did.

Q. And how did you go about doing that?

A. After Cougar had been acquired, I had gone to all the investors and that them that I loved everything about this experience and I loved what I had done taking, you know, drugs that had been sitting on a shelf and taking that and translating that into something that was great for patients.

I told them I wanted to do it again, and they were all very eager for me to do that again. So once I obtained the rights to neratinib, I went back to the exact same investors and raised money again to start Puma.

Q. How many people does Puma employ currently?

A. Somewhere between 300 and 350.

Q. And how many of those employees are in California?
A. The large majority are in California. Our field force obviously is out in the field. The in-house people are pretty much evenly split between Northern California and Southern California.
Q. And quickly, can you describe what neratinib looks like physically for the jury?
A. Sure. Neratinib is an oral pill. It's a very small pill that is taken by mouth once a day by the patient.
Q. And briefly, how does neratinib work to prevent breast cancer in HER2-positive patients?
A. So in patients who have HER2-positive breast cancer, which means that they have the HER2 gene, the cancer cell will have a part that is outside the cell and a part that's inside the cell.

You heard a lot earlier about a drug called Herceptin. Herceptin works by binding to the outside of the cell. Now, unfortunately cancer is very smart, and when you block it one way, it finds another way to go. So usually when you block cancer on the outside, it returns on the -- it relies on the internal mechanism to keep itself growing.

Neratinib hits that internal mechanism, and more specifically an area called the tyrosine kinase, which is what neratinib binds to.
Q. I'd like to jump right into questions you were asked

about breakthrough designation for neratinib.
A. Yes.
Q. Do you recall that line of questioning?
A. Yes, I do.
Q. If you still have the plaintiffs' binders in front of you, would you turn to Exhibit 1014. It's in the second binder, I believe.
A. Yes.
Q. And you were asked questions about preparing to submit a breakthrough request designation to the FDA for a meeting that you had with the FDA?
A. That is correct.
MS. JOHNSON: If we could put up 1014, Exhibit 1014.
BY MS. JOHNSON:
Q. Anyway, so plaintiffs showed this to you in your questioning. The exhibit says in its second paragraph: That way, if you're able to schedule an informal teleconference with Puma, the call can be coordinated.
Is this a document that was submitted to the FDA by Puma in advance of a teleconference meeting with the FDA?
A. That is correct.
Q. And did you participate in that meeting?
A. Yes, I did.
Q. What happened at the meeting?

A. So during the meeting for the breakthrough designation -- again, this was an informal meeting for us to determine whether or not we should or should not file for breakthrough designation.

What the FDA discussed with us was that the breakthrough designation was meant as a way for earlier stage companies to leapfrog the process and get approval earlier. So as I was referring to earlier, typically when you run clinical trials, there are three phases of clinical trials.

There is phase I, which is where you get your initial safety data. There is phase II, where you will start to get initial efficacy data. Then phase III, which is the large randomized trials where you will do a head-to-head against whatever the standard of care is for your disease.

The breakthrough designation was a way for the companies who had completed phase II to jump ahead to approval before running their entire phase III program.

So what was explained to us was they tended to want companies who were after phase II but before phase III, so they didn't feel it was appropriate for us. And they also mentioned to us that if a company had done a phase II adjuvant study like what we had done in a phase III, the bar they would have typically liked to have seen for the breakthrough designation to allow them to leapfrog phase III would have been a hazard ratio of 0.50, so a 50 percent

improvement.

Ours was a hazard ratio of 0.67, so a 33 percent improvement, so it was a little bit below the bar they had wanted to see. But they were also very clear with us that they encouraged us to file the NDA, which was the application for the approval of the drug.

Q. Does whether a drug receives breakthrough treatment have any impact on whether it is ultimately approved?

A. No, it does not. We've actually seen a number of drugs with phase II data that obtained breakthrough designation that actually failed their phase III trials.

So again, I commend the desire to have a way to fast-track these drugs to the market like this and leapfrog, but there has unfortunately been a very high failure rate of the drugs that have received this breakthrough designation.

Q. Did Puma end up filing a formal application with the FDA for breakthrough designation?

A. No, we did not.

Q. Why not?

A. It didn't appear to be a path that was going to result in the drug getting to the market any earlier, and the commentary from the FDA was just go right to your NDA.

Q. You testified earlier about breakthrough therapy being for phase II drugs --

A. Uh-huh. Correct.

Q. -- and you talked about the FDA's guidance on that point. We've marked for identification purposes Exhibit 987 at the front of the binder.

MS. JOHNSON: I'm reminded that 1014 is not in evidence, so I'd move 1014 into evidence if there's no objection.

THE COURT: Without objection 1014 is admitted.

(Exhibit 1014 received)

BY MS. JOHNSON:

Q. And 987 marked for identification is guidance for industry expedited programs for serious conditions, drugs, and biologics.

THE COURT: 987?

MS. JOHNSON: 987.

THE COURT: I don't have that on my list.

MS. JOHNSON: You don't because it was brought up by testimony, and we wanted --

THE COURT: Is there any objection to 987?

MR. COUGHLIN: No, Your Honor.

THE COURT: 987 is admitted.

(Exhibit 987 received.)

THE COURT: Again, counsel needs to assure we are accurate in our identification, particularly since this isn't on my list.

Go ahead.

MS. JOHNSON: We will do so, Your Honor.

Thank you.

So if you could put up 987.

BY MS. JOHNSON:

Q. Again, it's guidance for industry, and if you could turn to page 8. This is page 8 of that guidance document. At the top of that page the line -- it's a chart, and it says when to submit request. Do you see that?

A. Yes.

Q. And then under the column for breakthrough therapy, what does it say about when to submit a breakthrough therapy request?

A. It says in the highlighted right there on the right, the far right right there: Ideally no later than end of phase II meeting. So exactly as I was mentioning this morning, they would ideally like you to file for breakthrough designation after you've completed phase II and before you have started your phase III trial.

Q. The first bullet point says with IND. What does that refer to?

A. Your IND is the first application you're asking the FDA to start human trials. So that's before you've ever tested the drug in humans.

Q. How an IND already been filed for neratinib?

A. Yes, back in 2003.

Q. And had neratinib already proceeded through the end of phase II meeting?
A. Yes. That had occurred in 2008, I believe.
Q. So for a phase III drug what, if any, implication would achieving breakthrough therapy have on your FDA approval process?
A. Well, according to this, they want you to talk to them before you start your phase II, so it's not clear. I mean, you can see on the screen here there's a lot of different columns -- fast track, accelerated approval, priority review. Those are more of the paths you would take post your phase III data.
Q. All right. Mr. Coughlin showed you notes from Judy Segal. You mentioned you hadn't seen those before. I wanted to put those up again and ask you some questions about it. It's Exhibit 460. And he directed your attention to page 438.

MS. JOHNSON: And, Your Honor, before we get there, I'd like to move Exhibit 987 into evidence.

MR. COUGHLIN: No objection.

THE COURT: I thought we already did. It's in evidence.

MS. JOHNSON: All right. Thank you. Just making sure.

BY MS. JOHNSON:
Q. All right. Is this -- go down to the bottom. We talked about the first little paragraph there that spans the two pages, and then you pointed out the other paragraph that says, does not have implications on NDA. What's an NDA?
A. So an NDA is the formal FDA application where you ask them to approve your drug based on the data from your clinical trial. So this meeting where it says -- Patricia is listed as having that comment. Patricia is Patricia Cortazar. Dr. Patricia Cortazar at the time was the head of the FDA breast cancer group.
Q. And then after the meeting that you described and Ms. Segal is describing, did the FDA's guidance on breakthrough therapy have any implication for the NDA?
A. No, it did not.
Q. Did it have any implication for the filing of the NDA?
A. No, it did not. We were still able to file our NDA.
Q. And did it have any implication for the FDA's acceptance of that NDA?
A. No, it did not.
Q. We had some questions early in the trial about the cost of neratinib. Does Puma have a policy for patients who want neratinib but may be unable to afford it?
A. Yes, we do. The policy we have is that we always put the patient's interests first. So if there is a patient who

has insurance and can afford their copayment, that's great.

If there is a patient who has insurance and can't afford their copayment, we provide them with copayment assistance. So we pay that down to very low amount. I believe it's, if I recollect, it's $10 a month or something.

If the patient is uninsured, then we give them the drug for free. There is no patient who has ever wanted neratinib that did not get neratinib. We always put the patients first.

Q. All right. Let's talk -- we've talked a lot about the ExteNET trial here and I won't repeat questions that you've already been asked, but when did the ExteNET trial originate.

A. The ExteNET trial originated, if I remember correctly, it was April of 2009 under Wyeth, who was the original developer of the drug.

Q. How many clinical trials of neratinib have there been?

A. I don't know the exact number. My estimation would be somewhere in the range of 10 to 20.

Q. Were all of those started when Puma had ownership of the drug, or some before?

A. The majority of those were started before Puma got the drug. But because neratinib is a very active drug, there were still patients who had been taking it for many, many years.

Q. And what do you mean by active drug?

A. The drug has efficacy in the treatment of breast cancer. So, you know, when we first acquired this asset from Pfizer, I believe there was, like, 14 or so clinical trials, many of which had been started, you know, five plus years prior to us licensing it.

But this is an active drug, and it has a very dramatic impact on breast cancer patients. So if you started with, you know, a hundred patients five years ago, you move forward and you still have patients who are responding to it. So they were still on trial and, you know, we were happy to see them continuing to respond to it.

Q. How important was ExteNET in particular as a study of neratinib?

A. ExteNET was a very important study. You know, this is a group of patients who are very young, especially patients who are early stage and newly diagnosed HER2-positive breast cancer. These are very young patients. These are 40-year-old patients.

They're extremely young and they've got children and they want to see those children grow up and have children of their own. And when they get breast cancer, you know, it unfortunately jeopardizes that dream. So we have a drug here that, you know, we thought had the potential to prevent that deadly disease from coming back. So it was a very important trial to us.

Q. We've reviewed the outcome of the ExteNET trials. That's Exhibit 123 in evidence. And we've looked at page 6 -- if we can put that up -- that has some of the efficacy results from the ExteNET trial. Do you recall seeing this a number of times?

A. Yeah. Yes.

Q. And you've walked us through the different data populations. I want to jump right into what else Puma had, what other results Puma had as of July 2014 from the ExteNET data. What was the volume, if you could describe, of the data that Puma had access to as of July 2014?

A. So as of July 2014, we had a very large database with, you know, over 2,800 patients in there. Some of those patients had been followed, you know, well more than, you know, two years.

I think we had several hundred patients who had been followed for more than two years. So we had a very, you know, large complete database of patients who had been followed for quite a long period of time.

Q. Does Puma still have the database that existed as of July 2014 in its possession today?

A. Yes, we do. We took what's called a snapshot, which means we kind of saved the clinical database, as of July 2014, and that was the data that was used in our presentations to ASCO and in our presentations to investors.

So that database in that format we have of July 2014 we still have in our possession.

Q. And what is your understanding of whether that snapshot was provided to the plaintiffs in this litigation?

A. So my understanding of this is that, you know, we obviously recognized that that database was something that was very important to this litigation, and my understanding is that we provided that database containing all of the data that we had as of July 2014 to the plaintiffs and allowed the plaintiff to be able to do any and all analyses that they wanted to do on that database which is exactly the data we had as of July 2014.

Q. Were you and your team personally involved in providing that data snapshot to us for production to the plaintiffs in this litigation?

A. Yes, we did.

Q. All right.

Were there additional analyses other than these topline results that could be performed in that data snapshot as it existed in July of 2014?

A. Yes, there was.

Q. Did you at the time ask anyone to provide analyses in addition to the data that is existing in this page 6 of Exhibit 123?

A. Yes. There were analyses that the statistical team had

done themselves and a lot that I specifically asked for that they performed as well.

Q. We've talked about a couple of those additional analyses, and we've heard about a group of patients called centrally confirmed?

A. That's correct.

Q. What does that mean?

A. So the test to see if you are HER2-positive or not is a test to see if you have the HER2 gene present in your tumor. The way patients entered the ExteNET trial was they had to have that test done in their doctor's office.

Unfortunately the tests that are done in the doctor's office have a high degree of inaccuracy to them, meaning if there's a false positive rate, meaning that the doctor will say your cancer is HER2-positive, but in effect it's not.

The false positive rate can be anywhere between 15 and 20 percent. So the way of making sure the patient is indeed HER2-positive and has the HER2 gene present is by doing what we called a centrally confirmed study.

This means the test is sent out to a central lab. So your doctor sends it off to a central lab, and that lab specializes in this test and therefore and confirm the presence of the HER2 gene.

So for all the patients in ExteNET, we had the

local test done, which meant their doctor's office said they had the HER2 gene, but then we also sent the sample out for central confirmation as well.

Q. Was it required in order to participate in the ExteNET study that a person's HER2-positive status be centrally confirmed?

A. No. We allowed the patients to enter the study if their test at their doctor's office, which was the local test, said they were HER2-positive.

Q. Did the study track those two types of diagnoses, if that's the right word, of the HER2-positive gene?

A. Yes, it did.

Q. All right. Did you ask for an analysis of the centrally confirmed patient population back in July of 2014?

A. Yes, we did.

Q. You were asked questions about centrally confirmed analyses that were done later in time. Do you recall that?

A. Correct.

Q. Did you ask Puma statisticians to conduct that same type of analysis in the July 2014 time period?

A. Yes. The analysis in July of 2014 looked at whatever data we had at that time on the centrally confirmed population. They had done this because the prior drug we were talking about, Herceptin, which is the drug that's used in the year before neratinib, all of their clinical trials

only allowed patients to enter if they had centrally confirmed disease.

They didn't do like we did, that if your doctor's office said you had it, you could enter. So it was important for us to be able to kind of do the apples-to-apple comparison in comparing our results to theirs. So it key for us to be able to get those centrally confirmed results. So, yes, we did perform that in July of 2014.

Q. By the way, how many biostatisticians does Puma have or did Puma have in this time period?

A. Oh, I don't know the exact number because we used a lot of contractors and things like that. My ballpark would be 20 to 30 if I had to take a guess at it.

Q. Let's talk about the press release that we've seen before. Did you make plans, once you had the ExteNET data available, to make those results public?

A. Yes, we did.

Q. And Exhibit 102, which is in evidence, is that press release. I want to walk through it just briefly. We've seen it before.

This press release announces results from the phase III clinical trial noted as ExteNET. Is this the press release that announced the topline results of the ExteNET trial?

A. Yes, it is.

Q. And the third paragraph talks about the results that are being announced in this press release. I just want to read two of the sentences: The results of the trial demonstrated that treatment with neratinib resulted in a 33 percent improvement in disease-free survival versus placebo.

Did you see that?

A. Yes.

Q. Has that information ever been corrected?

A. No. It remains accurate today.

Q. The next sentence is: The hazard ratio was determined to be 0.67, which was statistically significant with a p-value of 0.0046.

Do you see that?

A. Yes.

Q. Has that information ever been corrected?

A. No. That continues to be accurate.

Q. A couple of other data points are disclosed here talking about the secondary end point: The results of the trial demonstrated that treatment with neratinib resulted in a 37 percent improvement in disease-free survival, including ductal carcinoma in situ versus placebo.

What does that statistic refer to?

A. So as we had mentioned yesterday as well as earlier this morning, there are breast cancer tumors that are actually malignant, meaning they're cancerous.

Then there are also precancerous lesions, and those precancerous lesions are referred to as ductal carcinoma in situ. These are precancerous lesions that can become cancerous. Obviously there's something that you also would like to prevent, so this is the definition that would include those premalignant tumors.

Q. And the hazard ratio for that population is .63?

A. That's correct.

Q. Was that -- was that correct, that that population was a secondary end point of the trial?

A. Yes. It was the main secondary end point of the trial.

Q. The press release then says: Based on these results from the ExteNET study, Puma plans to file for regulatory approval of neratinib in the extended adjuvant setting in the first half of 2015.

Was that the plan as of this July 22nd press release?

A. Yes, that was the plan as of the July press release.

Q. And then the full results according to the press release will be presented at a future scientific meeting.

We've heard about this a bit before, but what future scientific meeting did the ExteNET results get presented at?

A. Well, at the time this press release came out, that was not something that we, Puma, determined. We have an outside

group of, like, of doctors called the academic steering committee, and they had the right to choose which cancer conference this data was presented.

The one they ended up presented to was what we referred to as the American Society of Clinical Oncology meeting, which is also known under the acronym ASCO, A-S-C-O.

Q. Let's look at the back of the press release. We've seen the front. There is a second page to the press release, and it contains a number of risk warnings. I'd like to ask you about a couple of them that are highlighted here.

The company warned in this press release that results could differ materially from the statements due to a number of factors. Do you see that?

A. Yes, I do.

Q. What did you intend that risk warning to refer to?

A. These press releases are meant for investors, and we always put forward these type of, you know, forward-looking statements and risk factors so that investors understand the risks of investing in development-stage, small biotech companies like Puma.

Q. And one more risk factor. There's a number here, but I wanted to ask you about one more, the risk that the results of clinical trials may not support the company's drug candidate claims. What did you intend by that risk disclosure?

A. Again it was a risk factor for the investors which -- there you go. It was a risk factor for the investors which essentially was exactly what it says on the screen.

Q. Fair enough. Let's talk a little bit about ASCO. The conference that you presented at was in 2015, correct?

A. That is correct.

Q. And what generally happens at these types of medical conferences?

A. So these medical conferences -- and ASCO is an extremely large one. I think the attendance at ASCO is usually approximately 30,000 people, so this is quite a large conference.

Usually they get thousands of research studies being submitted to the conference. They have a whole panel of individuals who review these, and they kind of give them a rating. And the ones that get the highest ratings get to be presented at the conference.

So they kind of have three groups that they generally categorize the studies into. One is that they just publish them in a large book that they put out as part of the conference. The second is they have what I refer to as poster presentations. These are very large rooms where they have posters where you, you know, put them up against the walls, if you will, and people come in and can talk to you about them.

And then kind of the highest tier, what we refer to as oral presentations, these are done in very large rooms that can hold hundreds if not thousands of people. And they're big presentation with giant screens where you speak for 20 minutes and go through a PowerPoint presentation. And then there's usually an open question-and-answer period where doctors who are in the audience can come up and ask you questions.

So we submitted the ExteNET study to ASCO, and we were very pleased when it got accepted and specifically got accepted for an oral presentation.

Q. Did you personally -- you said you were pleased that it was accepted for oral presentation. Why were you pleased?

A. When you have a drug that has completed phase III -- you know, this is an industry that has a very, very, very high failure rate. For every 10,000 drugs that get discovered, one makes it to the market. So you're talking about an industry with a 99.9 percent failure rate.

So when you have a successful phase III, you know, as you can imagine, you feel very fortune. And especially when it's a drug that helps cancer patients, you have a great deal of excitement about it because you're now going to go head to market. You know, you've been successful, and now you get to do all the things that you want to do, which is help cancer patients.

So for us a very key step in that process was presenting it at a big conference where we could educate the breast cancer doctors about this drug and show them about the efficacy so they could, you know, hopefully one day use it in their patients. Also about the safety and how to control the side effects so that it didn't cause any harm to their patients.

The best way to do that is in these large oral presentations because these are, you know, big rooms that can hold, as I said, hundreds if not thousands of people. And it's the best way to educate the group as a whole.

MS. JOHNSON: I'd like to put up Exhibit 983, not move it into evidence but as a demonstrative.

THE COURT: Any objection?

MR. COUGHLIN: One second, Your Honor.

MR. FORGE: No objection as a demonstrative, Your Honor.

THE COURT: Demonstrative just means they're going to demonstrate, but it's not in evidence.

MS. JOHNSON: Just wanted to look at a picture after so many words.

BY MS. JOHNSON:

Q. Is this a picture of the actual ASCO conference in 2015?

A. Yes, it is.

Q. And you were obviously in attendance?

A. Correct.
Q. How many people attended ASCO, this 2015 conference, if you know?
A. The number is somewhere in the range of, I believe, 30,000 to 33,000 people or so.
Q. All right.
MS. JOHNSON: I'll mark this as demonstrative Exhibit 1, DX1. Again, we're not moving it into evidence.
(Exhibit DX1 marked for identification.)
BY MS. JOHNSON:
Q. All right. What was the process for submitting the ExteNET trial to ASCO for presentation at the conference?
A. So as I mentioned earlier, we had a group of outside breast cancer doctors known as the academic steering committee. We had gotten them all together at a meeting that takes place in December in San Antonio, Texas, which is called the San Antonio breast cancer meeting.
We went to them, showed them the data, and then turned it over to them to, what do you think would be the best conference for us to present this data at. They made the determination at that conference that they felt this would be ideal for ASCO.
And so we then went forward with putting together what's called an abstract, which is kind of a shortened summary of it that gets submitted to the conference and they

determine whether or not to accept it or to reject it.
Q. All right. Let's take a look at Exhibit 115, the ASCO submission form for getting the abstract into the conference.
MS. JOHNSON: I believe there's no objection on Exhibit 115 in evidence?
THE COURT: Without objection 115 is admitted.
(Exhibit 115 received.)
MS. JOHNSON: It's hard to read until we blow it up, so let's blow up the first part of it.
BY MS. JOHNSON:
Q. Did you assist with filling out this form to get the ExteNET abstract in to ASCO?
A. Yes, that is correct.
Q. And the box on the left -- if you could blow it up -- it provides the date of submission. If we can see it, February 1st, 2015. Was that the date that you submitted the ExteNET abstract to be considered by ASCO for presentation?
A. Yes. That's correct.
Q. All right. On page 3 of this document it has a confidentiality policy. Do you see that --
A. Yes.
Q. -- once we get there, page 3? And there's a box that's checked there saying, I agree to a particular confidentiality policy. Do you see that?
A. Yes.

Q. And if you can tell us, basically what is the confidentiality policy of getting into ASCO?
A. So in order to be able to present your data at any medical conference, you have to check a box very similar to the one you see on the screen which states that this data is confidential and it's never been presented in any public forum and will not be presented in any public forum prior to this meeting.
Q. Did you understand that -- let me ask you. The confidentiality policy applies when you submit the abstract for consideration, right?
A. The confidentiality policy is basically saying that as of the date I am submitting this, I have not made this data public information, that it is indeed confidential. You're also agreeing to keep it confidential until the meeting.
Q. All right. Let's talk about the process for getting ready for the ASCO conference.

You testified about this earlier, so I wanted to walk through it. Were there people outside of Puma that you submitted the ExteNET data to in getting ready for the ASCO conference?
A. Yes, absolutely. So in addition to the academic steering committee, we had shown this data to somewhere in the range of, you know, 50 or so breast cancer doctors. And we did this at the meeting I previously referenced, which was

the San Antonio breast cancer meeting which had been in December.

And we had scheduled one-on-one meetings with each of these individuals, usually about a half hour in length. We did this over the course of a week where we, you know, just kept bring in doctor after doctor, showing them the data and getting their thoughts on it.

THE COURT: When is a good time for a break?

MS. JOHNSON: Right now.

THE COURT: All right. That's what I thought.

So we'll break and come back at 3:15. Thank you.

THE CLERK: All rise.

(Open court - jury not present)

(Recess taken from 3:01 p.m. until 3:19 p.m.)

(Open court - jury present)

THE COURT: Ms. Johnson.

MS. JOHNSON: Thank you, Your Honor.

BY MS. JOHNSON:

Q. Mr. Auerbach, I was asking you if there were people outside of Puma that saw the data leading up to the ASCO conference, and you described an academic steering committee, right?

A. Yes. That is correct.

Q. Remind us again what the academic steering committee is.

A. The academic steering committee is a group of outside

breast cancer doctors who have been involved with the trial from inception, and the academic steering committee was meant to advise Puma on the trial and to also help -- they were the ones who originally helped design the study.

They were also the ones who had the mandate as to determining where and which medical conference this study would be presented at.

Q. And did you meet with the academic steering committee ahead of ASCO to discuss the ExteNET trial data?

A. Yes, we did. We first met with them at the San Antonio breast cancer meeting which was in December. That was the point at which we made the determination or they made the determination that this data should be presented to ASCO.

We then later got together with them where we had them all fly to Los Angeles in January where we sat down for an entire day in order to put together the abstract.

Q. How many doctors make up the academic steering committee?

A. I don't remember the exact number off the top of my head. It would be somewhere in the range of 10 to 15, if I remember correctly.

Q. Are any of them Puma employees?

A. No. They are all outside physicians.

Q. Does Puma pay them for their work to oversee the trials?

A. No. We do not provide them any compensation. They just

do this for the purpose of helping cancer patients. And they certainly don't want to have any conflicts of interest such that if they did present this data at a conference, you know, someone could imply that the only reason they're doing this is because they're getting paid. So, no, we do not pay them.

Q. And not in money, not in stock?

A. We don't give them any cash. They don't own any stock in Puma. We don't give them any stock in Puma. They are free and clear of all conflicts.

Q. And who is the head of the academic steering committee?

A. The head of the academic steering committee is Dr. Arlene Chan. She is a breast cancer physician in Australia.

Q. And are all my payment questions true for her as well? Puma doesn't pay her?

A. That's correct. We do not provide her with any compensation.

Q. All right. And before ASCO did you show the full ExteNET trial date to specifically the academic steering committee?

A. Yes, we did.

Q. All right. Let's turn to 952.

MS. JOHNSON: Don't publish it yet.

I believe there's no objection to 952, and we'd move it into evidence.

MR. COUGHLIN: No objection.

THE COURT: Without objection 952 is in.

MS. JOHNSON: Correct.

(Exhibit 952 received.)

MS. JOHNSON: So 952, starting at the first slide is ExteNET academic steering committee, San Antonio, December 9, 2014.

BY MS. JOHNSON:

Q. Is this the meeting that you were referring to?

A. Yes, it is.

Q. Who from Puma attended this meeting?

A. So from Puma I remember that I was at this meeting. Dr. Richard Bryce -- Bryce is spelled B-r-y-c-e -- who is our chief medical officer was at this meeting. Then I believe also Dr. Susan Moran -- Her last name is spelled M-o-r-a-n -- was at this meeting as well. I also believe that Dr. Alvin Wong -- W-o-n-g is his last name -- may also have been present at that meeting.

Q. And you as well, of course?

A. Correct.

Q. Did you present this slide deck to the academic steering committee at that meeting?

A. Yes, we did.

MS. JOHNSON: If we could turn to slide nine.

BY MS. JOHNSON:

Q. There is a summary of the efficacy information for the ITT population. Was this one of the slides that you presented to the steering committee?
A. Yes. This is correct.
Q. And does it include the DFS for the entire ITT population with the difference of 91.6 to 93.9?
A. Yes. That is correct.
Q. In addition to a number of other topline analyses of the data, right?
A. That is correct.
Q. And two slides later there's a picture of the Kaplan-Meier curves showing the entire ITT population. Was that a slide that you walked through with the academic steering committee in December of 2014?
A. Yes, that is correct.
Q. All right. And then let's -- I guess there's a number of other slides here. I don't want to necessarily go through all of them, but did you also present the diarrhea rates?
A. Yes, we did. I think it's a few slides forward.
Q. All right. Most frequent adverse events, 15 percent or greater. Is the 39.9 percent number for diarrhea presented in this slide deck?
A. Yes, it is.
Q. Among a number of other safety results, and then a few slides later do we have the 16.8 percent -- actually the next

slide, 16.8 percent for treatment discontinuation.

Do you see that?

A. Yes. Correct.

Q. Among a number of other pieces of information.

First of all, were you worried about getting kicked out of ASCO for presenting this data to the steering committee?

A. No. ASCO's policy is that the data cannot be presented in a public forum. This was under confidentiality. All of the doctors who are on our academic steering committee signed a confidentiality agreement, a CDA, with Puma. So they agreed to keep this confidential. So this would be a confidential discussion.

Q. And what were the reactions of the academic steering committee to the presentation of this data?

A. We were very encouraged by their feedback. The number one comment that we heard from the academic steering committee was we need this for our patients. And that was very encouraging to hear from them.

Q. Did you discuss the likelihood of FDA approval?

A. They had asked us at the time what our plans were, not just for the FDA but worldwide, because the academic steering committee is made up of doctors from the United States but also from Europe, from South America, Central America, places like that. Then obviously Asia Pacific, such as Dr. Arlene

Chan.

So they were asking us for our plans for filing for FDA approval but then also for filing in Europe and other countries as well.

Q. Did any of these doctors tell you that any of these data were troubling?

A. No. We did not hear from any physician that this data in any way caused any concerns or was in any way troubling to them.

Q. Did any of the doctors at this meeting tell you that the data were inconsistent with something that you had said previously?

A. No. We did not hear from any physician that this data was in any inconsistent with anything that Puma had said in the public domain or that I had said in the public domain.

Q. Did any of the doctors tell you that you had overstated the efficacy of neratinib, in words or in substance?

A. No. We did not hear from any breast cancer physician that we, that anyone in the company had ever overstated anything regarding the data.

Q. And did you hear from any of the doctors in words or in substance that you had understated the safety results?

A. No, we had never heard from any physician that we had understated safety results.

Q. Was neratinib then accepted for presentation into ASCO?

A. Yes, it was.

MS. JOHNSON: If we could turn to Exhibit 119. It's the 2015 ASCO acceptance for the ExteNET abstract.

I'll move it -- I don't know if it's in evidence. I'll move it into evidence -- I apologize. I did move 115.

I'd now like to turn to 119, and I would move 119 into evidence. I believe there's no objection.

MR. COUGHLIN: No objection, Your Honor.

THE COURT: All right. 119 is admitted.

(Exhibit 119 received)

MS. JOHNSON: If you could blow up the first paragraph.

THE COURT: Wait. We're talking about 119?

MS. JOHNSON: Yes.

THE COURT: Did I hear you say 115 was in? Did you say that? I just -- because it's not on my list.

MS. JOHNSON: I did say that.

THE CLERK: I have it, Judge.

THE COURT: You have it in, Ms. Bredahl, 115?

THE CLERK: I do.

THE COURT: I missed that. Okay. So 115 is in, and now 119 is in.

Just hold on one second, please.

(Pause in proceedings)

THE COURT: Okay.

Go ahead.

BY MS. JOHNSON:

Q. The first paragraph -- the letter is directed to Dr. Chan. Again, she is -- Mr. Auerbach?

A. Yes.

Q. Remind us of who Dr. Chan is.

A. Dr. Arlene Chan is the chairperson of the academic steering committee.

Q. All right. And ASCO says to Dr. Chan: Thank you for submitting your abstract.

Going to the second sentence: This year we received more than 5,900 abstracts which were reviewed by our scientific program committee and ASCO leadership. Then in bold and underlined: I'm pleased to inform you that your abstract was selected for oral presentation as part of an oral abstract session.

Do you see that?

A. Yes, I do.

Q. All right. You earlier testified about the different levels that a study can be accepted for. Of the 5,900 abstracts submitted, do you have any idea of a percentage of how many get in?

A. I don't know the number in terms of the percent that get to present at the conference. The way it works is those 5,900 abstracts are submitted to the ASCO committee. Their

review committee reviews all of those abstracts and gives them a score. The highest ones get what is referred to as an oral presentation.

Of the 5,900, I don't know what percent of them get an oral presentation. My guess is it's a single-digit percentage. But they rank those. The highest ranked ones will typically get to what's called the plenary session which is something held on a Sunday afternoon.

Then the others will usually get separated into disease categories. So they'll have, you know, one breast cancer one, one prostate cancer one, one lung cancer, et cetera. But it's certainly not the -- it's the minority of them that get to get that oral presentation.

Q. And which type of oral presentation was ExteNET selected for, the plenary or the rest of the oral presentations?

A. We were selected for the breast cancer presentation which was on a Monday that that occurred.

Q. Exhibit 119 contains a reminder of the confidentiality policy, that paragraph that starts with all abstracts are confidential. Do you see that?

A. Yes.

Q. What did that reminder mean to you about the confidentiality of the ExteNET data?

A. Well, as the confidentiality policy states, all abstracts are confidential from the time of submission until

the time of public release by ASCO. So what that meant was that you could not disclose the data contained in it. And if did you, you were at risk of being kicked out and not being able to present the data at ASCO.

Q. And did you understand that you were still bound by that policy?

A. Yes, I did.

MS. JOHNSON: Let's jump without further ado to the conference call on July 22nd, 2014. The transcript is Exhibit 103. If you could put up the first page of the transcript, second page of the document.

BY MS. JOHNSON:

Q. We talked about risk disclosures in the press release. Were there risks also disclosed in connection with the conference call?

A. Yes, I believe there was.

Q. All right. Ms. Collett -- who is Cheryl Collett?

A. Cheryl Collett works in the finance defendant at Puma, and she at the time was our controller. She has since been promoted to the vice president of finance.

Q. Ms. Collett says on the conference call: Please refer to documents that we file from time to time with the SEC, including -- you can read it there -- our form 10K. Do you see that?

A. Yes, I do.

Q. What is a 10K?
A. The 10K is the annual report that is filed with the Securities and Exchange Commission. It's available on the Securities and Exchange Commission website. It's the annual report on the financials of the company and also an update on the status of our business.
Q. All right.
If you turn in your binder to Exhibit 979. This is Puma's form 10K for 2013 filed on March 3rd, 2014, which was before the July 22nd, 2014, conference call.
MS. JOHNSON: I would move 979 into evidence. I believe there's no objection.
THE COURT: With no objection 979 is admitted.
(Exhibit 979 received.)
BY MS. JOHNSON:
Q. Were you involved in putting together Puma's 10K for year end 2013?
A. Yes, I was.
Q. If you would turn to page 24, there's a section entitled risk factors, risks related to our business.
A. Correct.
Q. Once we have it up -- I'll read it while it's being put up and you tell me if I'm doing this correctly: We currently have no product revenue and no products approved for marketing and will need to raise additional capital to

operate our business.

Why did you put that particular risk factor into this 10K?

A. We put that risk factor into the 10K because it's a reminder to the investors that this is not a company with products on the market. We are not a profitable company. We don't make money due to research and development having very, very high expenses.

The cost of bringing a drug to market is estimated to be anywhere between, you know, $900 million and $1 billion. Clearly in order to get our drug from where it was to the market was going to require a significant amount of capital.

Q. All right. The risk factors go on for some pages. If we could turn to page 38. There's a risk factor that's entitled: The price of our common stock could be subject to volatility related or unrelated to our operations.

Do you see that?

A. Yes.

Q. And there are a number of factors listed under the risk about our trading price could be subject to volatility, right?

A. That is correct.

Q. And going down a few of the bullets, one of them is timing and announcement of regulatory approvals.

Do you see that?

A. Yes.

Q. And any -- the next one, any future sales of our common stock or other securities in connection with raising additional capital or otherwise. Do you see that?

A. Yes, I do.

Q. Why did you put that particular bullet point about warning investors about raising additional capital?

A. Well, oftentimes when a company announces that it's raising additional capital, sometimes the stock price can drop, and that tends to be a general market reaction.

So as we had said previously, we knew we would need additional capital at some point, and this was just a reminder to investors that oftentimes when you raise capital, the stock does drop in relation to that.

Q. And why did you expect the need to raise additional capital?

A. Well, at the time obviously Puma was still a development-stage company, and we had a lot of expenses, the ExteNET trials as well as other ones, and we knew we would need additional capital at some point.

Q. All right. Let's go back to Exhibit 103 where we started when we started talking about risk factors.

You've been asked extensively about Dr. Werber's questions, so I wanted to give you a chance to explain what

you meant. His first question was: So in terms -- you probably have it memorized by now.

A. Yes. Correct.

Q. On page 5 -- all right. I'll just read it: So in term of the DFS of the placebo arm -- now I did it wrong. Okay. I will read Dr. Werber's questions. First one. One, give us a little bit of a sense what was the DFS on the control arm first. Do you recall that question?

A. Yes, I do.

Q. And your answer is: Okay. So in terms of the DFS of the placebo arm of the trial, it was in line with other reported trials. So it's in line with the Herceptin adjuvant studies.

Describe what Herceptin adjuvant studies you were referring to or that existed at this time period.

A. So as we discussed previously and again this morning, for the patients who have HER2-positive early-stage breast cancer, the standard of care is they receive surgery, and then they receive one year of treatment with chemotherapy and the drug Herceptin.

And the idea is to try to prevent the disease from coming back, and Herceptin has been very effective in doing this. Herceptin has been tested in four trials in this setting which is known as adjuvant breast cancer, and those four trials have some interesting names, so I'll go through

them slowly.

One of them we refer to as the joint analysis because it was actually two different trials that were merged together. The two trials, one was called NCCTG. The other one was called NSABP. So they merged the two together into one long acronym there.

The second trial was referred to as HERA, H-E-R-A. The third one was called BCIRG. And the fourth one, which was actually the most recent one, was called BETH just like the girl's name, B-E-T-H.

Q. All right.

A. What we were trying to do was to say that the placebo arm of our study was similar to the DFS rates that were seen in those four adjuvant trials.

Q. All right. Let's look first at Exhibit 300. Exhibit 300 is a printout from a website entitled Herceptin.

MS. JOHNSON: I would move 300 into evidence. There's no objection.

THE COURT: Without objection 300 is admitted.

(Exhibit 300 received.)

BY MS. JOHNSON:

Q. So on this page it looks like three of the studies that you described are listed here.

MS. JOHNSON: If we could blow up that box.

BY MS. JOHNSON:

Q. Are these three of the four studies that you just mentioned -- the joint analysis, the HERA study, and BCIRG?

A. Yes, those are those three studies.

Q. And what is the DFS rate of the treatment arm in the joint study? Can you tell from this?

A. I believe it says at -- in joint analysis it looks like at three and a half years, 86.7 percent.

Q. And you're looking at the right -- the pink shaded columns, you're looking at the right-hand one under disease-free survival, right?

A. That's correct.

Q. For at least the published point of the joint analysis, you see 86.7, right?

A. That is correct.

Q. And then what was the disease-free survival in the HERA study?

A. In the HERA study it was was 85.8.

Q. And in the BCIRG study what were the DFS rates?

A. It was -- for the last one, which is the standard of care, is 88.0.

Q. What do you mean by the standard of care?

A. There's two arms there. One is called TCH and the other is called ACTH. Because it's more effective, the ACTH tends to be the one more people use.

Q. All right. Then let's turn to 922 in your binder. You mentioned a fourth study. If you take a look at 922, it's a presentation on BETH, a randomized phase III study evaluating a number of things, including trastuzumab. Do you see that?
A. Yes, I do.
Q. And where was this study presented?
A. This study was presented at the San Antonio breast cancer meeting that took place in December of 2013. So this was actually the most recent Herceptin adjuvant study that had presented results prior to the ExteNET study.
Q. Were you in attendance at that meeting?
A. Yes, I was.
Q. San Antonio 2013?
A. Yes, I was.
Q. Is this document a true and correct copy of the presentation on the BETH study that was presented in San Antonio Breast Cancer Symposium in 2013 which you attended?
A. Yes, that appears to be correct.
MS. JOHNSON: Your Honor, I would move Exhibit 922 into evidence.
MR. COUGHLIN: No objection, Your Honor.
THE COURT: 922 is admitted.
(Exhibit 922 received)
BY MS. JOHNSON:
Q. First of all, if you'll turn to slide six. You

mentioned this was the most recent Herceptin study as of this July 2014 time period?

A. Correct.

Q. All right. On slide six it talks about the BETH trial design, and I wanted to ask you a question about central testing which we've talked about before.

At the top it says node-positive or high-risk node-negative breast cancer, HER2-positive by central testing. Were the data in the BETH study that studied, of course, Herceptin, not neratinib but Herceptin, was that study a centrally confirmed study?

A. Yes. All of the patients had to have their HER2 status determined by a central lab. So, yes, it was centrally confirmed.

Q. Let's jump to slide 26 that shows some of the efficacy results in the BETH study. The first column there is marked BETH. What were the efficacy results in the all-patients line?

A. The efficacy was 92 percent disease-free survival rate.

Q. So putting those two exhibits that we've looked at together, what was the range of the Herceptin studies that had been published by the time of your July 2014 comments with respect to the DFS rates of the Herceptin studies?

A. Yes. If you look at the all-patients line on the slide going across all of those Herceptin studies, you can see that

the prior -- the previously shown DFS rates for the Herceptin adjuvant studies ranged anywhere from 86 to 92 percent.

Q. Just based on your experience, why were the rates getting better over time with the same drug?

A. That's a very good question. The Herceptin adjuvant studies as you're seeing on the right-hand side of the slide, so this would be the B31, N9831, BCIRG, and HERA, these were all completed somewhere in the 2005 time frame. BETH was completed in 2013.

When it comes to new drugs, you know, you can think of this like any technology. So, for example, when you, you know, first bought your iPhone, it was probably difficult. You were probably, you know, not very comfortable with it. A few months later, years later, you've become very comfortable with it. You're much more, you know, technology user-friendly with it. It's very easy to use.

The same thing can happen with new cancer drugs where when a new drug comes out, the doctor is just learning how to give it, how to give it to patients, to balance out the side effects of it, to balance out the efficacy. Ten years later they really optimized that, so they're really able to deliver it and achieve the best results.

So what you're really seeing is that, you know, increase in the technology user-friendly nature of the drugs and doctors being able to give it and maximize the benefits

for the patients.

Q. So when you gave the answer to Dr. Werber and you referred to the placebo arm of the ExteNET trial being in line with other reported Herceptin adjuvant studies, are these the studies that you had in mind?

A. Yes, absolutely.

Q. And where within the range of those Herceptin adjuvant studies did the DFS for the control arm of ExteNET fall?

A. So the disease-free survival for both the all-comers, the intent-to-treat, as well as those that were centrally confirmed, so had their HER2 status determined by a central lab, all fell within that range.

Q. Now, let me ask you, why didn't you just tell Dr. Werber the actual number of the DFS of the control arm?

A. So, as we discussed previously, there's the confidentiality policy that ASCO has. And every medical conference has that exact same policy, which is, you have to swear that the data you are presenting is confidential and you have not put it in any public forum.

There are examples where companies violated that policy and actually got kicked out of the medical conference for doing that. So we certainly didn't want to have that happen. So unfortunately in these situations you need to walk kind of a fine line where you can, you know, disclose some things or give some generalities. But if you actually

disclose the data, you would be violating that confidentiality policy.

Q. You referred to your recollection of companies getting kicked out of the medical conference. Why is that a bad thing?

A. Obviously the goal is to bring new drugs to help cancer patients, and a very important step in that process is being able to present that data to doctors, to cancer doctors so that they can get comfortable with the efficacy of the drug as well as the side effects of the drug. The best place to do that is at one of these medical conferences.

If you don't do that, there's no way that these doctors are going to have comfort with the drug or be aware of the drug. It would just end up hurting the patients.

Q. Let's go back to 103, to your next exchange with Dr. Werber. You knew who Dr. Werber was in this time period?

A. Yes, I did. So as I had mentioned previously, I used to be a Wall Street analyst. Yaron and I were actually analysts at the same time. So Yaron is actually a medical doctor, a very smart guy.

When we were both analysts, we used to, you know, run into each other at conferences and we would talk about things, et cetera. So I know Yaron very well. I know how his brain thinks. And when I'm talking to him, I kind of know where the conversation is going to be going.

Q. Let's look at the four lines that you were asked about earlier in the testimony. At the bottom of page 5, you can see them there. You're thinking -- he says: You're thinking that, if I'm correct, the DFS is probably around mid to high 80s, around 86 or so, in the control arm? You say: I would be comfortable with that number. He says: And one would imagine you probably had to show around 90 percent or 91 percent? Is that reasonable? You say: Yes. I think you can do a 33 percent improvement in DFS and come up with that calculation given the numbers you gave.

I just want to ask you, in your own words what did you understand Dr. Werber to be asking when he asked you this line of questions?

A. So again, I've known Yaron for a long time, and when I'm talking to him, I always know where his questioning is going.

When he first asked the question of what the placebo arm DFS was, I knew exactly where he was going whereas he was trying to get some ballpark estimate of where the, you know, absolute DFS benefit was.

Again, I've known Yaron a long time. I knew exactly where he was going with this. Now, obviously we're in a very challenging situation because we can't just release that information or else it prevents us from presenting this at a medical conference obviously make it difficult for us to bring this drug to the market.

So the goal we were trying to achieve here was to give some kind of a ballpark range where we could give investors and Yaron some range as to where the DFS was and therefore give some, you know, general estimates of that range.

Q. And what was your understanding about the range that you took from his questions?

A. Well, as he said, mid to high 80s. I assumed that was anywhere from 85 to 89 percent. And when he said 90 to 91, you know, again taking the opposite ends of that spectrum, that was, you know, if the placebo arm, the high end, was 89, and the low end of the neratinib arm was 90, that's a one percent benefit.

If you take the opposite, which would be the mid range of the placebo with 85 and the high end of the neratinib is 91, that was six percent. I felt comfortable with that kind of guidance range, if you will, of one to six percent.

Q. And again, what is the basis for your understanding that Dr. Werber was interested in the range rather than the actual numbers he was asking about?

A. He didn't -- his question is specifically, you know, can you give us some type of sense. He doesn't actually ask for me to give him the exact number. He says, can you give us some type of sense.

So that triggered me to think he was looking for some type of a range, and he knew that, you know, we couldn't provide him with the actual data because it would inhibit our ability to present this at a medical conference.

Q. All right. So you've given us a range of deltas from Dr. Werber's estimates. You've described it as one to six percent. Let's just run through the actual DFS deltas for the different populations that we've talked about. The DFS delta for the entire ITT population was what?

A. 2.3 percent.

Q. And the DFS delta for the entire population including the DCIS events?

A. Was 2.9 percent.

Q. And we're probably good for now, but again what is DCIS, just so that we remember, in that population?

A. So the DCIS stands for ductal carcinoma in situ. These are the precancerous lesions.

Q. So in that population it was again?

A. 2.9 percent.

Q. All right. And the DFS delta for the centrally confirmed patients in the ITT population?

A. It was 4.1 percent.

Q. And finally the DFS delta for the centrally confirmed patients with DCIS?

A. I believe it was 4.5 percent if I remember correctly.

Q. Okay. And why not explain to Dr. Werber on the call what groups of patients you were focusing on in giving the range or agreeing to the range that he articulated?

A. When Yaron first mentioned on the call, you know, when we said it was in line with the Herceptin adjuvant studies, I remember having conversation with him where we were comparing the differences between the Herceptin adjuvant studies with the ExteNET trial.

And Yaron was certainly not the only one I had those type of conversations with. I remember having them with Matt Roden at UBS and Howard Liang at Leerink as well. One of the things that they all pointed out was that, you know, in the Herceptin adjuvant studies, some of them used an end point that was just DFS. Some included the precancerous lesions as well, the DCIS.

But the big one that they all mentioned was that allo of the patients in the Herceptin adjuvant studies had this centrally confirmed test for HER2. And we didn't have that as an entry criteria for the trial so patients could come in with just their doctor's office saying it, but we did measure it in the patients.

So the ability to do that kind of, you know, apples-to-apples comparison, that was something we had discussed beforehand with the majority of our analysts.

Q. All right. Let's focus one more time on the last line

of your exchange with Dr. Werber. You said: Yes, I think you can do a 33 percent improvement in DFS and come up with that calculation given the numbers we gave.

Would you just explain what the 33 percent improvement statistic means for the range of absolute rates that you were discussing with Dr. Werber?

A. Yeah. The 33 percent improvement is in relation to the hazard ratio. So you get the 33 percent. The hazard ratio we reported was 0.67. You subtract that from one and get 0.33. You express that as a percentage, and that's the 33 percent.

So all of these analysts have got very sophisticated tools, statistical packages, et cetera, where they can run all of these type of simulations, and they can -- you know, using that number and the hazard ratio of 0.67 and the range we gave for the placebo arm, they can generate the curves themselves.

Q. Okay. After this conference call there were analyst reports issued, and you were shown a couple of them in your testimony. I wanted to go back to one of them because in your questioning you asked to refer to a lower paragraph in the study -- rather, in the analyst report. So I wanted to give you a chance to do that.

If you would turn to Exhibit 301, which is in evidence. And go to the Cowen report, Bates 15853. I

believe you testified earlier that you would receive these analyst reports and generally reviewed them at the time when you received them?

A. That is correct.

Q. All right. And the Cowen report from July 23rd, 2014, is that the day after the conference call that we've been discussing?

A. Yes. That is correct.

Q. Who is the analyst from Cowen?

A. Eric Schmidt.

Q. And he issues a report saying "the cat with nerati-nib" strikes back. Do you see that?

A. Correct.

Q. You were asked questions about the first paragraph under ExteNET looks like a home run. You asked to see the second paragraph.

MS. JOHNSON: So if we could blow up the "we see few barriers to approval" paragraph.

BY MS. JOHNSON:

Q. It says: Our consultants have indicated that a two to three absolute improvement in DFS is clinically meaningful as the prevention of recurrence is tantamount to a cure in this setting.

You saw this report when it came out?

A. Yes, correct. That was the point I was trying to bring

up earlier, was that Cowen had previously done a call with a number of doctors and had done a lot of work with doctors asking them, you know, what result would be clinically meaningful.

When we say clinically meaningful, what we mean is what would be a result that would make you want to prescribe this to your patients. The number that they had said was two to three percent. And, you know, they importantly bring up that again in this setting, you know, if you can prevent the disease from coming back, you know, that's similar, if you will, to a cure. And that's exactly what these patients want to achieve.

So the two to three percent number he's referencing is obviously exactly in line with our ITT population, and the higher numbers he's mentioning is exactly in line with our centrally confirmed HER2.

Q. Dr. Werber, he's an analyst as well, right?

A. Yes. Correct.

Q. You said he was a medical doctor and obviously an analyst. He issued a report as well after the call. I'd like to look at that. It's Exhibit 766.

MS. JOHNSON: I would move 766 into evidence. I believe there's no objection.

MR. COUGHLIN: No objection.

THE COURT: All right. Without objection

Exhibit 766 is in.

(Exhibit 766 received.)

BY MS. JOHNSON:

Q. So again, 766 is an e-mail you received attaching some analyst reports. If we can go to the first page of the report, which is the second page of the exhibit, it's entitled: Puma technology, even the skeptics make it on board. Key takeaways and transcript from our recent ExteNET physician call.

Is this a report by Dr. Werber who at the time worked for Citi?

A. Yes. That is correct.

THE COURT: All right. Please make a note that 766 is not on the exhibit list. We're talking about 766.

THE CLERK: Judge, they added a page on the last, the very last page of your exhibit list.

MR. COUGHLIN: There was a page added with later exhibits.

THE COURT: I don't have that addition. I don't know where it is.

MS. JOHNSON: Okay.

THE COURT: Just make a note. Maybe you should make sure I get the addition or it gets to me. But 766 is in.

MS. JOHNSON: All right. Thank you.

BY MS. JOHNSON:

Q. And you read this report when it came out most likely?

A. Yes, I did.

Q. Okay. Middle of that first paragraph under key takeaways, Dr. Werber writes: At this point the KOL -- what is a KOL?

A. So KOL is an acronym that stands for key opinion leader. And what this means is that someone who in the breast cancer world is respected by his peers is having a view that can influence other breast cancer doctors as well.

Q. So Dr. Werber is having a discussion with the KOL about of the ExteNET trial? Is that what's going on here?

A. Yes, that is correct.

Q. And Dr. Werber writes: The KOL -- so the key opinion leader -- would like to see the full data to better understand how the placebo arm did, but he admits that the 33 percent improvement in DFS suggests that the data is very robust.

Do you see that?

A. Yes, I do.

Q. What did you take away from that about what the key opinion leader understood about how much data you were and were not disclosing at this point in time?

A. My understanding was that the physician or the key opinion leader had just seen the press release which was

stating the 33 percent improvement in disease-free survival, and his view was very positive on it.

Q. Okay. Going down in that page to the third bullet point, ExteNET data is unprecedented. Dr. Werber writes: Our expert noted that the hazard ratio of .67 observed is unprecedented in breast cancer since Herceptin's first study.

Do you see that?

A. Yes, I do.

Q. Did you agree that the ExteNET data and its hazard ratio were unprecedented since Herceptin?

A. Yes. So since the introduction of Herceptin, which was somewhere in the 2005 time frame, there had been many, many improvements to try to improve on Herceptin as we still have not cured this disease. Every one of those attempts failed.

So this was the first drug in, you know, approximately ten years to be able to improve on that standard of care. So that was one of the reasons I believe Yaron had said in his questioning this was somewhat surprising and unexpected. Every other attempt had failed. This was the first one to succeed.

Q. So attached then to the analyst report is what's called a raw transcript a couple pages later. It says moderator, Yaron Werber, of a call, it looks like, July 24th, 2014.

And you turn to that page in your binder?

A. Yes. (Witness complies.)

Q. Okay. That -- it's a transcript. Were you on this call?

A. No, I was not. This is for Citi's clients, which are mutual funds and things like that. They do not open this up to the public, and they do not open this up to companies. So, no, I was not aware of this call until I saw this report.

Q. Okay. Dr. Werber starts out the call, and then in the third paragraph he says: So today with us we have a very prominent physician who you all know. Hopefully he calls him doctor. He's associate professor of medicine at Harvard medical school.

So is that your understanding of who the KOL was who had this conversation with Dr. Werber six days after the July 22nd conference call?

A. Yes. It was one of the physicians from Harvard medical school, yes.

Q. All right. And if we'll turn to page 6, the conversation goes on for a while. Eventually they start talking about the DFS rates. And at the top of page 6, do you see in the middle of that paragraph, one question? Are you with me?

A. Yes.

Q. He says: One question -- and this is the doctor talking -- would be, what is the actual magnitude of difference? That is to say, if the control arm had an

88 percent disease-free survival at three or four years, what does the neratinib arm look like?

Do you see that?

A. Yes, I do.

Q. He goes on to say: Is it 96 percent, or is it, you know, 90 percent, with such that there's only a two percent difference?

What did you understand him to be estimating in this discussion?

MR. COUGHLIN: Your Honor, I'd object to his speculation. I mean, we can read it. I don't think he can speculate what another doctor in another phone call with somebody else was thinking.

THE COURT: I will sustain unless you can tell me that his understanding has some other significance.

MS. JOHNSON: Plaintiffs' counsel has argued that Mr. Auerbach's review of analyst reports was somehow relevant to his state of mind and his actions.

THE COURT: The objection is overruled.

You may answer.

THE WITNESS: When I read this report, my thought was that, you know, the doctor was suggesting that there is a, you know, potential range of outcomes for what the absolute benefit, DFS benefit, was in the trial. He is saying it could be, you know, two percent appears to be the

low end of what his expectations would be.

BY MS. JOHNSON:

Q. Let's go to the next page. Just for the sake of time, let's go to the discussion they had about the difference. On the next page, page 7, the doctor continues, third paragraph: You know, if the control arm did better than you anticipate, then, you know, you might be looking at something like a 90 percent baseline risk, and then a 33 percent risk reduction sort of shifts it down to, you know, maybe 92 percent. This is arguably the narrower window.

Do you see that?

A. Yes, I do.

Q. What was your reaction to what he was estimating at this point in the call?

A. Again, he appears to be guiding to an expectation for that two percent number. This is now the second time we see it, and I believe there's another one as well where he goes to, like, a two to three percent range or something like that.

So there are several times on the call where the physician seems to be guiding to around the two percent number.

Q. Okay. Let's jump to that next one, the paragraph that starts, in North America. At the end of that paragraph he says -- this is the doctor from Harvard -- you're probably

thinking about -- excuse me: You're probably talking about a baseline risk of 90 percent with the hazard you would get to a two to three percent improvement in disease-free survival.

Do you see that?

A. Yes.

Q. Dr. Werber responds and says: So we've actually asked on the call. Let's assume that the object kind of 86, 87 was showing 90, 91. Is that reasonable? And the answer was: Yes. So again we'll have to wait.

Do you see that?

A. Yes.

Q. And the doctor from Harvard responds and says: That seems credible. I wasn't on that -- you know, I didn't listen in on that call. But that seems, you know, that is very much in line with the numbers we just came up with; isn't it?

Do you see that?

A. Yes, I do.

Q. And what was your understanding of what that exchange meant?

A. It looked to me as though the physician was basically guiding to, look, there's a range here. It could be two to three percent. It could be a higher range. But it was all kind of the same.

Q. Okay. Let's go back. I want to switch with the time we

have left to the safety discussion in the conference call.
A. Yes.
Q. In the conference call Dr. Werber's second question was: Help us understand, what do you know about the safety profile?
A. Yes.
Q. And you said -- if we can put it up -- that the company had not yet seen the results as the data were still being validated. Do you recall that?
A. Yes, I do.
Q. You were asked a number of questions about it. Again, I just wanted to give you the opportunity to explain what was the basis for your statement that the safety data had not been validated.
A. So the safety data had been validated by Puma's outside vendor, which was a contract organization called Rho. They had validated the data, but we had not internally validated the data.

So we've certainly seen in the past that when we get databases that sometimes are validated from an external vendor, when we do them internally, the numbers change. So it's always a little challenging when you're in that in-between, if you will, type of position.

Q. You were shown an e-mail from Alvin Wong saying: Here are the safety tables. They are now validated.

Do you recall being asked about that Alvin Wong e-mail?

A. Yes, I do.

Q. Who at Puma are responsible for the statistical validation of the safety tables?

A. That would have been done by Claire Sherman and her group.

Q. All right. And what is your understanding about the internal statistical safety validation process?

A. My understanding of that is that the internal validation of the safety database was not completed until January of 2015.

Q. Do you know of examples at Puma where the data changed through the validation process?

A. Yes. Absolutely.

Q. And what -- describe your experience in that regard.

A. Oh, we've had studies both where the safety and efficacy data has changed upon validation. And, you know, the change can be, you know, it could be 50 percent lower than you originally thought. It could be 50 percent higher than you originally thought. So the data can definitely change.

Q. All right. Let's take a look at the safety tables that you did have as of July 2014. If you could turn to Exhibit 124, which is in evidence. And let's slip to slide five.

We talked about this before. This has the diarrhea for neratinib on one side and the placebo on the other. It has the 39.9 percent that we've talked about. It also has diarrhea rates for the placebo arm. Do you see that?

A. Yes, I do.

Q. And on placebo all grades of diarrhea -- that's one through four, I think is probably the highest that occurred here -- were 35.4 percent. So 498 people in the study had diarrhea of one grade or the other by taking a placebo pill.

What was your reaction to that data?

A. When we first received this data, what we were most concerned about was this diarrhea data because the 35.4 percent diarrhea rate for the placebo arm -- the placebo is basically a sugar pill. There's no reason this should cause diarrhea.

If you went and looked at all of the other studies that have ever been done with placebos, the diarrhea rate total was usually around ten percent or so. So the 35 looked quite high to us. We couldn't quite figure that out.

So we certainly thought all of the diarrhea data was a little too high, so that's why we wanted to wait for the validation.

Q. And in addition, grade-three or higher diarrhea, 23 patients in the study experienced grade-three or higher diarrhea, which is, I think you said, seven bowel movements a

day, from taking a placebo pill?
A. Correct.
Q. What was your reaction to that data?
A. Again, we found the placebo data both for the all-grade diarrhea and the severe, which is the grade three, it all looked high. So there was certainly reason to be concerned about the high rates.
Q. But the 39.9 percent did not end up changing, right?
A. That's correct.
Q. Did any of the safety results in all of those tables end up changing from the validation process?
A. I believe that there were safety data that changed after the validation. I don't recall which specific parameters changed.
Q. You testified earlier that you were thinking about diarrhea as a first-cycle effect. Can you explain that testimony?
A. Yes. So with neratinib we tend to see that the diarrhea, severe diarrhea, is what we refer to as being a first-cycle effect. So what does a first-cycle effect mean?

What a first-cycle effect means is that in the first cycle, which is the first month you're on it, that's when you see the highest incidence, the highest frequency of this severe diarrhea.

It then decreases in its frequency over time, and

that tends to be the GI tract adjusting. And this is a very interesting thing that happens with neratinib was this very short-term frequency where you tend to see a very high incidence of this severe diarrhea in the first month. And then the longer you're on it, the less likely you are to get it.

So we tend to get a lot of questions from investors about that first cycle percent of patients getting grade-three diarrhea because -- especially if they, you know, drop off study or things like that, you can end up having a lot of missing data. So that was where the questions on dropout rates, et cetera, kind of stemmed from, which was that first-cycle grade-three diarrhea.

Q. Again, in this context you're using cycle as months?

A. That's correct. The first cycle is first month.

Q. All right. Let's turn to 176, which is the data as presented at ASCO at the end of the class period. If we could turn to slide 17. You've seen it before.

This is out of order. This is my fault.

Slide 176 is the ASCO data. And if you have it in front of you, I can orient you to the page as we're talking. Does this page list some of the grade-three diarrhea results as it was presented in June 1, 2015, at ASCO?

A. Yes. So slide 17 which is now up on the screen -- thank you for that. So what you're seeing here on the screen is

the percent of patients who got diarrhea by month in the ExteNET trial. So as I mentioned, the diarrhea with neratinib tends to be a first-cycle effect. What that means is that in the first month is where you see the highest incidence of it.

As you can see on the screen, it's that first month where you see the big spike. That's exactly what I'm referring to. So there's color coding on the slide where each color is a different grade of diarrhea. The grade-three, which is the severe, is the green. So you will notice on the slide the highest green bar is in month one, and then it drops dramatically after that.

So that's exactly the phenomena I was talking about, this first-cycle effect, where that first month has a very high rate of the severe diarrhea, and then it goes down over time.

If you look closely at that first-cycle effect percentage, you can see that comes out to be, you know, somewhere around 28 percent, is that -- I think they're trying to highlight it -- somewhere around 28 percent. That's that first cycle you're seeing. And that's exactly what we were referring to on the call.

Q. All right. Let's walk through that first bar. You say first cycle is the first month?

A. Correct.

Q. And the X axis there is months?
A. Correct.
Q. So if we look at month number one, there's a bar for orange, and that's grade one, right?
A. That's correct.
Q. Where would you put that? How many percentage?
A. That appears to be somewhere around what a 38 percent, grade one.
Q. All right. Now I'm going to test your math. Grade two brings it up to about where?
A. So I got, what, .62 minus .38. That's putting it at about 24 percent, if I'm going that correctly.
Q. All right. And then the green bar, which you testified you were thinking of as a first-cycle, grade-three diarrhea, what is that green bar approximately?
A. So I'm looking at about a .62 on the low end, and I'm looking at about a 97, I'm guessing, on the high. So it's probably around 25-ish, a little lower.
Q. Okay. And that's the -- we'll check that math later. But that was what you were referring to by grade-three diarrhea in the first cycle?
A. That's correct.
Q. Okay. You are asked some questions about the prophylaxis in the ExteNET trial. Again, can you remind us what prophylaxis means?

A. So neratinib, as we know, has the main side effect as you see is severe diarrhea. With the neratinib-related diarrhea, once it starts, stopping it is very, very challenging.

So what we looked at doing when we first acquired the drug -- first licensed the drug, I should say -- is trying to find a way to prevent it from happening in the first place. So the idea was to give Imodium or loperamide day one with neratinib. So the very dose of neratinib you take, you're also taking Imodium.

Because of that first-cycle effect you see on the screen, you really just need to do that in the first month. If you can do that in the first month, you've kind of gotten over the hardest part. And that was the approach we took was to give a very high dose of the drug, taper it down.

So start with a very high dose on the first day, lower the dose every day as you got out over that month, and see if that could have a preventative effect where we prevented the grade-three diarrhea from occurring.

Q. Okay. You were asked about whether there was prophylaxis in the statistical analysis plan for the neratinib, and I wanted to give you a chance to explain.

If we could go to Exhibit 1043, which is in evidence. It's in the right of the plaintiffs' binder. Exhibit 1043 was the clinical investigation of neratinib

protocol that you were asked about under number of subjects in that first set of numbers.

It says antidiarrheal medications. People who did not take it, 12.6 percent. Antidiarrheal medication percentage who did take, 87.4.

Can you explain what these numbers are with regard to, you know, an Imodium prophylaxis in the study?

A. So this is not patients taking it for prophylaxis. This is patients who are taking Imodium when they get diarrhea.

Q. But aren't they able to take it from the first day? Doesn't that effectively count as a prophylaxis?

A. No. The idea of prophylaxis is preventing the diarrhea from occurring in the first place. This would be treating the diarrhea once it occurs.

So if a patient takes neratinib and on the first day they get diarrhea, then, yes, you're just treating existing. The idea of prophylaxis is -- prophylaxis means prevention. You're trying to prevent it from happening in the first place. With, you know, 87 percent of the patients taking it, they're taking it after the diarrhea occurred. That's not prophylaxis.

Q. So if these 87.4 percent of patients take a prophylaxis after they get diarrhea, do they nevertheless show up in the numbers for grade-three diarrhea?

A. If they get grade-three diarrhea at all, they show up in

the numbers for grade-three diarrhea. The prophylaxis that is referred to, I believe it's in the bottom section of the slide where it says number of patients receiving antidiarrheal prophylaxis --

THE COURT: Slow down.

THE WITNESS: I'm sorry.

At the very bottom of the slide, please. So you'll notice that the last part there says number of subjects receiving antidiarrheal prophylaxis following dose hold and/or dose reduction for diarrhea. So what that's saying is it's patients who already got bad diarrhea and now they're trying to prevent it from happening again.

That's very different than what we're talking about. What we're talking about is prevent it from ever happening, not from happening again but from the severe diarrhea ever happening.

BY MS. JOHNSON:

Q. And again, in the ExteNET slide presentation at ASCO, you reported a number -- a range of diarrhea rates when that prophylaxis is actually used preventatively, if that's not duplicative. What results were you presenting there?

A. So in the ASCO slides that we presented were results from other studies we had done where again we were trying to prevent the severe diarrhea from ever occurring. This was giving Imodium the very first day with the first dose of

neratinib before diarrhea ever occurred to try to prevent it from ever happening.

By doing that, we were able to reduce the grade-three diarrhea rates down to anywhere between 0 and 17 percent.

Q. And briefly, you were shown the statistical analysis plan for the ExteNET trial, Exhibit 129. For time reasons I won't put it up, but you were asked about the sentence: Number of subjects receiving antidiarrheal prophylaxis following dose hold or reduction due to treatment emergent diarrhea will be summarized by the treatment arm.

You remember that discussion?

A. Yes.

Q. Will you explain what that means about the statistical analysis plan's view of diarrhea prophylaxis?

A. That was actually just a slide we had up, which again -- so that is very different. That was trying to prevent diarrhea from happening again after it had already occurred.

So there was -- the technical terms they use is primary prophylaxis, which is preventing it from ever happening in the first place, versus secondary prophylaxis, which is you've already got bad diarrhea and you want to prevent it from happening a second time. That would be secondary prophylaxis, which is what they mentioned on the slide.

What we were talking about doing was primary prophylaxis, preventing the bad diarrhea from ever occurring.

Q. All right. Let's go back to the conference call and talk about dropout rates. Exhibit 103 at page 9, you are asked one of a couple of questions about the dropout rates in the trial.

If you could turn to that in your binder.

A. (Witness complies.) Yes.

Q. All right. An analyst from Cowen, Mr. Schmidt -- is that the Cowen report we saw earlier with the two to three percent DFS rate mentioned?

A. Yes, that is correct.

Q. He asks: Thanks. And lastly, I think you probably do know the dropout rate from the trial. Could you remind us of that? You ask: Dropout rate due to side effects? Next page. He says: Sure, or anything if you have it.

You say: I don't have that. I apologize. That's part of the stuff being validated. So we anticipate typically in the neratinib studies, the legacy ones that were done before when Pfizer was running it without any prophylaxis, it was usually in the five to ten percent range, was the dropout rate due to AEs. So we'd anticipate it's in the same vein.

Do you see that?

A. Yes, I do.

Q. Would you just explain in your own words to the jury why you said that?

A. So I believe we discussed this yesterday and a little bit this morning. We have two distinct definitions here. One is what we refer to as discontinuations. The other one is what we refer to as dropouts.

Discontinuations means you stopped taking neratinib but you continued in the study, meaning you stopped taking neratinib but you kept going to your doctor and every three months the doctor was checking you to see if your cancer came back.

Dropout means up stopped taking neratinib and said: I'm going away from the study. You're not getting any more data from me. I'm not going to continue to go to my doctor and get my cancer checked. I'm disappearing completely as of this date.

The dropouts is always more concerning to investors because in the dropouts, you can end up having a lot of errors because of it -- so if you had, say, a thousand patients who are taking neratinib, and after two years, you know, 90 percent of them didn't have their cancer come back.

Well, if of those, you know, 900 hundred patients you had 100 who had dropped out so you didn't have a measurement on them, you can imagine there's an error rate in there where, look, maybe they dropped out of the study but

their cancer came back. You just don't know because they disappeared.

So it can introduce a lot of error with that type of missing data. That's why the dropouts is a very important aspect that the analysts were concerned about.

Q. All right. Let's look at data you had as of the July 22 conference call, Exhibit 124.

MS. JOHNSON: If we can go to slide seven.

Thank you.

BY MS. JOHNSON:

Q. All right. This is a table on diarrhea. It's where we see the treatment discontinuation line and the withdrawal from the study line. Can you explain what those two statistics mean?

A. So, the treatment discontinuations are what I was referring to earlier as discontinuations, meaning they stopped taking neratinib but they continued in the study. So they continued going to their doctor to see whether or not their cancer came back or not.

The withdrawal from study, that's the dropouts. Those are the ones who physically dropped out of the study or withdrew from the study, so we're not getting any more data from them.

Q. And which of those two categories were you referring to in answering the dropout question?

A. So Eric Schmidt's comment was on dropouts, and that would be displayed as withdrawal from study on the slide. So I believe we give a range of five to ten percent. And as you can see on the slide, the withdrawal due to diarrhea, which is the highest side effect, was 1.6 percent.

Q. All right. Final set of questions here on the dropout rate. You were asked a second question on the call about the dropout. Do you recall?

A. Yes. It was by Matt Roden at UBS.

MS. JOHNSON: Go back to 103.

BY MS. JOHNSON:

Q. Do you know -- is that a Dr. Roden?

A. I believe Matt is a Ph.D. I don't think he's a medical doctor. But, yes, I've known Matt a long time.

Q. Okay. And he says at the bottom of page 14 -- I'll start reading: I just wanted to clarify an earlier answer to a question. So you were asked about the dropout rate, and I think you wanted to defer to dropouts due to -- discontinuations due to adverse events. But can you just mention, or maybe I missed it, how many patients actually completed the year of therapy? Or another way of saying it is, how much missing data is there from the DFS analysis?

Do you see that?

A. Yes.

Q. And you answer: Yes. So in terms of patients who

dropped out due to AEs, like I said, historically with neratinib that should be somewhere in the five to ten percent range.

He asks: Okay, but do you have a sense for dropouts for any reason across the study? You say: No. The main one we would expect is due to AEs and obviously if they progressed or died.

Will you explain in your words what were you saying here about the dropout rates?

A. So again, the concern would be in the patients who, you know, dropped out of the study or actually withdraw from the study. There's basically three reasons patients are going to withdraw from the study.

One is that they had some type of an adverse event and they don't want to the participate anymore. The second is that, you know, unfortunately their cancer comes back. The third, and more unfortunate, if they happen to pass away.

So I didn't have -- obviously I couldn't give the other two numbers because that would be giving what the DFS rates were and things like that. But in terms of the ones due to the adverse event, which the main adverse event is diarrhea, the five to ten percent number was the range we were guiding to.

Q. So we saw that 1.6 number in the dropouts due to diarrhea, and the question is dropouts due to all AEs. How

does that number in your mind compare to 1.6?

A. If diarrhea is the most common side effect, you know, we can probably assume that the dropouts due to the diarrhea would be probably at most half of the dropouts in the study.

So if you doubled the 1.6 percent, that would give it a 3.2 percent. I would still be comfortable with the five to ten percent number then.

MS. JOHNSON: Is this a good place to stop, Your Honor?

THE COURT: Well done. Right on point.

So you have a bit of a break here. We won't be returning until Tuesday. Please be here for, quote, starting Tuesday at 9:00. So, four-day weekend. Don't discuss the case. Don't research the case. Keep an open mind.

Thank you.

THE CLERK: All rise.

(Open court - jury not present)

THE COURT: Sir, you may step down. We'll see you all on Tuesday.

MR. COUGHLIN: Thank you, Your Honor.

MS. JOHNSON: Thank you.

(Proceedings adjourned at 4:32 p.m.)

CERTIFICATE

I HEREBY CERTIFY THAT THE FOREGOING IS A TRUE AND CORRECT TRANSCRIPT OF THE STENOGRAPHICALLY RECORDED PROCEEDINGS IN THE ABOVE MATTER.

FEES CHARGED FOR THIS TRANSCRIPT, LESS ANY CIRCUIT FEE REDUCTION AND/OR DEPOSIT, ARE IN CONFORMANCE WITH THE REGULATIONS OF THE JUDICIAL CONFERENCE OF THE UNITED STATES.

/s/ Miriam V. Baird 01/23/2019

MIRIAM V. BAIRD
OFFICIAL REPORTER

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