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 4

SANTA ANA, CALIFORNIA

TUESDAY, JANUARY 22, 2019

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A P P E A R A N C E S

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EXHIBITS:

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SANTA ANA, CALIFORNIA; TUESDAY, JANUARY 22, 2019; 8:56 A.M.

THE COURT: All right. Is everyone here?

MR. CLUBOK: Yes, Your Honor.

MR. COUGHLIN: Yes, Your Honor.

THE COURT: The things I wish to discuss is, number one, a sick juror. Number two, estimates for when you think the trial will end. Number three, discussions about when we may discuss the very voluminous jury instruction disputes.

So let's start on what do the -- when do the parties think we will end? We've been aiming for Friday.

MR. CLUBOK: Your Honor, I think we're on schedule, given your timed -- I'm sorry, Your Honor. The parties spoke over the weekend. We compared our notes regarding how much time. We are actually in agreement over how much we each respectively used, assuming that we just allocated evenly the other time. But if you have -- obviously if you have guidance on that, we'll adjust. But we have an understanding amongst ourselves as the difference for the time we counted, and we can share that with you.

THE COURT: Okay.

MR. CLUBOK: Based on that, we made estimates about our remaining witnesses and how much time we calculated you gave us left in the trial. We think we're on schedule to finish on Friday -- perhaps, you know, a little bit into

early afternoon, but on Friday.

THE COURT: Okay. I have a hard stop Friday at three. I just happen to have that. But we would start on Friday at 8:00 and probably go without a lunch, which means we would get in a full day Friday. What does the defense think about when we might end?

MR. CLUBOK: On Friday, Your Honor.

THE COURT: The plaintiff. Excuse me. My bad.

MR. COUGHLIN: The same, Your Honor. I think that we should be able to get it all done before your hard stop at three.

THE COURT: Now, I told you I trust the counsel in this case, and I wasn't necessarily inclined to impose a timed trial. I must say the voluminous documents and the jury instructions have caused me to reconsider that, but I'm not as wedded to ending on Friday as I was before because I'm -- the Ninth Circuit conference was canceled. Remains canceled. That means I have all next week available.

Ms. Bredahl, I'm just going to ask you live. I haven't checked with you on this. Is this an impatient, get-it-done jury? I've got a doctor's appointment thing?

THE CLERK: Not at all.

THE COURT: Okay. So you have a little bit of flexibility on that. I think we did tell them Friday. I'm just telling you how that works.

So next, I should tell you my times charged to each person. I've not been charging any time in the back even though we've -- I've been working pretty hard in back on things like jury instructions and such. But I have the plaintiff going two and a half the first day, 7.3 -- I'm sorry. Two and a half the first day, 4.8 the second day, three hours the third day, for a total of 10.3.

I have the defense going 2.7 the first day. Their voir dire took a little bit longer. No, their opening statement took a little bit longer. 1.7 the second day, 2.6 the third day, for a total of seven. So we have the plaintiff at 10.3, the defense at seven, for a total of 17.3. That's how we're moving along.

Next is our sick juror. I would prefer not to reveal who it is. The juror phoned, and I don't think the juror was faking it. The juror had a very bad cough. The juror told me that the juror would like to serve but that the juror was fearful of infecting others.

Based on that call early this morning, I told this juror not to come in and infect others. The cough that I heard on the phone was particularly violent. It wasn't --

MR. CLUBOK: Let the record reflect a faked cough.

THE COURT: So I usually have a discussion with counsel about this, but I decided I didn't want this juror to come in. So your options are accepting that decision -- I'm

not asking you to waive any rights. I think your rights would be limited on that judgment call. But you can accept that decision without waiving any rights, or we can cancel today, phone this juror, see when this juror will get here live, cross-examine this juror in the jury box or whatever, and see if this juror remains. You follow me?

That's what I normally do when a juror wants to be excused, but I did not want this juror coming in. So feel free to talk amongst yourselves on that.

MR. COUGHLIN: I think, Your Honor, with all -- since we had planned on being done Friday and the way we have the witnesses coming in, I think -- and certainly that's the reason we sat three extra jurors -- that we'd like to move forward. We hate to lose anybody on the jury, but --

THE COURT: Okay. I'll say one other thing, which actually surprises me. Ms. Bredahl, are you ready?

THE CLERK: Yes.

THE COURT: This is a live statement. I am not sure what your answer will be now. But in the last 13 years, how often have we -- hold on. In the last 13 years, how often have we excused a juror?

THE CLERK: I think twice -- three.

THE COURT: Two or three. This will be number three or four. It amazingly doesn't happen in this court. I guess -- I'm not sure why. Maybe I convince them they're

serving their country. This particular juror was appreciating the opportunity to serve his or her country.

What is the defense position on this? Feel free to take any position you like.

MR. CLUBOK: Your Honor, that's acceptable to us.

THE COURT: Okay. So, Ms. Bredahl, would you tell the juror she is excused?

THE CLERK: Okay.

THE COURT: It is a she. It's juror number seven, as I recall. Chapman?

THE CLERK: Campbell.

THE COURT: Campbell. Yeah, juror number seven, Campbell.

With that, any questions to answer before we get going?

You need what?

Can you describe for me what's -- you see, let me just tell you the practicality of this. I don't know how to incorporate this into what I have.

MR. COUGHLIN: We'll --

THE COURT: It's always an issue, because I must tell you, if you look at this thing, it's quite a work in progress with lots of dates and lots of comments. When I get this, I kind of don't know what to do it with it.

MR. COUGHLIN: We'll update it, Your Honor. We'll

put in what's admitted and what's not and put it all in one document at the end of today, if that's all right.

THE COURT: All right. I'll stick this at the end and see how we use it. Thank you.

Anything else?

MR. COUGHLIN: No, Your Honor.

THE COURT: Okay. Then would the witness take the stand, please.

Is it Ms. Johnson?

MS. JOHNSON: Yes, Your Honor.

THE COURT: Take the podium.

Alan Auerbach, Plaintiffs' witness, previously sworn

THE COURT: While we're getting ready, I might have some preliminary discussions at 4:30 concerning the jury instructions. This will not be conclusive. This won't be the all-out, but it will be preliminary discussions.

THE CLERK: All rise.

(Open court - jury present)

THE COURT: Before you sit down, I'll let either juror number six or juror number -- there's an empty seat there. You can fill it if you want, or you can leave it there in honor of Ms. Campbell, who is feeling ill. She phoned in, and I excused her based on the seriousness of her cough.

She had a serious cough and she was concerned about

infecting you folks. She said how much she wanted to serve, but I did not want her to infect others. So we have an empty seat there which you can fill in if you want, or you can leave it open. Sometimes it's just easier to see the screen, and I'm not sure which way you're looking.

Welcome, all. Be seated. Appreciate you here on a Tuesday morning. Before you came, we were discussing excusing Ms. Campbell. We decided that is in the interest of justice, and we're ready to proceed.

You'll recall when we left you, we were into the examination of Mr. Auerbach by Ms. Johnson. Go ahead.

MS. JOHNSON: Thank you, Your Honor.

CROSS-EXAMINATION RESUMED

BY MS. JOHNSON:

Q. Good morning, Mr. Auerbach.

A. Good morning.

Q. To jump right in, we were talking on Thursday about whether prophylactic Imodium was part of the protocol for the ExteNET study. Do you recall that discussion?

A. Yes, I do.

Q. I wanted to ask you to clarify some facts on that point. To be very clear, did the original protocol developed by Wyeth provide for prophylactic Imodium?

A. So just to clarify, when we refer to prophylactic Imodium or prophylactic loperamide, we're talking about

giving the loperamide or the Imodium the very first day they start neratinib. The goal of that is to prevent the grade-three diarrhea from ever taking place. So it's to try to prevent the grade-three diarrhea from ever occurring.

There was no prophylaxis in the original Wyeth protocol that involved the implementation of any type of Imodium prophylaxis or any other drug prophylactically to prevent the grade-three diarrhea from occurring.

Q. All right. Let's take a look at the original trial protocol. It's Exhibit 619 in your binder.

MS. JOHNSON: This is not in evidence yet. I don't believe there will be an objection, but I would move 619 into evidence.

MR. COUGHLIN: No objection, Your Honor.

THE COURT: 619 is admitted.

(Exhibit 619 received.)

MS. JOHNSON: Thank you.

BY MS. JOHNSON:

Q. So Exhibit 619 --

THE COURT: Hold on. Let me just say that it is not on page 9 where you might expect it. I'm just making a record. It will help in the end. Okay. So 619, it's not in this big list. It is on this supplemental list. So 619 is admitted. Go ahead.

MS. JOHNSON: Thank you.

BY MS. JOHNSON:

Q. So 619 is the original protocol developed by Wyeth. What is the date there on the document?

A. The date in the upper left-hand corner and under the date of original protocol is listed as April 29, 2009.

Q. So back in this original protocol for the ExteNET trial, if we could jump to page 51 where it talks about treatment of diarrhea, if we can pull out that bullet point and can read along: Subjects should be instructed to treat diarrhea at its earliest occurrence. If significant diarrhea persists, prophylactic loperamide or other antidiarrhea medications are recommended.

Would you explain what the original trial protocol was requiring or permitting with regard to loperamide?

A. Yes. So as it says on the screen, subjects should be instructed to treat diarrhea at its earliest occurrence. If significant diarrhea persists, or continues, prophylactic loperamide or other antidiarrhea medicines are recommended.

So essentially what this is saying is that after the diarrhea has occurred, to prevent it from occurring again, you could give prophylactic loperamide. So this would not be prophylactic loperamide to prevent the grade-three or the severe diarrhea. This would be to prevent it from happening again.

So in the context that Puma used prophylactic

loperamide, it was to prevent the grade-three diarrhea from ever occurring. That was, as you can see, not done in this trial. What was done in this trial was after it had already occurred, trying to prevent it from happening a second or third time.

Q. If diarrhea occurred the first time, would that patient appear on the grade-three diarrhea statistics for ExteNET?

A. Yes.

Q. All right. How many protocol amendments were there in the trial?

A. To my recollection, at least 13.

Q. All right. Let's look at Exhibit 800, which is the 13th amendment to this protocol.

MS. SMITH: Your Honor, can we approach --

MS. JOHNSON: Can we approach?

THE COURT: Yes.

MS. SMITH: -- with a supplemental witness binder? All of the exhibits should be --

THE COURT: Okay. So this is the fifth binder for this witness, I believe, two from the plaintiff, three from the defense?

MS. JOHNSON: Yes, Your Honor.

Exhibit 800 is the 13th amendment to the trial protocol for ExteNET. I believe there's no objection. I would move for it to be admitted.

MR. COUGHLIN: No objection, Your Honor.

THE COURT: All right. Exhibit 13 is admitted?

MS. JOHNSON: 800, the 13th trial protocol amendment.

THE COURT: Exhibit 800 is admitted.

(Exhibit 800 received.)

BY MS. JOHNSON:

Q. So this lists all of the amendments to the trial protocol, and this one is dated January 16th, 2014. Let's jump to the same section, which is page 37.

MS. JOHNSON: If we can pull up the same bullet point.

BY MS. JOHNSON:

Q. It reads: Subjects must be instructed to treat diarrhea at its earliest occurrence, et cetera. Is this the same language, similar or same language to the trial protocol that Wyeth originally put in place?

A. So if I can just read this: Subjects must be instructed to treat diarrhea at its earliest occurrence. If significant diarrhea persists, prophylactic loperamide or other antidiarrheal medications are recommended.

This appears to be the exact same language in the original one, which is not recommending anything to prevent the grade-three diarrhea from occurring. It is recommending to prevent it from occurring again, a second or third time

after it has already occurred.

Q. All right.

We looked at Exhibit 1043 in your testimony previously, and I just wanted to be crystal clear about what the numbers on 1043 mean.

This is in evidence, and we talked about this 87.4 number of patients who took loperamide after they got diarrhea. I wanted to ask you: How many of ExteNET patients of that 87.4 percent used prophylactic loperamide with their first dose of neratinib?

A. We looked at this -- I remember that my team analyzed this in great detail. My understanding was the analysis showed that no patients used prophylactic loperamide starting day one to try to prevent the grade-three diarrhea.

Q. And was that figure, no patients, zero patients, consistent with the 13 trial protocol amendments in place for ExteNET?

A. Yes.

Q. A couple more questions on the safety of neratinib. Did you ever speak publicly about the safety other than the July 22nd, 2014, conference call?

A. Yes. To my recollection there were two instances when we discussed the safety in the ExteNET trial, and more specifically the grade-three diarrhea rates.

Q. All right. Was one of them a Leerink conference?

A. Yes. That's correct.
Q. And was that conference public?
A. Yes. So Puma is a public company, so we often get incited to conferences that are held by investment banks. Sometimes they can be large banks like JPMorgan, or they can be some of the smaller banks. Leerink is a smaller, healthcare investment bank that just focuses in the healthcare field.

These conferences tend to be -- you go into a room, and there can be anywhere from 50 to 100 investors sitting there. You do a full PowerPoint presentation, and the presentation is webcast so all investors can listen to it live.

Q. Was there also a transcript of that conference that you're describing?
A. Yes. After every presentation at a conference like that, a transcript is always published as well.
Q. All right. If we can look at Exhibit 851, which is the Leerink conference transcript in February 2015.

MS. JOHNSON: I believe there's no objection. We would move that into evidence.

MR. COUGHLIN: No objection, Your Honor.

THE COURT: 851, correct?

MS. JOHNSON: Correct.

THE COURT: 851 is admitted.

(Exhibit 851 received.)

BY MS. JOHNSON:

Q. So Exhibit 851 is the transcript from the Leerink conference that you're discussing. Let's jump to page 2 to see what comments you make.

MS. JOHNSON: If you can pull up the paragraph, thank you, starting with the second sentence: As I mentioned, the ExteNET trial, which is our phase III, did not use Imodium prophylaxis, so the grade-three diarrhea rates are in line with what we've expected in the 30 percent to 40 percent range.

BY MS. JOHNSON:

Q. Do you see that?

A. Yes.

Q. So as of this time period, February 2015, had the safety data now been internally validated by Puma?

A. Yes. To my recollection we had internally validated the safety data in January of 2015. So by this point we had a fully validated safety database.

Q. You mentioned that you also presented a slide deck. Did that occur at the Leerink conference?

A. Yes. There's an investor PowerPoint slide deck that we presented as well.

Q. All right. I'd turn your attention to Exhibit 977.

MS. JOHNSON: With no objection I would move 977

into evidence.

THE COURT: Without objection 977 is admitted.

MR. COUGHLIN: No objection, Your Honor.

(Exhibit 977 received)

BY MS. JOHNSON:

Q. So this is the PowerPoint you presented, correct?

A. That is correct.

Q. And let's look at slide seven which talks about the prophylaxis with loperamide. What is this slide showing with respect to the diarrhea rates in prior studies of neratinib?

A. So on this slide what you see is seven studies that have been done with neratinib. The three columns on the left are studies that we did where we didn't do anything to lax the patients to prevent the grade-three diarrhea.

As you can see on the slide, when that occurred, our grade-three diarrhea rates ranged anywhere from 27 percent to 53 percent. Then on the right-hand side are the studies that we did where we did do something to prophylax the patients.

So as you can see, the third row down it says loperamide prophylaxis regimen. You can see for the first three columns, it says none in each one. Then in the next three columns, it says -- it lists a 16-milligram dose. Going down, what it's saying is we start with a very high dose of Imodium and then we taper it down over the period of

that first cycle, which is the first month. That's when the grade-three diarrhea occurs.

By doing this, as you can see on the highlighted part of the slide, we were able to reduce the grade-three diarrhea rates down to anywhere between 0 and to 17 percent.

Q. You were asked some questions about the total patient numbers in these studies being relatively low. Does that cause you any concern?

A. Well, if I look at those studies, which is the total patients in, if I look at the studies done with no prophylaxis regimen, it looks like it's anywhere between 15 to 66 patients in each of those trials.

If I look at the studies done with the prophylaxis, it appears those trials had anywhere between 6 and 41 patients in those trials. So I would say it's fair to assume that the two are similar. There's slightly more patients in the ones where no prophylaxis was done, but I don't think that appears very meaningful. I mean, we do -- they appear to be very similar.

Q. What was the duration of the diarrhea in the studies that did use a loperamide prophylaxis regimen?

A. So we haven't really discussed this, but I'm more than happy to, which is that not only did we find when we used the prophylaxis that it reduced the incidents of the grade-three diarrhea, but it also appeared to reduce the duration of all

the diarrhea.

So as you can see on the slide, in the studies on the left, when we didn't do anything to prophylax the diarrhea, patients had on average 14 days of diarrhea. It's approximately two weeks the patients had diarrhea.

When we used the prophylaxis, we -- that was reduced down to two days. So as you can imagine, you know, reducing the incidents of the grade-three diarrhea is something that makes the quality of life for the patient much better. Also, reducing the duration of it down from two weeks to essentially two days, that also is a benefit to the patient.

Q. Is this conference that we're talking about the only time you spoke publicly about the ExteNET data after the July 22nd conference call?

A. I seem to remember that we also attended a conference held by RBC, which is Royal Bank of Canada, which was a similar conference. I believe it was a week or two earlier than the Leerink one. And we made similar comments with regard to expecting the grade-three diarrhea rates to be between 30 and 40 percent in the ExteNET trial.

Q. Finally, does neratinib cause any long-term side effects?

A. I'm not aware of any long-term side effects that have been caused by neratinib.

Q. Let me ask you about the Kaplan-Meier curves. Exhibit 123 is in evidence. At slide -- page 10 there's a picture. We've seen this before. I wanted to ask you, the curve on the neratinib arm has a dip, what appears to be a dip at the end. Does that mean anything about whether the curves were separating or coming together at two years?

A. If you look at the shape of the curves, you can kind of see that they, you know, contract, expand, contract, expand. That tends to be the normal, you know, sinus rhythm, if you will, that they go into.

That doesn't appear to show to my eye a narrowing at the end. It just appears to be, you know, similar to the patterns that have been seen earlier on that just appears to be continuing.

Q. And why is that?

A. You know, I think that a lot of that just has to do with, you know, the way the disease or occurrences are occurring. I don't think it's, you know, anything meaningful. I think that just is a pattern we're seeing there, the kind of expanding and contracting of the curves over that 24-month period.

I mean, in the end the numbers are showing that we're clearly seeing an expansion -- that the curves are separating. It does not appear that those curves are narrowing.

Q. You were asked questions about the conference call obviously on Exhibit 103 regarding these Kaplan-Meier curves. Do you recall that?

A. Yes.

Q. And Dr. Liang asked you: Can you give us a sense as to whether the separation is widening over time? Do you recall that?

A. Yes.

Q. And then here is your answer. For the sake of time I'll skip to the end. Then you say: The curves appear to be continuing to separate as you go out year over year, and the absolute DFS difference is increasing year over year as well.

What data for patients in the ExteNET study beyond two years did Puma have in its possession at the time you gave this answer?

A. So to give a time frame here, the ExteNET trial started in April of 2009. I believe the cut that we took for the data was in October of 2013. So as you can imagine, we did have patients that had gone out more than two years.

So at the time we got the data in July of 2014, we were able to look at all the patients, all the data. So not just cutting it with two years of follow-up, but looking at kind of all of the data as far out as we had patient data.

Q. Did you see that data that you've just described prior to July 22nd, 2014?

A. Yes, I recall seeing it.
Q. So to be very clear, prior to July 22nd, 2014, did you see curves showing the patients that had been in the ExteNET study beyond the two-year cutoff?
A. Yes. I remember it being shown to me. It was shown to me in -- on paper. My recollection is that the data that was shown to me showed a 2.3 percent DFS benefit at two years and approximately 3.5 percent at three years.
Q. Does Puma still have in its possession today the data set that existed as of July 2014?
A. Yes. We ended up locking that database, so we saved it as is in that form. And we still have that today.
Q. Is that locked data set kept by Puma in the ordinary course of its business?
A. Yes. We do keep that.
Q. Does Puma still have the piece of paper that you testified recalling seeing, showing that data beyond the two-year cutoff?
A. I am not aware that we have been able to find the exact piece of paper that was shown to me in July of 2014. However, my recollection is that we have on numerous occasions redone that analysis at later dates using the exact same data set that was used in July of 2014.
Q. You were asked a number of questions by Mr. Coughlin about: Did the data disappear? Did you have a computer

shutdown? I just wanted to ask you to explain in your own words, you know, was there a reason Puma might not have kept printouts when it had the locked data set preserved?

A. In terms of us keeping the exact piece of paper it was printed on, that's just not something we do in the normal course of business. If something is shown to someone, it's shown to someone.

And that's, you know, I -- the person who created it, I -- I don't know what they did with that piece of paper that was shown to me. So I -- I don't know the answer as to why that person didn't keep the exact piece of paper that was shown to me.

Q. So regarding that locked data set that still exists with the data that was in existence as of July 2014, was that the same data set used to create the topline analysis that we've seen, Exhibit 123 in this trial?

A. Yes. Correct.

Q. And was that the same data set used for the ASCO presentation that we've also seen, Exhibit 176?

A. Yes. That is correct.

Q. Was that data set also submitted to the FDA?

A. Yes, that was submitted to the FDA.

Q. In your understanding do all parties in this litigation have that locked data set that existed as of July 2014?

A. My understanding is that the plaintiff was given that

database that was locked as of July 2014 sometime in 2017 so that they could run whatever analyses they would like to with that data.

Q. And you mentioned that you have asked your team to run analyses with the data that was locked as of July 2014, right?

A. That is correct.

Q. Who did you -- whom did you ask to prepare that analysis?

A. Bin Yao, who is our head of biostatistics. I requested that he rerun those analyses because I believe it was asked for by the plaintiff.

Q. Do you ask your team to run those types of analyses using the July 2014 locked data set in the course of Puma's business?

A. Now we have much longer-term data going out, you know, multiple years. So I can't really recall -- other than this litigation, I can't really recall too many times we've had to go back to that data set. We have it if we need it, but I don't recall us needing to. We've usually worked with the more updated data set.

Q. I'd ask you to turn in your binder to Exhibit 985.

MS. JOHNSON: And I understand there is an objection to this document.

BY MS. JOHNSON:

Q. I want to ask you, Mr. Auerbach, is Exhibit 985 the curves that were created more recently but using the data set as locked on July of 2014 -- in July of 2014?

A. Yes. This to my recollection is the data that was shown. This is showing, let's see, 94.2 minus 91.

MR. COUGHLIN: Your Honor, there's an objection to this exhibit.

THE COURT: Sustained. Don't reference the document until it's admitted.

THE WITNESS: My apologies.

Yes. It appears to show the numbers I said, which was 2.3 percent and 3.5.

BY MS. JOHNSON:

Q. And does Exhibit 985 reflect the analysis that you asked to be run on the July 2014 locked data set?

A. Yes.

MS. JOHNSON: I would move Exhibit 985 into evidence.

MR. COUGHLIN: I would object, Your Honor. I mean, they just made up this curve in the last year. They gave it to us. We cannot replicate it. We have tried to. If you take a look at it, they use the FDA censoring rule.

THE COURT: Hold on. Here I resist too much of a speaking objection.

MR. COUGHLIN: Okay. I understand.

THE COURT: And your objections are?

MR. COUGHLIN: My objection is it was just created after the fact. It is really an expert-type documentation, but an employee has been tasked to create it from Puma. We cannot and have tried with our experts to replicate it. And they used a censoring rule, the FDA censoring rule, which was not used on the original --

THE COURT: So in terms of objections --

MR. COUGHLIN: There's no basis for this chart.

THE COURT: Foundation. What else?

MR. COUGHLIN: Foundation. It's expert-type testimony done by an employee after the fact. It was done at the time --

THE COURT: Okay. Other objections? Hearsay, whatever?

MR. COUGHLIN: Hearsay: It's a party opponent trying to admit it.

THE COURT: Response?

MS. JOHNSON: Mr. Auerbach has laid the foundation. It is the type of analysis that Puma employees do in the ordinary course. It was created --

THE COURT: You don't think this is, what, an 803.6 exception to the hearsay rule? You think this is ordinary course? I mean, he's gone back and forth on that. I can

read you his testimony: In terms of us keeping the exact piece of paper it was printed on, that's just not something we do in the normal course of business.

I do not believe this is an 803.6, so move on to other arguments.

MS. JOHNSON: Your Honor, it's not hearsay because it demonstrates what Mr. Auerbach saw in the time period because -- I believe Mr. Coughlin has just acknowledged that they do have the data set, so they can cross-examine on the topic on the numbers, but they have --

THE COURT: The truth of the matter is it's an interesting response in a case where there are allegations of it being misleading. What do you say about that? I believe the argument would be it's not offered for the truth. It's offered to show that it can't be -- that it wasn't misleading because this is what he thought.

MR. COUGHLIN: Well, Your Honor, it is offered by a party opponent that created it himself. So it creates a misleading impression. They just created it. We cannot duplicate it. It's certainly not a business record.

It's really the subject of expert testimony, and yet Mr. Auerbach, who did not create it, is up here testifying he saw something like this. And it's just completely inappropriate. And on its --

THE COURT: Would you like to take him on voir dire

at all?

MR. COUGHLIN: Sure.

THE COURT: Would you like to ask him some questions?

MR. COUGHLIN: Sure.

THE COURT: Let's do a brief voir dire by you.

You all can remain where you are. I don't want the voir dire to get extensive.

(Whereupon, the cross-examination of the witness was interrupted for examination as follows:)

VOIR DIRE EXAMINATION

BY MR. COUGHLIN:

Q. You say you saw a curve something like this?

A. Yes, that is correct.

Q. Okay. And the censoring rule that was in effect at the time in -- for the main data in July of 2014, didn't you have -- you had a different censoring rule than the FDA; is that correct?

A. No. There were two censoring rules that were used. One was --

Q. Wait a second.

A. -- the Puma censoring rule, and one was the FDA --

THE COURT: Next question.

BY MR. COUGHLIN:

Q. Mr. Auerbach, the main rule for the censoring rule of

the population that you discussed on July 22nd, that was the Puma censoring rule; is that correct?

A. It was done with both, and the same results were obtained.

Q. You did both on July 22nd and the same results --

THE COURT: Be careful with the word you. It's vague. His company? Him? His aide? Who?

BY MR. COUGHLIN:

Q. Mr. Auerbach, you did both results on July 22nd at the time of the conference call?

THE COURT: Okay. Again you say you. You might not have been listening to what I said. It's pretty important.

BY MR. COUGHLIN:

Q. Mr. Auerbach, Puma did both types of analysis in July of 2014 and got the same results?

A. My recollection is that the statistical team did both analyses on the primary analysis, the two-year data, and using the Puma censoring rule and the FDA censoring rule got the same results.

Q. And the SAP dictates that Puma for reporting purposes at this time for the primary analysis that Puma uses the primary censoring rule that Puma had, which means that you don't censor somebody if they've missed two or more visits; is that correct?

A. I don't recall exactly what the Puma censoring rule was.

THE COURT: You're getting into a cross-examination of the exhibit, and these questions aren't directly going to concerns I've been expressing about admissibility.

Are you finished on your voir dire?

MR. COUGHLIN: Just one more.

BY MR. COUGHLIN:

Q. You didn't create this document; is that correct?

A. Can you clarify when you say you? Me, Alan Auerbach, or Puma?

Q. Puma created the document, but you personally -- this is a you personally -- you did not create this document?

A. No. This was done by our statistical team.

MR. COUGHLIN: He has no personal knowledge of this document. If they want to bring Mr. Yao, who is scheduled to testify, in to talk about it and get the foundation --

THE COURT: All right. The objection is sustained.

MR. COUGHLIN: Thank you, Your Honor.

MS. JOHNSON: Thank you, Your Honor.

(Whereupon, the cross-examination of the witness resumed as follows:)

CROSS-EXAMINATION RESUMED

BY MS. JOHNSON:

Q. Without referencing the numbers or the information in this exhibit, does the data you saw in July of 2014 about

patients that were in the trial longer than two years reflect that the curves were continuing to separate as you go out year over year?

A. Yes. That's correct.

Q. You were asked questions about the censoring rules. Why was Puma using the FDA censoring rule when it looked at the data?

A. The FDA has produced guidance documents, which are kind of manuals for the industry on how data should be interpreted and analyzed. The censoring rule that was in our statistical analysis plan was different than the one that was in the FDA's guidance. So we were always wary that it was a very high probability that the FDA would not accept our analysis using our censoring rule.

So to hedge, if you will, we would analyze the data using both of them. For the primary analysis, which was our two-year data, the analysis looked the exact same. We still got the same 2.3 percent difference and the hazard ratios were essentially the same.

So we didn't really feel for the primary end point of the trial that there was any risk from that perspective.

Q. You were asked questions on Thursday about the number of patients in the study going out beyond two years, and you were asked questions about eight events. Do you recall that discussion?

A. Yes.
Q. I wanted you to clarify. Does that mean there are eight patients in the study going out beyond two years, or eight events? Can you explain that?
A. Yes. To clarify, the eight events means there are eight patients who had their cancer return or passed away. That's not the number of patients that have been followed. That number was much larger than that.
Q. When you say much larger, how many patients did you have in the database going out beyond two years, you know, immediately after the two-year cutoff that you used for the topline data?
A. My recollection is it was approximately 400.
Q. All right.

Did you review analyst reports after the ASCO conference in June that talked about the Kaplan-Meier curves?
A. Yes, I did.
Q. All right. I'd ask you to turn to Exhibit 969, which is a Leerink analyst report put out by the same Dr. Liang who asked you the questions about the Kaplan-Meier curves. The date of the report is June 2nd.

MS. JOHNSON: I would move 969 into evidence. I believe there had been no objection subject to the limiting instruction that the parties have already indicated they've agreed upon.

THE COURT: All right. Then without objection, 969 is admitted.

(Exhibit 969 received.)

BY MS. JOHNSON:

Q. All right. So this is a June 2nd, 2015, analyst report by Dr. Liang who asked the questions. He has a paragraph that says: Bottom line.

MS. JOHNSON: Can we blow that up?

BY MS. JOHNSON:

Q. He says -- now, this is after the presentation at ASCO. He says, focusing on the comments about the curves: Clearly separated disease-free survival DFS curves that persisted to widen somewhat from one to two years.

Do you see that?

A. Yes, I do.

Q. What was your reaction to seeing his comment about the clearly separated curves?

A. I felt that it was very -- my recollection is I felt that he was being very accurate. A big concern that people had with regard to the ExteNET curves is that there was another study that had been done with Herceptin, which we talked a lot about last week.

Herceptin is also a drug that blocks HER2, and in that study they had looked at giving two years of Herceptin versus giving one year of Herceptin. So they were trying to

see is more better, if you will. What they found in that study was that if you gave two years of Herceptin versus one year of Herceptin, the curves separated at two years and then came back together by year five. So there was no benefit overall.

So a big concern investors had with regard to this study was this was the first study post that Herceptin trial that looked at giving a HER2 agent for an additional period of time. The concern was, would the effect be short-lived, which meant that the curves would separate and come back together. Or would it mean that the curves would stay separated, meaning that there was a long-lasting impact on the patient.

So that clearly separated curves was something that, you know, we had heard from investors they found to be encouraging.

Q. Let's look at one more, Exhibit 764.

MS. JOHNSON: No objection, as I understand it, subject to the same limiting instruction.

THE COURT: Without objection 764 is admitted.

(Exhibit 764 received.)

BY MS. JOHNSON:

Q. 764 is a UBS report from June 1, again after the ASCO conference, after everyone has seen the curves. This analyst from UBS writes about the curves.

MS. JOHNSON: If we can blow that up.

BY MS. JOHNSON:

Q. Curve separation, impressive. Did you have the same reaction that you've just described to this particular report?

A. You know, his opinion being the curves are impressive is his own opinion obviously. But him noting that the curves were indeed separating I felt was an accurate statement.

Q. Did you review any analyst, media, or investor comment that viewed the curves as negative news?

A. I don't remember any reports either from analysts, from investors, or from the media that suggested that the Kaplan-Meier curves were in any way negative.

Q. To be clear, have you heard any person other than plaintiff or its hired experts say that the curves were not separating?

A. I don't have any recollection of anyone -- breast cancer physician, investor, et cetera -- saying anything to us suggesting the curves were not separating.

Q. All right.

You were asked a number of questions about --

THE COURT: May I -- just so it's on the record, 764 is not on the initial list I have. Go ahead.

MS. JOHNSON: Thank you.

BY MS. JOHNSON:

Q. You were asked a number of questions about data you provided to Pfizer. Do you recall that discussion?

A. Yes.

Q. And you testified that you provided Pfizer with three-year simulated curves. I wanted to ask you to explain what is a simulated curve.

A. So my understanding of this is that the way these simulations were done is that it took the actual ExteNET data for years one and two and the period after that, so all of the data we had, even the patients beyond two years. Then it is assumed that the hazard ratio --

MR. COUGHLIN: Your Honor, I have to object. There's no foundation. He used the word you, that he had done it, but I believe that's one of the things that Puma did it, not him personally.

THE COURT: I have some concern about that. So let's begin -- so one objection would be, vague. Then depending on the answer to that, we might get foundation.

The objection is sustained. Rephrase your question or lay a foundation.

BY MS. JOHNSON:

Q. I believe my question was what are simulated curves. If you can be clear about what those simulated curves were that were provided to Pfizer?

A. So the Puma biostatistical team performed a simulation, and my understanding of what was done is that they took the actual ExteNET data set and assumed that for the period after two years, the patterns of when the cancers came back in these patients during the first two years continued after that period.

So the simulated curves represent the actual ExteNET data, is my recollection, for time point 0 to time point 2. Then the simulation kicks in after the simulated portion of it, is the time point after two years.

Q. And did those Puma biostatisticians run those curves at your direction?

A. Yes.

Q. Exhibit 475 is in evidence. If we could look at figure 1.2. Are these the curves that you're describing that were provided to Pfizer?

A. Can we expand that on my screen?

Yes. So the curves that were provided --

THE COURT: Let me just say my record shows that 475 was admitted for five pages.

MS. JOHNSON: Correct.

THE COURT: Okay.

MS. JOHNSON: And the extra pages have been added to your binder, Your Honor.

THE COURT: All right.

THE WITNESS: So this -- the original curves that were shown last week had a scale where the Y axis or the vertical axis went from 0 to 1. In addition, in that e-mail we sent Pfizer expanded curves where we expanded that range. You'll note it goes from 0.8 to 1.0. The reason was so that you could get a better view of the Kaplan-Meier curves.

So what the Y axis represents is basically the disease-free survival. And then to express it as a percentage, you multiply that number by 100. So 1.0 would be a hundred, and 0.8 would be 80 percent.

MS. JOHNSON: Thank you.

And for the record, this is page 4 of Exhibit 475.

BY MS. JOHNSON:

Q. Did the number at the end of three years of this simulated curve tell what the difference was at two years?

A. There are two ways of being able to derive that. So as I explained earlier, this -- the simulation when the statistician performed it uses the original ExteNET data for years 0 through 2. And then the simulation is after the two years.

So you'll notice that it says on the screen at year three it's a 91.6 percent DFS rate in the neratinib arm, and 88.8 in the placebo arm. So that's a difference of 2.8 percent at three years.

In a previous document that we were asked about --

that I was asked about last week, we had told Pfizer that the preliminary three-year data curves that we were generating were showing a delta of 0.5 percent year over year.

So if you took a 2.8 percent that is shown there and subtract the 0.5, that would give you a 2.3 percent benefit at two years. So that was one way that Pfizer could have derived this.

Second is if you actually look on the curves themselves, if you look at going at month 24, if you look at that delta, it comes out to be roughly 94.1 percent for the neratinib arm and approximately 91.8 percent -- it's -- it basically shows a 2.3 percent delta at two years.

So it's something you can do with a ruler, or obviously it can be done digitally as well. But that curve essentially, if you just map it across, will show you that 2.3 percent delta at two years.

Q. And this is information you provided to Pfizer in the August to November time period?

A. Yes, that is correct. I seem to recall this would have been sent somewhere around the October, November 2014 time frame.

Q. Yes. We can look at page 1 of this same exhibit and see when it was sent.

MS. JOHNSON: If you can pull up page 1.

BY MS. JOHNSON:

Q. The date is November 5th. Do you see that?

A. Yes. That's correct.

Q. Okay. Let me briefly ask you to explain how do the assumptions of the simulated curves relate to the three-year data that you testified you saw with actual numbers? Is there a relationship there?

A. It would've been the same data set -- my understanding from the statisticians is that it's a starting point, is the same data set. And then the simulation is used after year two on top of that.

Q. Okay. Plaintiffs' expert, Dr. Jewell, testified about the importance of the event numbers in each arm, the 109 events on the placebo and the 70 disease events on neratinib.

Did you provide Pfizer with those numbers?

A. I seem to recall that we sent Pfizer a breakdown of the events in each arm of the study. So last week I believe there was an exhibit shown where we showed which of the recurrences, the cancers that came back.

Some of them were with the breast themselves. Some of them were what we call distant, meaning they went to the liver or the lungs. And there kind of a detailed breakdown. My recollection is that that exact slide was sent to Pfizer as well.

Q. If I could direct your attention to Exhibit 994.

MS. JOHNSON: I don't believe there will be an objection.

MR. COUGHLIN: Let me get 994.

THE COURT: Take your time.

MR. COUGHLIN: Your Honor, I have -- the only objection I have is that for completeness, we have to put in Exhibit 796 and 486 if we're going to put in -- start putting in other Pfizers. Your Honor has already ruled in your motion in limine that this document -- that these documents do not come in.

THE COURT: Okay. Hold on. 994 is not on my original list, so give me a moment. And 994 is not on my supplemental list.

MS. JOHNSON: For the record, it's Exhibit 994R.

THE COURT: 994R is on my second supplemental joint exhibit list. It sounds like you would allow it in if other exhibits came in on the rule of completeness. What are those other exhibits?

MR. COUGHLIN: Those other exhibits, Your Honor, are 796 and 486.

THE COURT: All right.

What's the defense position on 796 and 486?

MS. JOHNSON: Give me a second.

THE COURT: Sure.

MS. JOHNSON: Your Honor, there's no relationship

between the exhibits.

THE COURT: So your -- you don't accept the offer?

MS. JOHNSON: I do not.

THE COURT: Okay. Aside from completeness, what are your objections to 994?

MR. COUGHLIN: I have no objections to its admission, but I --

THE COURT: I understand.

MR. COUGHLIN: We've got a ruling out there, and I just want it complete.

THE COURT: Hold on. It's a simple question. Aside from an argument on completeness, what objections do you have to 994 so that I may rule on them? It sounds like it's a motion in limine. You tell me. I don't want to put words on your mouth. I just have to rule, and I have to have an objection to rule on it.

MR. COUGHLIN: I object that this document was not created in the ordinary business, but I have no objection to its admission.

THE COURT: When you say it was not created in the ordinary business, your objection to 994 sounds like hearsay.

MR. COUGHLIN: It is.

THE COURT: Your response to 994 under a hearsay objection?

MS. JOHNSON: It's not offered for the truth of the

matter whatsoever. It's offered --

THE COURT: What is it offered for?

MS. JOHNSON: For what -- for evidence of what was shown to Pfizer during this time period which the plaintiff has put into dispute.

THE COURT: All right. Just a moment. Now I need to find the exhibit. I'm looking at this exhibit on the issue of hearsay. I have in front of me a two-sided document of eight pages. All right. The objection is hearsay.

The defense says it's not offered to prove the truth of the matters asserted here. Succinctly tell me what it is offered to prove.

MS. JOHNSON: What information was provided to Pfizer to respond to allegations that Pfizer did not see enough data that it was requesting.

THE COURT: All right. The hearsay objection is overruled, and the document then is admitted.

MS. JOHNSON: Thank you.

(Exhibit 994R received.)

BY MS. JOHNSON:

Q. So let's put up Exhibit 994R. This document, this e-mail was provided to Pfizer on October 13, 2014, right?

A. That is correct.

Q. And the attachment was information you sent to Pfizer on that date, correct?

A. Yes, that is correct.
Q. If we'll go to page 1 of the attachment, was this information provided to Pfizer in the October 2014 time period?
A. Yes. Can we expand that, please?
Q. Please explain how these numbers provide the event numbers and the patient numbers in each arm to Pfizer.
A. So what you're seeing on the screen is the location of where, when the cancer came back, the cancer was found. So this is basically the site of recurrence. So you can see there are local recurrences, meaning it came back to the same breast that the cancer was originally found in.

You can see that there are some that are called distance recurrences, and they're listed where they -- these are again ones that went far away from the breast. You can see the exact site of those is listed -- the prone, the brain, the lymph node, the liver, the lung, et cetera.

So if you add up each of those columns, it should be, if I'm correct, 70 in the neratinib arm and 109 in the placebo arm, which exactly matches what the ExteNET data showed.
Q. And did you also provide Pfizer with the patient numbers in each of the neratinib and placebo arms?
A. Yes. It's at the top of the screen and it's highlighted.

Q. And the question about the last row is that deaths without recurrence. What does that refer to?
A. So you'll see at the top it says type of DFS events. So again at the end point of this trial was DFS. What DFS stands for is disease-free survival. So that means the time with which the patient lives either without the cancer coming back or they pass away.

So the deaths without recurrence are patients who passed away, but it wasn't prior to the breast cancer coming back.
Q. It was not or it was prior?
A. Was not. Death without recurrence.
Q. Thank you.

Did you also provide Pfizer with forest plots for the subgroup data in the ExteNET study?
A. Yes. I believe that was presented in the exact same document.
Q. If we can go to page 3 of this document for an example of the forest plot. Is this a forest plot of subgroup data that you provided to Pfizer in the October time period?
A. Yes. Can we please expand that? Yes. Thank you. So, yes. This is what's referred to as a forest plot. Specifically what it does is it looks at each of these subgroups or subtypes of patients and whether or not each one of them derived benefit from neratinib.

So the way of looking at this is you'll see the line in the middle of the screen. If the dot that you see is on the left-hand side of that line, of the 1.0 line, that means that those patients got more of a treatment effect from the neratinib.

If it's on the right side of that line, it means that the placebo group had a better treatment effect. So as you can see from that graph, the majority of those dots are to the left-hand side of the line, meaning that all of those subgroups got a benefit from the drug.

Q. And this information was requested by Pfizer and provided to Pfizer by Puma in this time period?

A. Yes. That is correct.

Q. Did Puma also provide Pfizer with the 39.9 percent diarrhea number in this time frame?

A. Yes. I seem to recall that we sent them the full AE data they had requested, and in that was the grade-three diarrhea rate being 39.9 percent.

Q. Did that information also include the 16.8 percent discontinuation rate due to diarrhea?

A. Yes. I seem to recall we sent that separately, and that included the treatment discontinuations and also included the dropouts, which is the patients that completely dropped out of the study.

Q. And after all of this back-and-forth communication about

data provided to Pfizer, was Pfizer satisfied with the information Puma provided?

MR. COUGHLIN: I'd object, Your Honor.

THE COURT: I need to hear an objection.

MR. COUGHLIN: I would object to how would he know how Pfizer --

THE COURT: Here's what I would prefer. Objection, foundation.

MR. COUGHLIN: Objection, foundation. Sorry.

THE COURT: Is that what you're saying? Just a moment. The objection is sustained.

BY MS. JOHNSON:

Q. Did you have conversations with Pfizer after this time period?

A. Yes. We continued to have conversations with Pfizer regularly.

Q. Based on those conversations, is it your understanding that Pfizer was satisfied with the information you provided them?

MR. COUGHLIN: I'd object. Still hearsay, Your Honor.

THE COURT: You went from foundation to hearsay.

MR. COUGHLIN: I did.

THE COURT: I'm not sure what still means. All right. Just a moment. Response?

MS. JOHNSON: It's provided for his state of mind and what he understood about what Pfizer was asking for, not for the truth.

THE COURT: State of mind I believe goes to the declarant, not the hearer. But I think you're making an argument that it's not offered to prove?

MS. JOHNSON: Not offered to prove the truth. That's correct.

THE COURT: On that grounds the objection is overruled.

You may answer.

THE WITNESS: Can you repeat the question, please?

BY MS. JOHNSON:

Q. Based on --

THE COURT: Hold on. I don't want to get into another argument, and I would ask my reporter to repeat the question, please.

THE WITNESS: Thank you.

(Record read)

THE WITNESS: Pfizer had initially sent us a whole laundry list of requests for data. We --

THE COURT: I'm going to say that's not responsive. I don't need to hear about a laundry list. It was a simple question.

THE WITNESS: My understanding is that they were

satisfied.

THE COURT: All right. Next question, please.

BY MS. JOHNSON:

Q. After all the data came out at ASCO, did Pfizer ever express any concerns to you that you had not given them any particular data?

A. We did not -- I don't remember hearing any concerns from Pfizer that they were concerned because there was any parts of data that we had not sent them previously that was presented at ASCO.

Q. Does Puma still have a business relationship with Pfizer?

A. Yes, absolutely. They've been very helpful to us.

Q. That was my next question. What is the nature of your business relationship with Pfizer currently?

A. Pfizer is our partner, and they have been very helpful to us. You know, when we were preparing to file for FDA approval, there was a lot of times we needed old data sets or old documents or old manufacturing records. And, you know, quite impressively they always would turn around the requests of what we asked for within, you know, 24 to 48 hours.

Q. Let's move on and talk about the stock offering process that Puma undertook in January of 2015.

What stock was sold in that offering?

A. So the stock that was sold in the January 2015 offering

were newly issued shares.
Q. And was that your stock?
A. No. That was not my personal stock.
Q. It was Puma's newly issued shares?
A. Yes, that is correct.
Q. What was the money raised in the offering used for?
A. The money that was raised in the January 2015 offering was used to support the ongoing research and development activities with neratinib.
Q. For biotechnology companies like Puma, how common is it to need to raise money through capital offerings?
A. It is very common. This is a very capital-intensive industry. It costs a lot of money to develop a drug. The typical estimates are that it can take up to $1 billion to bring a drug to the market. So these type of offerings tend to be very common in the industry.
Q. Did you raise money by stock offerings at Cougar?
A. Yes. At my prior company we did this as well.
Q. Has Puma raised money by stock offerings other than this January 2015 offering?
A. Yes, we have.
Q. I would ask you to turn to Exhibit 989.
MS. JOHNSON: It's Puma's 2015 10-K. I don't believe there will be an objection.
MR. COUGHLIN: No objection, Your Honor.

THE COURT: For the record it's not on the original list. 989 is admitted.

(Exhibit 989 received.)

BY MS. JOHNSON:

Q. So this is Puma's 10-K filing with the SEC for the year 2015. If we can jump right to page 42. There are lines for money raised through financings and money spent on R&D for a number of years. So I wanted to direct your attention.

Let's start with 2012. We could look at 2011, but let's just start with 2012 because that's where the numbers appear to become meaningful. Did Puma conduct a stock offering in 2012?

A. Yes. So if we could please highlight the last bar.

MR. COUGHLIN: What page is this?

MS. JOHNSON: Page 42.

THE WITNESS: And then the one that says research and development, please. Thank you very much. Yes.

So as you can see, in 2012 net cash provided by financing activities, those are when we raised money. So you can see we raised approximately $129 million. And as you can see, that money was then spent on research and development because in 2012 we had 49.6 million in R&D, and then in 2013, 45 million.

BY MS. JOHNSON:

Q. Let me interrupt you for one second and say: What is

research and development? What are those expenses?
A. The research and development expenses are the costs of us doing the clinical trials, et cetera, to get neratinib to the market to help the patients.
As you move forward in development, the trials get larger and get more expensive, and that's why you can see the research and development numbers going up as you go out year over year.
Q. And then what happened in 2014?
A. So in 2014, as you can see, our research and development costs went up to 122.9 million. So because -- in order to fund that, we then raised, as you can see below, 136 million.
Q. Is that 136 million all a stock offering, or are there other financing components in there to your recollection?
A. So usually when we raise money, we keep the money in the bank. And I think back then there was actually an interest rate that we were getting that was meaningful. So I believe that also would be the interest on the money that was in the bank as well.
Q. And then turning to the 2015 offering, what happened in 2015?
A. So as you can see on the top, in 2015 our research and development costs went up to 208.5 million. So to support that, we raised 233 million, as can you see on the bottom there. That was the net cash provided by our financing

activities.
Q. After June 2015 did anything happen at ASCO that affected Puma's ability to continue raising money and spending it on research and development and cancer trials?
A. No, not to my knowledge.
Q. All right. Let's turn to the process for how the company raises money.
What is the process for selling stock in each of these offerings?
A. So the process for selling stock is that usually there are underwriters who are hired. These underwriters are investment banks. Those can be groups like JPMorgan, Bank of America Merrill Lynch, et cetera. They will be the ones who will physically conduct the offering. This means they will reach out to investors to see if those investors are interested in investing, and they will be the ones who physically sell the stock to those investors.
Q. Do they conduct due diligence?
A. Yes, they do.
Q. What does that refer to?
A. So due diligence is their process of looking under the hood, if you will, and looking at the research and development activities, the financial activities, patents, et cetera. And that is part of the due diligence process.
Q. Are the underwriters represented by lawyers in this

process?
A. Yes. So usually the lawyers are referred to as underwriters' counsel. That would be the lawyers that these underwriters have hired for this specific due diligence process.
Q. And who was underwriters' counsel in connection with the January 2015 offering?
A. The underwriters' counsel was a lawyer named William Hicks or Bill Hicks.
Q. Did you meet with Mr. Hicks in this process?
A. Yes, I did.
Q. Why did you meet with him?
A. I had met with Mr. Hicks because the underwriters had set up a process by which instead of us showing them the data for ExteNET, to protect the confidentiality of it, we presented the data to Bill Hicks who is their attorney. And then that way he was under a confidentiality agreement with Puma.

So that way he was given the information, but we didn't have any risk of the banks leaking the data and then us potentially being prevented from presenting it at a medical conference.
Q. Did you meet with Mr. Hicks in person or on the phone?
A. I met with Mr. Hicks in person.
Q. All right. Turning to Exhibit 855.

MS. JOHNSON: I believe there is no objection.
THE COURT: 855?
MS. JOHNSON: Correct.
MR. COUGHLIN: What is 855 if I might ask?
MS. JOHNSON: His calendar.
MR. COUGHLIN: No objection, Your Honor.
THE COURT: All right. 855 is admitted.
(Exhibit 855 received.)
BY MS. JOHNSON:
Q. All right. 855 is a page from your calendar in the January 2015 time period; is that correct?
A. Yes, correct.
Q. Do you see a meeting with Mr. Hicks?
A. Yes, at the bottom of the page there, if we could please expand that. Thank you.
Yes. That's the meeting with Bill Hicks that took place Wednesday, January 14th, 2015.
Q. And where was that meeting?
A. That meeting took place -- that week was another one of these healthcare investment conferences which was the JPMorgan healthcare conference. This tends to be a very large conference at the beginning of the year.
Typically what you will do is JPMorgan themselves, the day you present at the conference, they will usually host meetings for you at their hotel. Because everyone is up

there, you can do lots of meetings. Usually companies will get a room at a hotel nearby where they can hold other meetings.

So this meeting was at the JW Marriott Hotel in San Francisco which was about a block or so away from the Westin St. Francis Hotel, which is where the JPMorgan meeting took place.

Q. What time did the meeting take place?

A. It appears to be at 5:30 in the evening.

Q. And is that Pacific time on your calendar?

A. Yes, that would be Pacific time.

Q. To your recollection how long did the meeting last?

A. The meeting was scheduled for an hour. I seem to recall it went over.

Q. Was there anyone else present other than you and Mr. Hicks?

A. Just me and Mr. Hicks.

Q. And what did you discuss?

A. The purpose of the meeting was to share with Mr. Hicks the ExteNET data. So I ended up going through the slide presentation which we had done with our academic steering committee, which is the group of outside doctors who designed the trial, helped run the trial, gave us advice over the course of it.

We had just met with them at a cancer conference

referred to as the San Antonio Breast Cancer Symposium. That took place in December of -- the prior month from -- this was December 2014, so the prior month from this meeting.

Q. Exhibit 952 is already in evidence. If we can look at the front slide, it says ExteNET academic steering committee San Antonio, December 9th. Is that the presentation you were just referring to?

A. Yes, that appears to be the presentation.

Q. And is this the presentation you showed to Mr. Hicks?

A. Yes. This appears to be the presentation.

Q. Did you walk through each slide? How did the meeting go?

A. I went through each slide. And as Mr. Hicks had questions, he just asked them as I was presenting.

Q. Let's briefly look at some of the slides just so we can orient ourselves to the type of data in them. Slide nine, does this show the DFS differences as two years for the primary and secondary end points?

A. Yes, it does.

Q. Slide 11, does this show the curve data for the ITT population?

A. Yes. This shows the Kaplan-Meier curves.

Q. Slide 24, does this show adverse event information including the 39.9 percent?

A. Yes, it does.

Q. Slide 25, does this show the discontinuation rate of 16.8 and the dropout rate of 1.6 for diarrhea?
A. Yes, it does.
Q. A couple more slides. Slide 16, does this show a forest plot of the ExteNET data by primary and secondary end points?
A. Yes. That is correct.
Q. And as one more, slide 21, did you also discuss the subgroup analysis by centrally confirmed and hormone-receptor positive status?
A. Yes, that is correct.
Q. Did Mr. Hicks ask you questions as you walked through this data with him?
A. Yes. I seem to remember he asked a number of very detailed questions.
Q. Did he express any concerns about the ExteNET trial data?
A. He did not express them to me. If he had them, they were not expressed to me.
Q. All right.

What was his reaction overall to the data?

A. He was pleased. He appeared to be pleased with it. He did ask me at the end of the presentation if I felt there was anything in the presentation that, you know, people were going to have issues with or any, you know, or bring up any concerns about.

I seem to recall I had said to him that, you know, we -- we had obviously had developed the Imodium prophylaxis that was not used in this trial. So I expressed to him that, you know, the concern would be we didn't use it in this trial.

But I felt there would be a way we could communicate at ASCO that since this trial had been run, we came up with the Imodium prophylaxis as a way to improve the safety of the drug, and I felt that could be effectively communicated.

Q. You were asked questions about Exhibit 528 in evidence. Exhibit 528 is a diligence memorandum that was prepared by the underwriters, and you were directed to a bullet point that talked about Puma having details of new data that they had not disclosed and the banks said they have decided not to reveal the data with any of the banks involved in this transaction. Do you recall that discussion?

A. Yes. Correct.

Q. Why didn't you want to reveal the data to the banks once again?

A. So as we discussed last week, a very important validation step in a drug getting from, you know, the development to the patients is presenting this data at a medical conference.

The medical conferences are very, very stringent on

making sure that the data has not been previously disclosed. If it is, they will prevent you from presenting it. So our concern that we had was, you know, these banks are large entities and there's a lot of moving parts. The risk that somebody somehow leaks the data in some way, shape, or form was high.

It has happened in the past that, you know, people are doing offerings and something leaks out. I didn't want to prevent this data from being presented because it was very important to us that we get this drug to the patients, and any step that jeopardized that was something that we were very concerned about.

Q. Were the underwriters for the 2015 offering comfortable with the approach decided on, which was to share the information just with Mr. Hicks?

A. What was -- what I remember they represented to me was that this issue comes up a lot. This is not the first time it had come up. And that was where they came up with this proposal.

So again, it was the banks who came up with the proposal to bring Mr. Hicks in and allow Mr. Hicks to see the data. This was proposed by JPMorgan and Bank of America Merrill Lynch. This was not proposed by Puma.

And they said this is something they had done in the past to circumvent these type of issues. And from what

they had said, this was something that, you know, was not uncommon to occur.

Q. And all the underwriters signed off on the offering?

A. Yes, they did.

Q. All right. Let's talk about the meeting that Puma had with the FDA in November of 2014 and the minutes of that meeting. I want to start with the simple question: Did you hide the ExteNET data from the underwriters in the offering?

A. No, we did not hide the ExteNET data from the underwriters in the offering.

Q. When did you find out that there were two versions of the FDA minutes for -- of the minutes for the FDA meeting in November of 2014?

A. I first found out that the wrong version of the minutes had been sent to Mr. Hicks at my deposition in January of 2018.

Q. And how did you feel when you found that out?

A. When it was first presented to me, I, you know, I was puzzled. I was confused. And I was, you know, in a state of just trying to, you know, better understand what took place.

Q. And tell us what is -- what responsibility do you take for sending the revised version instead of the official version to the underwriters?

A. You know, clearly the version of the FDA meeting minutes that was sent to Mr. Hicks was Puma's internal version that

included our own, you know, analysis and our own views on what took place during the meeting. It was a mistake. There's no question.

Now, the nice part about this is it looks like the information that was sent to Mr. Hicks was indeed accurate, so it wasn't that inaccurate information was sent. But, you know, I -- obviously as the CEO of the company, I take full responsibility for this and I take ownership of this.

I -- you know, in hindsight I probably should have checked to see to make sure that the version that my team had sent to me was the correct version. It was an oversight and, you know, a mistake that was made.

But thankfully the version that was sent was indeed accurate and did accurately reflect the discussion that took place at the meeting and the discussions that had taken place after meeting.

Q. So let's talk about that. What was the purpose of the November 2014 meeting between Puma and the FDA?

A. So we discussed this a little bit last week. The purpose of the meeting with the FDA in November of 2014 was to discuss nonclinical data.

So just to again reiterate, you have two types of research studies that get done. There's the nonclinical and clinical. Clinical is where you are actually testing the drug in humans and are showing the safety of the drug and the

efficacy of the drug.

Nonclinical are tests that are done in test tubes and petri dishes or are done in mice and rats to look at other things that can't be looked at in humans. The specific thing we were talking about was nonclinical data, and specifically carcinogenesis studies.

So we discussed this a little bit last week. But just to clarify and refresh everyone's memory, carcinogenesis studies are studies that are done in rats where you give your drug to rats for a period of two years. What you're looking for is to see whether or not your drug causes other tumors.

And you will typically -- rats are known to spontaneously produce tumors. So what you will typically do is give your drug to rats for two years. Then give a placebo to rats for two years and look for any major changes between the two.

If the one that gets your drug has a lot more tumors that have developed compared to the placebo, that would mean your drug has risk. It's causing other cancers. If they're about the same, then you don't have that risk.

Q. All right. In advance of this meeting to talk about preclinical data, did Puma submit materials to the FDA?

A. Yes, we did. We submitted what's called a briefing book, which is a book that contains all of the data we would like to discuss with them at the meeting.

Q. I'll turn your attention to Exhibit 940.

MS. JOHNSON: If there's no objection, I would move 940 into evidence.

MR. COUGHLIN: What's 940? What is 940?

MS. JOHNSON: It's an e-mail with the briefing package.

MR. COUGHLIN: No objection.

THE COURT: 940 is admitted.

(Exhibit 940 received.)

BY MS. JOHNSON:

Q. Exhibit 940 is a September 24th, 2014, e-mail attaching a nonclinical type C meeting request and briefing package. Do you see that?

A. Yes, I do.

Q. Is this information Puma provided to the FDA in advance of the November 2014 meeting?

A. Yes. That appears to be correct.

Q. All right.

MS. JOHNSON: I'd like to look at pages 18 to 21 of the attachment, if you could just put them all up there.

BY MS. JOHNSON:

Q. Are these pages the clinical trials results for ExteNET, the 91.6 to 93.9, the KM curves, the 39.9 percent diarrhea? Do you see that?

A. Yes. That was in the briefing book that was sent.

Q. So this is information that Puma provided to the FDA in advance of this preclinical meeting?
A. That is correct.
Q. All right. When the meeting occurred, was it in person or by telephone?
A. The meeting was over a teleconference.
Q. And what was discussed at the meeting?
A. When we had the meeting with FDA, we were trying to get them to -- because we didn't have two years' worth of carcinogenicity data, and we didn't want to delay our FDA filing which is called an NDA filing, a new drug application, we didn't want to delay it by two years.

So we -- our proposal to the FDA was, you know, based on the clinical data and on medical need, if they would give us a waiver, if you will, and allow us to file without the carcinogenicity data and then supply them with the carcinogenicity data after the FDA approval of the drug.

When we got to the meeting, what the FDA said was this is a nonclinical meeting and there is not to be any discussion of clinical data at this meeting. So at the meeting we had, the clinical data was off the table.
Q. After the meeting did the FDA send you its minutes of the meeting?
A. Yes, they did.
Q. Exhibit 773 is in evidence. It is -- it starts with an

e-mail to you regarding the minutes, and it says: Please review and let me know if you have any comments or if anything needs to be corrected.

Do you see that?

A. Yes. That is correct.

Q. And that's an e-mail to you from Christine Woods?

A. Correct. And I believe it also appears on the FDA's letter as well.

Q. Let's turn to that. The next page of the exhibit is the FDA's cover letter to Ms. Woods. First of all, it says --

MS. JOHNSON: If we can blow it up.

BY MS. JOHNSON:

Q. -- the purpose of the meeting was to discuss your proposed carcinogenicity studies in support of an NDA.

Do you see that?

A. Yes, I do.

Q. And then the FDA's cover letter says: Please notify us of any significant differences in understanding regarding the minute outcome.

Do you see that?

A. Yes. That is correct.

Q. Do you recall having discussion with your team after this meeting about what was discussed at the FDA meeting?

A. Yes, I do.

Q. What do you recall about that discussion?

A. So at the meeting we had -- they had initially taken the hard line of saying we need full two-year data in the carcinogenicity study -- so, two years of rats given your drug -- before you can file for FDA approval.

When we met with them at the meeting, we discussed with them, look, we've a drug here that can help patients. Can we submit to you interim data, so kind of an early look at the data? If that doesn't show any signal that neratinib can cause other cancers, would you allow us to file the NDA?

And at the meeting they agreed with that proposal. The meeting minutes did not reflect that discussion.

Q. Did you have -- did you then have a follow-up meeting with the FDA on that topic?

A. Yes, we did. In December of 2014 we had a meeting with the FDA, which was an SPA meeting. SPA stands for special protocol assessment. What this meeting is, is you have a meeting with the FDA where they agree on a protocol. This can either be a clinical protocol in human studies or a nonclinical protocol -- and in this case, rats.

The SPA that we discussed with them included two years of carcinogenicity studies, but there was an interim look at the data. There was kind of three groups. One got the drug for two years. One got the placebo. Then the one got a halfway point. I think it was, like, a year or so of drug. We were going to use that year to go look at -- to

bring the data to FDA and show them that the interim data was okay, and then we could file the NDA.

So the SPA that included that interim look was submitted to the FDA and was agreed upon with FDA.

Q. All right. Let's talk specifically about the two versions of the minutes with that background. The clinical data was in the original minutes but not in the revised minutes that Puma had. Would you explain what was discussed at the actual meeting about the clinical data?

A. Yeah. They would not allow us to have any clinical discussion because it was a nonclinical meeting. And so a clinical discussion did not take place.

Q. The rest of the changes that we saw between the two versions had word changes to the questions and answers. Did the original version or the revised version reflect the discussion at the November 2014 meeting?

A. Yeah. The revised version appears to be a more accurate description of the actual discussion that took place with the FDA.

Q. And what ultimately happened? Did the FDA accept one year of carcinogenicity data, or did they require two years?

A. No. The NDA was filed with just one year of carcinogenicity data. That NDA -- there's three steps in an NDA process. You file the NDA. They then can either accept or reject the filing just based on the contents, meaning did

you check all the boxes that you need. Then approximately one year later is the decision where they make the decision to either approve the drug or reject the drug.

The NDA was filed, and 60 days later they accepted the NDA, and that NDA acceptance included just one year of carcinogenicity data.

Q. I'd ask you to look at Exhibit 938 in evidence.

MS. JOHNSON: Sorry. It is not in evidence. 938 is marked on the exhibit list, and I understand there is an objection. I would move 938 into evidence.

THE COURT: It's not in any of the five binders I have for this witness. Please approach.

And why don't we take our break now.

MS. JOHNSON: Thank you, Your Honor.

THE CLERK: All rise.

(Open court - jury not present)

THE COURT: Sir, you may step down.

THE WITNESS: Thank you.

THE COURT: I didn't give them a time we're coming back. I should have. It might be a little more than 15 minutes.

You object?

MR. COUGHLIN: I do, Your Honor.

THE COURT: Your objection is?

MR. COUGHLIN: The time limit. This is in a 2016

document, so it's outside the time period, way beyond the end of the class and the 90-day lookback.

THE COURT: So I guess what I'd like to hear is irrelevant because it's outside the class period.

MR. COUGHLIN: Totally irrelevant. Totally irrelevant, Your Honor.

THE COURT: Just a moment.

Response?

MS. JOHNSON: Your Honor, it is outside the class period, but it was put at issue by the plaintiffs' articulation of the minutes as phony. So this document corroborates the revisions as being accurate rather than the original minutes because the revisions reflect that only one year of carcinogenicity data would be required.

THE COURT: Slow down. When you say carcinogenicity, when you say words like that, the syllables flow. Slower would be better. Okay.

Now, this is in response to the plaintiff arguing the minutes were incorrect, right?

MS. JOHNSON: Correct.

THE COURT: Okay. Which minutes?

MR. COUGHLIN: The FDA minutes. There are two documents at issue. There is document 773, which is the official minutes. Then there are the altered minutes, which I believe is document 491.

I would just say this, Your Honor. The context that we were asking those questions is this is an explanation that has never come up before frankly, but it goes against everything that is in the record.

We asked counsel where on Puma's servers did this altered document show up, and they could not locate it and told us no such document exists in their servers. So now to be allowed to put in a document a couple of years subsequent that somehow justifies the manipulation of this official FDA document, which, I don't know if I heard him right, he believes it's okay to alter an official FDA document.

I don't think he's saying that, but yesterday he testified he didn't recall altering the document and he didn't recall asking anybody to alter the document. Now he's somehow trying to justify the alteration of the document with the document that appears two years later. That's 773 and 491.

THE COURT: Okay. At this point, given what I just heard from plaintiffs' counsel, I do have to ask: Why is this document not listed in the, may I say, very extensive document 585-1?

MS. JOHNSON: Your Honor, it's a response to what we heard in opening and in the questions of Mr. Auerbach referring to these minutes as phony. I believe he absolutely did not testify that it was okay to alter an official FDA

record. He did not testify inconsistently with his recollection that he didn't -- that he didn't recall revising it or asking someone to revise it.

Instead, he is looking at the two versions and saying what actually happened. And this document is responsive to show that what actually happened was consistent with the internal version.

MR. COUGHLIN: One final thing, Your Honor. It's not an internal version. They never could locate this document on their servers anywhere at Puma. So the idea that it is somehow an official, you know, internal version that they have kept and altered to reflect something that happened after is just false. There is no record of this document on their servers, and the requested flash drive that Mr. Auerbach had has never been produced to us.

THE COURT: Response to that?

MS. JOHNSON: That is incorrect. We produced --

THE COURT: Where is it incorrect?

MS. JOHNSON: We produced a complete image of the flash drive and produced all responsive nonprivileged documents from that flash drive. The document did exist in Puma's server because it was sent to Mr. Hicks by Mr. Auerbach.

THE COURT: Just a moment. Go ahead.

MS. JOHNSON: Counsel is correct. It does not

exist outside of the e-mail that was sent, but the e-mail is on Puma's server and was produced. There were certainly discovery disputes over this, but that does not change the record, which is he sent the minutes. There is corroborating evidence about what happened at the meeting.

THE COURT: Can anyone tell me the significance, if you wish -- maybe there is none -- of the Bates stamp beginning Puma followed by a seven-digit number beginning 38?

MR. COUGHLIN: Your Honor, that --

THE COURT: Six-digit number.

MR. COUGHLIN: That just means that they -- those numbers were produced. Those are the defendant's production numbers, so they're just the Bates number for the production.

THE COURT: Okay. I understand. What about the number, six digits beginning with 38? When were they produced, is what I'm asking?

MR. COUGHLIN: They were produced in the ordinary course --

MS. JOHNSON: During discovery.

MR. COUGHLIN: During discovery.

THE COURT: Hold on. Hold on. Do you mean that the letter dated -- gosh, I don't see a date -- it's page 2 of this exhibit, was produced in the ordinary scope of discovery?

MR. COUGHLIN: Which document do you have in your

hand, Your Honor?

THE COURT: Well, that's what I'm talking about. I have in my hand this new document --

MR. COUGHLIN: Oh --

THE COURT: -- numbered 938 that begins with an e-mail. It's what we were just talking about.

MR. COUGHLIN: Yes. It was produced in the ordinary course.

MS. JOHNSON: In response to ordinary discovery requests from the plaintiff.

THE COURT: I must say that for all the effort that's gone into this case, I do wish someone had paid a little more attention to what I urged the parties, which is get control of your documents.

I now have five separate witness books for this witness, as well as 16 trial exhibit books. You know, it's my thought that if people really strived towards coming somewhat close to the 80 percent rule, they would have a better handle on the documents. They would have -- they would be better able to more effectively examine the witness. I'm just saying that's my view.

You seem to want to say something, Ms. Johnson.

MS. JOHNSON: I just want to explain to Your Honor that there were motions in limine regarding these FDA minutes.

THE COURT: I understand the motion in limine document, so you did not anticipate this. But I'm not sure that I've run contrary to my motion in limine, and I'm not sure that I altered my motion in limine.

MS. JOHNSON: With respect to motion in limine two about Pfizer, I would respectfully suggest that there are new things coming in that we had to respond to.

THE COURT: You know, did you object on the motion in limine and I overruled the objection?

MS. JOHNSON: Correct.

THE COURT: Okay. Well, that may go to this particular thing. I know that counsel has utterly and completely ignored anything I said about mastering the documents such that would approach my 80 percent rule.

I think they just decided we're not going to do that. I think as a result, they have not fully examined the implications of the documents to be used. I'm just saying that there may be counter arguments, adjustments in the motion in limine might be countered.

But really, counsel? Five separate exhibit books now with another document that isn't in any of the five separate exhibit books? It's partly why cases like this get out of control. I just wish that there had been a closer desire to limit the number of documents and that we wouldn't have five separate exhibit books for one witness.

Now, with that, I'm going to ask plaintiffs' counsel to state the objections so that I can make a ruling on this new Exhibit 938.

MR. COUGHLIN: The objections are, Your Honor, that it's irrelevant because it is after the class period. Your Honor has ruled on motion in limine four that --

THE COURT: When you say after the class period, how did minutes come in relating to the class period?

MR. COUGHLIN: Different documents that were created during the class period.

THE COURT: Wait. Are you saying the minutes come from the class period?

MR. COUGHLIN: Those minutes do not.

THE COURT: Okay. So how did we get a discussion of minutes that were not in the class period?

MR. COUGHLIN: He started talking. They started -- they identified a new exhibit, and I objected. We haven't gotten into that exhibit at all yet. When I saw the date of the exhibit that they were trying to enter, I objected. We've had no discussion about that. They're now trying to bolster his testimony.

THE COURT: You objected to me?

MR. COUGHLIN: Yes.

THE COURT: Those minutes have come in?

MR. COUGHLIN: No, no. We're talking about the

ones that are in front of you. I'm sorry.

THE COURT: I must say, I'm a bit confused.

MR. COUGHLIN: The ones during the class period have come in without objection. Both sides.

THE COURT: How about minutes outside the class period?

MR. COUGHLIN: They have not.

THE COURT: Does Exhibit 938 concern minutes outside the class period?

MR. COUGHLIN: Yes.

MS. JOHNSON: 938 is not minutes. It's --

THE COURT: No. My word was concern.

MS. JOHNSON: Yes.

THE COURT: I'm understanding your argument. You're saying 938 is necessary to refute arguments made about minutes.

MS. JOHNSON: That is correct.

THE COURT: The minutes are outside the class period?

MS. JOHNSON: And I'm taking --

THE COURT: Can I get an answer to that?

MS. JOHNSON: 938 is outside the class period.

THE COURT: No. No.

MS. JOHNSON: It concerns --

THE COURT: Let me state the question again. Does

938 concern minutes that are outside the class period?

MS. JOHNSON: No.

THE COURT: What does the plaintiff say about that?

MR. COUGHLIN: It certainly does, Your Honor. It concerns the follow-up by Puma with the FDA to submit an NDA without a two-year study. It's certainly issues outside the class period.

THE COURT: So Mr. Coughlin has objected. Outside the class period.

What other, if any, objections does Mr. Coughlin have?

MR. COUGHLIN: None, Your Honor.

THE COURT: The objection is overruled and 938 may come in. Thank you.

MS. JOHNSON: Thank you.

THE COURT: Ms. Bredahl, let's go until ten minutes to. Well, the testimony has been hot and heavy. We'll make it 15 minutes. We'll come back at 10:55.

MR. COUGHLIN: Thank you, Your Honor.

MS. JOHNSON: Thank you.

(Recess taken from 10:40 a.m. until 10:55 a.m.)

THE CLERK: All rise.

(Open court - jury present)

THE COURT: All right, folks. Sorry for the delay. We had another evidentiary discussion concerning that exhibit

which is now admitted. It is number 969?

MS. JOHNSON: 938.

(Exhibit 938 received.)

THE COURT: I'm so sorry. 938. All right. Just a moment here. There it is. Yes. And 938 has been admitted.

Go ahead.

MS. JOHNSON: Thank you, Your Honor.

BY MS. JOHNSON:

Q. Mr. Auerbach, what is Exhibit 938?

A. So 938 appears to be an e-mail that is forwarded from the FDA. You will see in the subject line it says type A meeting. So it's a forward type A meeting. Thank you.

Type A meetings are the highest priority to the FDA. These are ones they promise to get back to you within 30 days. They realize they are very, very time sensitive.

The other meetings we were talking about were Type C, so lower in priority. This is us officially showing them the one-year carcinogenicity data and them making the decision on whether or not that data would support an NDA filing.

Q. Let me ask you, your internal person, Mei Ling Chang, forwards this to you and says: Congratulations. FDA agreed that we can file based on the one-year data.

I just want to ask you, is that decision consistent with Puma's internal version of the minutes from the November

meeting we were talking about?
A. Yes. Absolutely. What she's referring to is FDA agreed we can file based on the one-year carcinogenicity study, and we would submit the two-year data at a later date.
Q. Just so we know, what was the result of the carcinogenicity studies? Did neratinib cause secondary cancers?
A. The data showed that neratinib did not cause other cancers.
Q. All right. Let's turn to your compensation as CEO of Puma. Were you granted stock options in 2014?
A. Yes, I was.
Q. And briefly, how does a stock option work?
A. So a stock option is the right to buy a stock at a fixed price. So when options are issued to employees, it's usually over a vesting period. So, for example, an employee can be granted 3,000 options. You get to the right to one-third of those every year.

So after one year from the date it's granted, you get the right to 1,000 of them. After the second year, the second thousand. And then after the third year, the third thousand.
Q. Did any of the options you were granted in 2014 vest prior to the ASCO conference on June 1st, 2015?
A. As I recall, the options were granted in December of

2014, so I would've gotten the right to the first of those in December of 2015. ASCO was June of 2015, so, no, none of those options vested.

Q. Did you exercise any Puma stock options in 2014-2015?

A. No, I did not.

Q. Did you sell any Puma stock during this time period 2014-2015?

A. No, I did not.

Q. How much money did you make because of Puma's stock price between July 22nd, 2014, and June 1st, 2015?

A. I didn't make any money. I didn't sell any stock.

Q. You were asked a few questions about Celgene. Do you recall that discussion?

A. Yes.

Q. And you asked to explain the context. So I wanted to give you a chance to explain your interactions with Celgene over what appeared to be an offer letter.

A. So I believe last week we discussed that Celgene had sent a non -- what they referred to as a nonbinding offer to acquire the company. I believe the price was $10 billion.

We had tried to set up a meeting with Celgene to kind of take the next steps in that. They went radio silent on us and didn't respond. They ended up buying a different company called Receptos, which I believe they paid $9 billion for, if I remember correctly.

So our assumption was, you know, Celgene's cash balance wasn't that large. And clearly when you acquire a company, there's a lot of things that take place after, the integration and things like that.

So we didn't hear from them for quite some time. Then about six months after that acquisition closed, they then re-engaged with us and we've continued to have discussions with them regarding various research proposals that we can do together, you know, potential joint ventures and things like that. Those have continued to the present day.

Q. Okay. Let me jump to a different topic and ask you: What kind of a place do you live in?

A. I live in an apartment.

Q. Do you own it or rent it?

A. I own it.

Q. When did you buy it?

A. I bought it in 2000.

Q. When did you sell Cougar?

A. In 2009.

Q. And you still live in the same apartment that you bought in 2000?

A. That is correct.

Q. Do you own any other property other than that apartment?

A. No, I do not.

Q. How many cars do you have?
A. One.
Q. Have you ever flown in a private plane?
A. No, I have not.
Q. Tell us, how many days a week do you typically work?
A. I am very lucky to love what I do, and I am very lucky to work seven days a week.
Q. What kind of vacations do you typically take?
A. To my recollection, my last official vacation was in 1998.
Q. And what is it that you spend your time doing?
A. I am very lucky to love what I do. And in life, you do what you do to be happy. I am very happy spending my time building companies that help cancer patients.

So where some people may think it's odd that I don't take vacations and I'm not married and I don't have any kids, and I spend seven days a week working, it makes me extremely happy to know that I'm dedicating my life to helping cancer patients.

Having lost a father to this disease and seeing the impact it has on one's family, I am very, very, very proud to be able to do what I do and help cancer patients and their families. And, you know, God willing, I can do this for the rest of my life.

Q. All right. Thank you.

Let's turn now to Exhibit 503, which is the abstract that's in evidence. This is the abstract published on May 13, 2015. Who made this abstract public?

A. ASCO made this public.

Q. Did you actively work to have the abstract made publicly?

A. When you submit an abstract to the ASCO conference for submission, you can either check a box that says I want this held confidential, in which case they will not release it before the conference; or you can not check that box and allow it to be made public prior to the ASCO conference.

In this case we did not check the confidential box, so we allowed it to be made public prior to the ASCO conference.

Q. And you wanted that result?

A. Yes. We were very happy to have this presented earlier.

Q. All right. Under authors on Exhibit 503, we see the first one is Arlene Chan. We've talked about her before. She's the head of the academic steering committee that oversaw the study?

A. Yes. That is correct.

Q. And who are the rest of the people listed there?

A. So all of the authors you see on the first, second, and the first part of the third line ending with Dr. Michael Gnant, those are all of the members of the academic steering

committee. So this is outside doctors that help design the trial and help to run the study. Then you can see their affiliations and what hospitals they're at later in the abstract.

Q. Are any of these doctors paid by Puma?

A. No. We do not give them any compensation.

Q. Are any of these medical facilities with which they are affiliated paid by Puma?

A. Many of them run clinical trials, in which case the costs of the trial are paid for. But we don't provide, you know, funding to them outside of that.

Q. And you previously testified that all of these doctors had seen the ExteNET data prior to this time period?

A. Yes, that is correct.

Q. Going down the abstract gives the background of the study, the methods, and then the results. I wanted to ask you a couple questions about the results on the last two lines.

It says preplanned subset analyses. What does preplanned subset analyses mean?

A. Preplanned subset analyses mean that there are subsets of the patients or subgroups of the patients that we had planned on performing prior to unblinding the study. Those are the analyses that are shown.

Q. And do those preplanned subset analyses include

hormone-receptor positive patients and centrally confirmed patients?

A. Yes. And that's shown in the highlighted portion there.

Q. And do those results as reflected there indicate that these two subgroups performed better than the entire population as a whole?

A. Yes. So you can see it says HR equal to 0.51 for the hormone-receptor positive and hazard ratio of 0.52 for the centrally confirmed. So the lower it is, the better. So those are both lower than the 0.67 seen in the trial as a whole.

Q. And these two subset analyses were planned in advance before the results of the study were known?

A. Yes. That's correct.

Q. All right. Let's go to page 2 of the abstract. It talks about the diarrhea side effects. It's listed as 40 percent grade three, one patient grade four, and then it says diarrhea, the most common AE or adverse event was manageable. Do you see that?

A. Yes, I do.

Q. All right. Let me ask you questions about the subgroups. On the July 22nd conference call that we've been discussing, did you tell investors that neratinib worked differently among different subgroups?

A. Yes. I seem to recall in answer to one of the questions

saying that there were some subgroups that it worked better in and some it didn't work as good in.

Q. Let's look at Exhibit 103 in evidence and the top of page 8. I believe this is what you're referring to. Dr. Liang asks you can talk about various subgroups. Do you see that?

A. Yes. Correct.

Q. And first you say, I don't want to the comment too much on the data because I don't want to jeopardize it being presented. Then you give an answer about it working differently in different subgroups. Do you see that?

A. Yes.

Q. Of course, you had data by subgroups, including the subgroups that are articulated in the abstract, by July 22nd, 2014, right?

A. That is correct.

Q. Let's quickly look at Exhibit 123 in evidence, on the very last page. 123 is what you had prior to July 22nd, 2014. Is this data on subgroups, was this data available to you as of July 22nd?

A. Yes. That's correct.

Q. What does this forest plot mean for the subgroups?

A. So for each of the subgroups, the forest plot shows whether or not neratinib works better or worse than the placebo in each of those subgroups. So if you look at the

first two, for example, ER/PR positive is the hormone-receptor positive. As I was describing earlier, if the dot that you see is to the left of the one, that means that neratinib has a favorable treatment effect in that group.

If it's on the middle or to the right, it means it has less of a treatment effect. So you'll notice in the ER/PR positive, the hormone-receptor positive, it's pretty far to the left there. And the hazard ratio is, you know, 0.51. That's clearly showing a very good treatment effect in those patients.

For the ones who are ER/PR negative, which means they're hormone-receptor negative, you will notice that one is much closer to that red vertical line. That's a hazard ratio of 0.92. So that means in those patients it didn't work as well.

Q. You were asked some questions about the study being amended to discontinue enrolling node-negative patients. Do you recall that?

A. Correct.

Q. And you explained that this change enriched the population of people that were more at risk, right?

A. Yes. That is correct.

Q. Would you explain what that means for the study?

A. What it meant for the study was that we included more

patients who had a higher risk of the disease coming back. So if at the time of diagnosis the disease is found not only in the breast but also in the lymph nodes that surround the breast, those patients tend to have a higher risk of the cancer coming back.

That also becomes a more difficult-to-treat tumor type, and it's more difficult to prevent that disease from coming back. So it enriched the trial in terms of patients who would potentially have events, but it also made it a little bit harder for the drug to show a positive effect because you were going with a much riskier population.

Q. So to be clear, did this change that enriched the population for high-risk patients skew the results in favor of neratinib?

A. No, I don't believe it skewed the results in favor of neratinib. I think it made it a little more challenging to show a treatment effect.

Q. Did you review analyst reports after the abstract 508 that we just looked at?

A. Yes, I did.

Q. I'd turn your attention to Exhibit 974, which I believe with the limiting instruction is not objected to.

MR. COUGHLIN: Yes. That's correct.

THE COURT: Just a moment.

Okay. Without objection 974 is admitted.

(Exhibit 974 received)

BY MS. JOHNSON:

Q. 974 is the day the abstract came out by Leerink. Dr. Liang, he says ExteNET data looks strong on close examination. If we can highlight the furthermore paragraph. He talks about unlike HERA, which enrolled only centrally confirmed HER2-positive patients in ExteNET, only locally confirmed HER2 positivity is required, and approximately 80 percent of those patients were confirmed upon central testing.

What was your reaction to this particular analyst report?

A. I felt he got this accurate. Again, you know, the prior drug, Herceptin, all of the patients in those trials had the test for the HER2 gene done by a central lab. So it was centrally confirmed data. So you knew very, very accurately they indeed had it.

We had -- we discussed this last week. This -- trying to do the, you know, if you will, apples-to-apples comparison between the Herceptin adjuvant studies and the ExteNET study, you needed to look at the patients who had had that central test positive, so, the centrally confirmed group in ExteNET, with the ones in the Herceptin trials to do that apples-to-apples comparison. I felt he did a good job of explaining this here.

Q. All right.

MS. JOHNSON: Exhibit 966, I would move that into evidence with the same limiting instruction.

MR. COUGHLIN: No objection.

THE COURT: 966 is admitted.

(Exhibit 966 received.)

BY MS. JOHNSON:

Q. 966 is an RBC analyst report the day after the abstract, so on May 14, 2015. That analyst gives an outperform ranking. You as a former analyst, what does an outperform ranking mean?

A. Every investment bank will have their own rating system. They usually break down into three categories -- buy, hold, or sell -- they tend to express them in different ways. So outperform usually means that the analyst believes that this investment will outperform the benchmark, whatever that be, the S&P 500, the Dow Jones, whatever. It's their firm's way of saying buy.

Q. Let's look at Exhibit 845.

MS. JOHNSON: I would move that into evidence with the same limiting instruction.

THE COURT: Without objection 845 is admitted.

(Exhibit 845 received.)

BY MS. JOHNSON:

Q. 845 is another RBC report, but this one is on May 27th,

2015. So between the abstract and the ASCO conference and the RBC analyst discusses diarrhea -- if we could pull up that -- he said this drug has a bad diarrhea profile, but prophylaxis seems to take care of that. Neratinib clearly has an issue with diarrhea, about 30 percent grade three, and seems to have been poorly developed by Pfizer. However, loperamide should be able to address it.

This analyst lists about 33 -- about 30 percent for diarrhea even though the abstract on May 13th had listed 39.9. What did that say to you about whether that difference matters?

A. I recall when I read this, I felt that what the analyst was communicating was, you know, 30, 39, they're very similar.

Q. And what was he communicating about whether the high-dose loperamide prophylaxis is important?

A. He's clearly communicating, you know, he says, moreover, the loperamide prophylactic regimen is only in play for --

THE COURT: Hold on. Take a deep breath.

THE WITNESS: Yep.

THE COURT: If you're reading the quote, please start over. Surely you don't expect people to record when you're talking that fast.

Go ahead.

THE WITNESS: So I think in terms of the

loperamide, he starts in the third line there saying: However, when high-dose loperamide prophylaxis is used, the incidence of grade-three diarrhea declines significantly.

So what he appears to be communicating is that even though previously there was a high rate of grade-three diarrhea, when you use the loperamide prophylaxis, it does reduce the grade-three diarrhea rates.

BY MS. JOHNSON:

Q. And finally on this topic, Exhibit 967.

MS. JOHNSON: I would move to admit that with the same limiting instruction.

MR. COUGHLIN: No objection, Your Honor.

THE COURT: 967?

MS. JOHNSON: 967 is a UBS report dated May --

THE COURT: Hold on. I need to say the words.

967 is admitted. Go ahead.

(Exhibit 967 received)

MS. JOHNSON: Thank you.

BY MS. JOHNSON:

Q. 967 is a UBS report dated May 28th, 2015, so again between the abstract and the conference. And this UBS analyst says -- if we can pull it up -- we are maintaining our buy rating into ASCO.

Briefly what does that mean?

A. What that means is that as an analyst he's recommending

buying the stock before ASCO.

Q. Then the ASCO conference occurs on June 1st, 2015. Were you in attendance at the conference?

A. Yes, I was.

Q. Would you turn in your binder to Exhibit 963.

MS. JOHNSON: I believe there may be objection, but it's a photograph I wanted to ask you about.

A. Yes.

Q. Is this picture an accurate depiction of one of the rooms in the ASCO conference on June 1st, 2015, which you attended?

A. Yes. This is an accurate depiction --

Q. Just yes or no?

A. Yes.

MS. JOHNSON: I would move 963 into evidence.

THE COURT: Any objection?

MR. COUGHLIN: I'd object, Your Honor. This is not where they presented. So it's the general conference room, so it's irrelevant.

THE COURT: Response?

MS. JOHNSON: Part of the same conference. It's correct that it is not the exact room. The exact room was in a different part of the conference, but it is on the date of the conference.

THE COURT: The objection is sustained.

MS. JOHNSON: May I use it as a demonstrative, Your Honor?

THE COURT: Objection?

MR. COUGHLIN: Objection, Your Honor.

THE COURT: Sustained.

MS. JOHNSON: Okay. We won't look at the picture.

BY MS. JOHNSON:

Q. Did Dr. Chan present at ASCO?

A. Yes, she did.

Q. All right.

MS. JOHNSON: I have about a one-minute clip of her presentation. It's Exhibit 719. I believe there's no objection. I would move that into evidence.

MR. COUGHLIN: No objection.

THE COURT: Without objection 719 is in evidence.

(Exhibit 719 received.)

THE COURT: Hold on. Can you stop it? So when you move a video like this into evidence, it may not be with the jury in the jury room unless we go through a fairly extensive procedure of providing equipment for that.

At this point I know of no efforts to provide such equipment. So this is in evidence. And it's what number?

MS. JOHNSON: 719.

THE COURT: It's not clear that it will be available for the jury.

All right. You may play 719. Go ahead.

(Videotape recording played)

BY MS. JOHNSON:

Q. So in that presentation did Dr. Chan walk through the slides that are in evidence as 176 showing all of the ExteNET data?

A. Yes, she did.

Q. What happened next?

A. So after Dr. Chan's presentation, the next thing that occurs is there is a discussant. The discussant is usually an outside physician who has nothing to do with the trial and wasn't involved. Their role is to, for the audience, to discuss their thoughts on the study.

Q. Was the discussant not affiliated with Puma in any way?

A. No, she was not.

Q. And you were present for her discussion, of course?

A. Yes.

Q. How did she characterize the DFS data of ExteNET?

A. The doctor, who I believe was Shanu Modi from Sloan Kettering. Her analysis was that the DFS data was positive and was significant.

Q. Then there was a Q&A presentation?

A. That's correct. So they then open the floor to questions. This is again a large room where they have, you know, microphones set up in various parts of it. If someone

goes to the microphone, they're going to be recognized. There is one, two, three, I think it goes up to, like, eight or nine. Then there are questions that are asked from the audience.

Q. Did you know in advance which doctors would ask questions?

A. No, I did not.

Q. Did you know what questions they were going to ask?

A. They do not submit those beforehand.

Q. And what was your reaction to the questions asked about the ExteNET study by those three individuals?

A. The main questions tended to center around the fact that we had only followed the patients for two years. The concern was -- you know, again, we were trying to prevent breast cancer from recurring in these young women, and the concern was that we really needed to see longer-term data.

The Herceptin study, the one that I referenced earlier, where they used two years of Herceptin against one, and the curves initially separated and then came back together, that appeared to be what generated a lot of the questions, because the concern was, you know, we only have two years' worth of data. If we go out to year five, the curves may come back together the way the Herceptin ones did. So we really need much longer follow-up on these patients.

Q. Did anything that happened at ASCO cause Puma to delay

filing its NDA?
A. No. Going into ASCO we had anticipated filing for FDA approval, you know, sometime within the next year. You know, more or less we indeed were able to do that.
Q. Did you plan an investor conference for later in the day on June 1st?
A. Yeah. That evening we had a meeting with investors, which we also webcast so other people could listen in as well. And we had Dr. Chan and some other breast cancer oncologists there as well to present the data and to take questions from investors.
Q. Was that additional meeting and data presented via a slide presentation?
A. Yes. Correct.
MS. JOHNSON: I'd ask that 886 be put up. It's in evidence.
BY MS. JOHNSON:
Q. Is this the slide presentation?
THE COURT: Just a moment.
MS. JOHNSON: Sorry.
THE COURT: Don't put it up until we admit it.
All right. 886 is admitted.
MS. JOHNSON: I believe it was already in evidence, but thank you.
THE COURT: Wait. I'm sorry. 886?

MS. JOHNSON: Correct.

THE COURT: I'm sorry. Hold on just a moment.

Yes, it is in evidence.

Go ahead.

MS. JOHNSON: Thank you.

BY MS. JOHNSON:

Q. Is this the slide presentation that was presented at that evening meeting on June 1, 2015?

A. Yes, it appears to be. Correct.

Q. Let's look at slide eight. This is a curve for, it says, centrally confirmed HER2-positive hormone-receptor positive patients. Do you see that?

A. Yes. That is correct.

Q. And for that subgroup, what were the results at two years? What was the DFS difference?

A. That appears to be an 8.6, so 97 minus 88.4. So that's an 8.6 percent DFS benefit.

Q. And who are the women in this subpopulation exactly?

A. This subpopulation would be the women where they had hormone-receptor positive disease, meaning it's estrogen-receptor positive, and where they had a central lab test to make sure they had the HER2 gene.

Q. And what does an 8.6 percent DFS difference mean for breast cancer in these women?

A. As you can see, that's a very large magnitude benefit.

You know, it's interesting to look at -- you're talking at, you know, two years, the absolute DFS rate is, you know, 97 percent. That's a really, really high number. So that's a really outstanding efficacy in those patients.

Q. All right. Did you review analyst reports after the ASCO conference?

A. Yes, I did.

Q. I'd ask you to turn your attention to Exhibit 764.

MS. JOHNSON: I would move that into evidence with the limiting instruction.

THE COURT: 764 without objection is admitted.

MS. JOHNSON: Thank you.

MR. COUGHLIN: It's already in.

THE COURT: It is already in.

BY MS. JOHNSON:

Q. This is a June 1 Cowen report by Eric Schmidt; is that correct?

A. Yes, that is correct.

Q. And Mr. Schmidt writes: ExteNET as advertised but questions remain on FDA strategy and market opportunity.

Do you see that?

A. Yes.

Q. And he writes: Full data from ExteNET -- if we can pull up the quote right below. Full data from ExteNET largely as previewed. I won't read the whole thing, but the second

sentence is: Overall we took comfort in the fact that the trial was clearly positive in terms of meeting its primary end point and that the presentation was free of any major negative surprises.

Do you see that?

A. Yes, I do.

Q. And then on safety, going down in the paragraph, he writes: Safety was in line with previous trials with grade-three diarrhea being the only major issue experienced by about 40 percent of neratinib patients.

He talks about the median duration of five days and then says: Nonetheless, Dr. Chan noted that Imodium prophylaxis could be effective in managing this AE.

Finally at the end: We would expect compliance rates to improve with prophylactic Imodium.

What was your reaction to these comments in Mr. Schmidt's analyst report on June 1?

A. Yeah. I felt he did a good job being accurate and accurately portraying the data that was presented.

Q. And one more, Exhibit 968.

MS. JOHNSON: Would move to admit with the limiting instruction.

THE COURT: 968 is admitted.

MR. COUGHLIN: No objection, Your Honor.

(Exhibit 968 received.)

BY MS. JOHNSON:

Q. 968 is a June 2nd Bank of America Merrill Lynch analyst reports. That's the day after the ASCO conference. The BAML analyst writes: We do not see significant issues or risks rather for FDA approval. Do you see that?

A. Yes.

Q. And he writes: The primary end point of the ExteNET trial is invasive disease-free survival for the intent to treat population at two years. This will be the basis for NDA filing and we believe for NDA [sic] approval. Do you see that?

A. Yes.

Q. Did you agree at the time with his prediction for FDA approval?

A. Yes. And, you know, interestingly both he and the prior report from Cowen mentioned the number one concern that we were hearing from investors, which was, you know, what was going to be the timing of being able to file for FDA approval and would we be able to file just on the two-year data, or would we need longer-term follow-up data that could, you know, delay our filing by, you know, multiple years, by four or five years or something.

Q. In summation, let me ask you a couple questions. Is neratinib a safe and effective drug for the treatment of HER2-positive breast cancer patients?

A. Yes, I believe it is.
Q. Have you been able to work to accomplish Puma's mission that you told us about?
A. Yes. The mission of this company is to help cancer patients, and I have -- we have definitely done that. The Puma team has definitely done that with neratinib.
Q. Did you tell the truth on the July 22nd, 2014, conference call?
A. Yes. I believe all of my statements with truthful.
Q. Has anyone ever suggested that you tried to prevent the full ExteNET data from being presented at ASCO?
A. No. To my recollection no one has ever said that I tried to prevent the data from being presented.
Q. And what is your hope for neratinib going forward?
A. My hope for neratinib is that the drug continues to help cancer patients, and we're doing a wonderful job with the drug in breast cancer.

But there are a lot of other tumors where this HER2 gene is expressed such as lung cancer, such as cervical cancer, such as colon cancer. My hope is that we will have the opportunity to be able to help those patients as well.

Q. Just in the United States or worldwide?
A. Globally.

MS. JOHNSON: Thank you, Mr. Auerbach.

THE COURT: All right. Thank you.

Redirect, please.

MR. COUGHLIN: Thank you, Your Honor. Just housekeeping before we get started so they don't slow us up. This is recross, and I have five additional exhibits -- 319, 324, 1082, 1084 --

THE COURT: I don't know what I'm supposed to do with this. Do you want me to write all these down? Where are we going?

MR. COUGHLIN: I was doing it for the record.

THE COURT: No. I understand. Are you moving their admission?

MR. COUGHLIN: Not yet. I don't think they're objected to, or will be.

THE COURT: I don't know what to do. Go ahead.

Folks, I'm really concerned where we're going with the documents. I need to state that ultimately it is up to -- and I need to make sure everyone is listening. It's up to the parties here to make sure the proper exhibits go to the jury.

I have second supplemental joint exhibit lists. I won't go through all I have. It is not what I had hoped for in this trial, and I say that to both sides. But you may now proceed.

MR. COUGHLIN: Thank you, Your Honor.

THE COURT: I just have to say now, this would be

the sixth exhibit book for this witness?

MR. COUGHLIN: It would be, Your Honor.

THE COURT: Okay. It's not what I intended, folks. It's what I specifically urged both sides to avoid. You have three exhibit books from each side on this witness. That's not what my instructions anticipated, nor what they urged.

Go ahead.

MR. COUGHLIN: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. COUGHLIN:

Q. Mr. Auerbach, I think it's still morning. So, good morning, Mr. Auerbach.

A. Good morning.

Q. I'd like you to turn to the first exhibit in the book, Exhibit 1072. Take a look at that. It's a document dated June 6, 2014, from Claire Sherman to you.

Could you remind us who Claire Sherman is?

A. Claire Sherman at this time was the lead statistician on the ExteNET trial.

Q. Okay.

MR. COUGHLIN: I don't believe there's any objection to this document, so I'd like to move for the admission of this document.

THE COURT: Number again?

MR. COUGHLIN: 1072 on the supplemental list, or

the supplemental, supplemental, supplemental. I apologize, Your Honor.

THE COURT: All right. 1072 is admitted.

(Exhibit 1072 received.)

BY MR. COUGHLIN:

Q. Now, this document is dated in June of 2014 and appears to be a document created for that time to examine the Kaplan-Meier curves before the unblinding; is that correct?

A. That is partially correct. What we had done to my recollection here was we were in the process of still collecting the data, cleaning it, et cetera. So we were trying to get an idea of how much data we had in, et cetera.

So if I remember this correctly, Claire created what's called a dummy code, which is a code basically where she decides randomly who would be in the neratinib group and who would be in the placebo group. The trial is still blinded, and in some way she has created a dummy code where she says, you know, patient one is on neratinib; patient two, placebo, et cetera. That's what these results are.

Q. It wasn't so random. Didn't she do this based on the grade-three diarrhea rate for neratinib?

A. As I remember this correctly, the dummy code she used was she used -- there were five side effects. It was one group for the patients who had that and one group for the patients who didn't. I seem to remember she used grade-two

or higher diarrhea. She played around with various variables to my recollection to try to get it where it was 50/50. I thought it was grade-two or higher diarrhea.

Q. So you didn't read her testimony that: One of the things I did, knowing that grade-three diarrhea is unique to neratinib, I tried to identify the patients in the neratinib arm.

You didn't know she had testified to that?

A. That is the first I've heard that.

Q. Okay. So you didn't know how this curve was created; is that right?

A. She had just said that -- my recollection in talking to her on this was that she had said that she took a group of, I thought it was, five adverse events, five side effects. And one group was the group who had that and one group was the group who did not. It was not just diarrhea to my recollection. There were others in there as well.

Q. Okay. If you turn to the table at page 2 of 5, the disease-free survival of the intent-to-treat population. Do you see that?

A. Yes.

Q. Up there we have some disease-free survival rates. We have a 5.66 up there after two years and 28 days. That leaves us a number of 94.44 in the neratinib arm; is that about right?

A. Correct.
Q. And if we take a look at the 7.84, that leaves us with a 92.16, if we're comparing apples to apples with the unblinded data, for an absolute difference of about 2.38 percent?
A. Correct. These are not Kaplan-Meier estimates, though.
Q. Kaplan-Meier curves.
A. But I think those are the actual rates, not the Kaplan-Meier rates.
Q. So those are the actual rates?
A. That's correct, yeah.
Q. So before this stuff is unblinded, before the trial is unblinded, you have a 2.38 percent absolute potential delta; is that right?
A. Using the dummy analysis, yes.
Q. Yes. This is an analysis that you had done so you could try to figure out where you were before the unblinding; isn't that correct?
A. No. The purpose of the dummy analysis was to look at the data that was coming in to see in terms of the event, number of events we were getting, number one. Number two, it was also how complete the data set was.
Q. So you weren't interested in the absolute delta at 2.38 percent?
A. So doing these dummy analyses --
Q. Could you just answer that question. You weren't

looking for the absolute delta. That was not a concern of yours?

A. It's -- it was not a concern because there have been many examples in clinical trial history where you do these analyses and you get it wrong and actually the reverse happens where all the people you thought were in the treatment arm are in the placebo arm, and all the people in the placebo arm were actually in the other arm.

Q. Okay.

A. So that's very dangerous to try to interpret these.

Q. But that's the information that you received in June, the month before the study was unblinded; is that right?

A. Correct.

Q. Okay. You testified the other day that when Yaron Werber was asking -- was about to ask you some questions, that you knew -- that you knew Yaron; is that right?

A. Yaron. Yes.

Q. You said: I know Yaron very well. I know how his brains thinks. And when I'm talking to him, I kind of know where his conversation is going.

Do you remember that testimony?

A. Yes, I recall that.

Q. I'd like you to look at the next exhibit line. It's exhibit -- new Exhibit 1082, next in your book. This is analyst report, an e-mail from Mariann Ohanesian dated June

23rd, 2014, to you with the attached report.

MR. COUGHLIN: So with the limiting instruction, I would move for the admission of this exhibit.

THE COURT: It's always helpful when you say move for the admission of this exhibit to give a number. You see, there will come a time when we're going to have to go through the whole transcript and figure out what's in and what's out. It's just helpful to give the number. And the number again is?

MR. COUGHLIN: Your Honor, it's 1082.

THE COURT: Without objection 1082 is admitted.

(Exhibit 1082 received.)

MR. COUGHLIN: Thank you, Your Honor.

BY MR. COUGHLIN:

Q. I'd like you to flip in to Mr. Yaron's report, and I'd like you to go to page 13 of 33. At the bottom, at the very bottom, I'm using those numbers for identification. I'd like you to look down at the lymph node status provides first event rate driver. Do you see that?

A. Yes, I do.

Q. I think that's some of the things that we were talking about, how I think you called it enriched. Some other people have said that, enriched. It's a higher risk population, right, the node negative; is that correct?

A. That is correct.

Q. Okay. And you had disclosed to the market that the ExteNET enrolled approximately 20 percent node-negative women; is that correct?
A. That is correct.
Q. Okay. And that compared to some of the other trials which had, I guess, a higher percent of node negative. And correct me if I'm wrong. Isn't the fact that if you have node negative, you're less at risk than node positive? Correct?
A. That is correct. You're less at risk, and it's more difficult to treat node positive.
Q. Because the cancer has traveled to your lymph nodes; is that correct?
A. That's correct.
Q. Once it has, you're more at risk; is that right?
A. That is accurate.
Q. And neratinib was something directed to treat these higher-risk people; is that correct?
A. Neratinib was being tested -- I don't think it's an accurate statement that neratinib was directed -- we were directing it at HER2-positive cancers. You know, if it's a higher-risk patient, there's no data to suggest neratinib works better. We didn't know.
Q. Okay. And you were testing that. And these compared to some studies that you put up on the board the other day, the

ALTTO trial. Do you see that?
A. Yes. I don't remember us discussing ALTTO.
Q. Okay. How about the BCIRG? Do you see that?
A. Yes.
Q. Okay. You had compared it to that. So neratinib was at 20 percent and BCIRG was at 29. Do you see that?
A. Yes.
Q. Okay. So was it hoped that you would get more events and see how efficacious neratinib was in this higher-risk group?
A. I'm sorry. Can you repeat the question?
Q. Was it hoped by this testing -- and this was amendment three where Pfizer had changed the enrollment to only enroll node positive; is that correct?
A. Correct.
Q. So you had a lower node negative in your overall population; is that right?
A. It was similar -- ours was around 22 to 23 percent in ExteNET. It's similar, as you can see in this paragraph. The BCIRG trial was 29. The NCCTG was six percent. So I would say neratinib's percent of patients who were node negative was, you know, similar to the Herceptin trials.
Q. And the HERA trial had a 33 percent; is that right?
A. Correct.
Q. Switch over to the next page, which is 14 of 33. This

is Dr. Werber talking about the ExteNET trial and what it is powered to show, the DFS benefit at five years. Do you see that?

A. Yes.

Q. Okay. So this is after you had changed it for the trial to go out into years three, four, and five, amendment 13, I think?

A. Correct.

Q. Okay. And over here on the left-hand side it says: But the bar is high as the study requires a DFS of 91 percent on the neratinib versus -- I believe that's, is it, 86 on the Herceptin alone? Do you see that?

A. Yes, I see that.

Q. Okay. So that was Dr. Werber's expectation as of June 2014, a month before you release the data?

A. I believe what he is doing is -- I think he states in the second paragraph ExteNET is 85 percent powered to show a hazard ratio of 0.67 on DFS at five years. We assume that the expected rate of DFS at three years is 86 percent on the Herceptin placebo versus 91 on the Herceptin neratinib.

So that was where that came from. We did not give that to him. He just came up with that on his own.

Q. Okay. But you knew that's what he -- you received this report of his. He's a friend of yours. He's a doctor that you worked with as an analyst, right?

A. We knew each other, yes.
Q. Okay. Let's move to the next exhibit. If I could have you turn to Exhibit 1083. It's dated -- actually, I'm not going to move to 1083. I misspoke. I'd like to first move to 1083. It's one more back in your book than your next exhibit in line.
THE COURT: I'm confused. You said you didn't want 1083, and now you just said you did want it.
MR. COUGHLIN: I did want 1083.
THE COURT: Let's make sure we finish statements just so the record is clear. So now you do want 1083?
MR. COUGHLIN: I do want 1083.
THE COURT: You move its admission. Any objection?
MS. JOHNSON: None, subject to the limiting instruction.
THE COURT: All right. 1083 is admitted.
(Exhibit 1083 received.)
BY MR. COUGHLIN:
Q. I ask you to take a look at that.
A. (Witness complies.)
Q. So, Mr. Auerbach, do you see that's a -- well, it's an e-mail to you delivering an analyst report?
A. Yes. That is correct.
Q. We'd also talked about Mr. Liang, Howard Liang, the other day. Do you remember that?

A. Yes.
Q. You also knew him?
A. Correct.
Q. Talk to him often, right?
A. Regularly.
Q. Okay. And if we flip in to his analyst report, I'd like to go to page 10 of 27. I'd like to go to the paragraph that has DFS for the control arm could be below 87 percent based on HERA data. Do you see that? It's the first paragraph, the bold -- page 10?
A. Sorry. I was on a different page.
Q. It's on the screen, if that's easier to read.
A. Yes, I see that.
Q. Okay. So this was dated June 24, 2014, again about a month before your conference call where you gave the numbers; is that correct?
A. Yes, that's correct.
Q. Okay. And here again it looks like Mr. Liang notes at the bottom of that, that given the lower node negative patient population in the ExteNET trial, 20 percent versus 33 for HERA, DFS for the control arm should be lower than 87 percent. Do you see that?
A. Yes, I see that.
Q. So this is a second analyst that's thinking that your DFS in the placebo arm is 86, 87; is that correct?

A. That is correct.
Q. And you knew that was the expectation of the market going into your conference call, right?
A. No. These analysts are just speculating and we -- I don't remember any investor telling me that they had an expectation that the control arm would be 86 or 87 percent.
Q. They seem to hit it right on the button, right, 86 to 87 and the 91 that was discussed by you on the conference call?
A. They are using the HERA data which was from ten years prior. We had a number -- I definitely recall having a lot of calls with investors asking about the BETH trial because that had been the most previous, the most recent Herceptin adjuvant study where there the control arm I believe was 92 percent and the differences between those older studies like HERA and the more recent ones like BETH.
Q. But you had a higher, quote, enriched population, a higher lymph node negative population. Isn't that why the street believed that you would be coming in at a lower rate, 86, 87, on the placebo?
A. No. In the HERA study they gave the chemotherapy before -- the patients completed chemotherapy before starting Herceptin. The more modern standard of care is to give it what we call concurrently, meaning that you give it at the same time, the chemotherapy and the Herceptin together.
When you do that, you get much better outcomes.

That's why, for instance, in the BETH study, it was given concurrently, and that ended up raising that DFS rate to somewhere around 92 percent.

So if you looked at any of the other studies where they gave it concurrently -- and you may remember from the forest plot we showed, in our study we allowed either way -- the DFS rates were much higher in the patients who got it concurrently.

Q. I understand that, but you understood that the street at this time expected you to have an 86 or 87 percent in the placebo, whether they were wrong or not or just speculating, you understood that that's what these two analysts that you talked with constantly, that's what they expected. Despite everything you just said, that's what they expected at the time?

A. I did not get the perception that that was in anticipation at all.

Q. You talked to them around this time?

A. I talked to them, and they had their perceptions and all their simulations they were running and things like that. They tended to care more about what the absolute magnitude of the benefit was rather than the exact rate. But we would certainly talk to investors and analysts who would think it could be 95 percent as well.

Q. Isn't that why the first questions asked of you on that

analyst call were the absolute benefit numbers and the rates?
A. Well, I think that the, as I recall the call, I think where Yaron was trying to get to was to get some range of expectations as to what the absolute magnitude of the DFS benefit would be, which is why he spoke in the generalities of saying, you know, mid to high 80s for the placebo arm and 90 to 91 for the neratinib arm.

He appeared -- I think he actually said, can I get a little bit of a sense. He was appearing to look for some type of a range.

Q. Didn't he say 86? He actually said the number 86, and you said you would be comfortable with that number?
A. I seem to recall that what Dr. Werber said was wouldn't the placebo arm be in the mid to high 80s, around 86 percent or so? I don't remember Dr. Werber saying won't the placebo arm be 86 percent, period.
Q. You said you would be comfortable with that number, but you didn't say you would be comfortable with that range?
A. We -- when we said I'd be comfortable with that number, we were endorsing the range. We certainly spoke with a lot of investors who understood that as well.
Q. Let's go to Exhibit 190. It's before the last exhibit in the book.

MR. COUGHLIN: I don't believe there's any objection to this exhibit, Your Honor. I'd move for its

admission. That would be Exhibit 190.

MS. JOHNSON: No objection, Your Honor.

THE COURT: 190 is admitted without objection.

(Exhibit 190 received.)

BY MR. COUGHLIN:

Q. This is an e-mail dated July 21st, 2014, from Mariann Ohanesian. If you take a look at it, it has to do with, quote, setting the lineup for your investor call of July 22nd, 2014?

A. Yes. That is correct.

Q. She says on that first page: Alan, please check the order of Q&A and adjust as desired. Do you see that?

A. Yes.

Q. Okay. And if you flip over to the next page, it talks about when the press releases are going to be released, the new licensing agreement with Pfizer. And then it talks about the release for time for the ExteNET trial. Then it talks about the question and answer, that the conference call is going to start, you know, some 20, 25 minutes after the release of the press releases. Then it has an order, a Q&A order. Do you see that?

A. Yes. That is correct.

Q. You actually picked the order for those analysts to come and ask those questions; isn't that correct?

A. We had predetermined what order the questions would come

in. We didn't know what questions were going to come in.
Q. No, but you know these guys very well. You said you knew what Dr. Werber was thinking before he even talked yesterday or the other day; isn't that correct?
A. I don't recall saying I knew what he was asking before he even talked. I seem to remember saying that while he was talking, I understood where the questioning was going.
Q. Okay. So you left that lineup just like it is; is that correct?
A. I believe we did.
Q. We talked a little earlier about your back-and-forth with Pfizer, and you said you had shown them everything that they had asked for; is that correct?
A. Yes, I believe that is correct.
Q. Okay. So I'd like to start with an exhibit that is already admitted, and that's Exhibit 480. This exhibit is dated September 12, 2014, and it says: As discussed during our September 9th call, please find attached list of documents. Do you see that?
A. Yes.
Q. Okay. And if you flip over to the first page, 2 of 4, it asks you to provide any written documentation -- the fourth bullet point down -- any written documentation including slides, tables, and other written reports provided to Puma or prepared by Puma regarding the ExteNET study

results up to the present.

Do you see that?

A. Yes. That is correct.

Q. Okay. This is about -- this is in September, so it's about a month and a half after the July 22nd conference call. One of the first things they ask is for the primary efficacy analysis, down at the bottom of that page. And those -- and that's what we looked at the other day in those charts, those tables, is that correct, out of Exhibit 123?

A. I apologize. I don't remember Exhibit 123.

Q. Well, it's your primary efficacy analysis. Do you remember what those tables look like?

A. I seem to recall it, yes.

Q. Okay. And they asked for those at years one, two, and three years. Do you see that?

A. Yes.

Q. Then they go on and they ask for the secondary efficacy analysis. Do you see that?

A. Yes. That is correct.

Q. Okay. So they were asking those in September, September 12th. And on September 19th -- if we could look at Exhibit 481 which has already been admitted -- four days later you respond to them, to Pfizer. Do you recall that?

A. Yes.

Q. Okay. And you sent them the table that is at page 6

of 7 -- if we could look at that. That's the chart that you sent Pfizer, and the DFS rates are cut out of that chart. Do you see that?

A. The table does not present the DFS rates. That's correct.

Q. Right. It's an altered chart from your original safety analysis, right?

A. That was what they had requested.

Q. Well, didn't we just look at what they had requested? And there's no limitation there in the request, correct?

A. The list they've given here is -- in Exhibit 480 is extremely extensive. As we discussed last week, when we spoke to Pfizer, we had told them that we were going to be triaging this and we asked them what was the most highest priority thing they wanted and what were the lower priority things they wanted. And we are sending this in batches.

Q. You said you had already showed them all of this data in August of 2014, right? You went to New York. You said you shared the whole table with them; is that correct?

A. There was a face-to-face meeting that took place in New York in August of 2014 between Pfizer and Puma, and we had discussed with them all of Puma outside of ExteNET and then also discussed ExteNET.

Q. Okay. And then you sent this table some four days later, and you cut out the rates that you had talked about on

the July 22nd call; isn't that correct?
A. I seem to recall that we also had a lot of phone calls with them to get an idea of on this long list what they wanted. And initially what had been communicated was they wanted the table with all the hazard ratios.
Q. Let me understand this. You said you were a small company. It was hard for you to gather all this stuff quickly. So you wanted to know exactly what they wanted. And instead of just sending them tables, you took the time to alter them to cut out the heart of this table and send it to them. And you said -- it's your testimony that's what they wanted. Don't send us the important stuff?
A. My recollection is that all of the data was seen as important to Pfizer. We had asked them what was the stuff they wanted more immediately and what were the stuff that we -- what was the information that they wanted us to send them at various time points.

Initially what they wanted to see was for both of these populations the differences in the hazard ratios.
Q. Okay. And you had to alter both tables to cut that information out about the absolute deltas, right?
A. I don't understand your question.
Q. You had to alter both the top table and the bottom table to take out the DFS rates, the center of these rates?
A. I don't remember how the table was created.

Q. Okay. Let's take a look at the next document which has been admitted --

THE COURT: Hold on. Take a look over your right shoulder.

MR. COUGHLIN: I'd like to stop here, Your Honor.

THE COURT: Was it something I said?

All right, folks. We'll stop and we'll see you all at 1:30. Remember, don't discuss the case. Keep an open mind. Don't research the case.

Thank you.

THE CLERK: All rise.

(Open court - jury not present)

THE COURT: Thank you, all. See you at 1:30.

(Recess taken from 12:00 p.m. until 1:33 p.m.)

THE CLERK: All rise.

(Open court - jury present)

THE COURT: Mr. Coughlin, please continue.

MR. COUGHLIN: Thank you, Your Honor.

BY MR. COUGHLIN:

Q. Mr. Auerbach, good afternoon.

A. Good afternoon.

Q. If we could turn to what your counsel showed you earlier this morning, Exhibit Number 994, which is now in evidence. We're still discussing some interaction between Pfizer and Puma. Do you see that?

A. Yes, I do.
Q. Okay. And you testified about this exhibit, and this is dated October 13, 2014. It's an e-mail to you from some people at Pfizer; is that correct?
A. Yes, that appears to be correct.
Q. Okay. And you identified Vatnak last week, and he sent you -- you were sending him some information; is that right?
A. Yes. That is correct.
Q. Okay. And you were sending him some subgroup analysis of patients and various -- the number of patients and the percentage by type of DFS event -- if you turn over to page 2 of 7; is that correct?
A. So this is not subgroup analyses. What this is, is the location of when the DFS event happened, where in the body it occurred.
Q. Okay. And these are the events that the Kaplan-Meier curves chart when they happen, in what arm they happen, either placebo or neratinib; is that correct?
A. That is correct.
Q. And in the neratinib arm, it was 70 events that we saw in some of the earlier charts; is that correct?
A. Yes. That is correct.
Q. And then 109 events in the placebo; is that right?
A. Correct.
Q. Okay. I would like you to flip to Exhibit 475.

A. (Witness complies.)

MR. COUGHLIN: Exhibit 475 has already been admitted.

BY MR. COUGHLIN:

Q. Mr. Auerbach, this is dated November 5th, 2014. This is you sending Pfizer those simulated curves that you talked about last week; is that correct?

A. That appears to be correct.

Q. Okay. And your testimony was that Pfizer knew that they were simulated; is that right?

A. They knew that from year zero to two was the actual ExteNET data. The simulation had started after year two.

Q. Okay. And if we flip in to page 4 of 5 in that document and take a look at that KM curve chart, I believe that's the, you know, that's the .80 to 1 to enlarge so you can see the delta; is that correct?

A. That appears to be correct.

Q. Okay. And that has an absolute difference there of 2.8 percent; is that correct?

A. At year three it is 2.8 percent. At year two it is 2.3 percent.

Q. Okay. Now, this is different. This is different information than the 3.5 percent chart you say you had seen earlier; is that correct?

A. That is correct. The two are distinct.

Q. Okay. Now, let's flip to Exhibit 796. This is a document back from Vatnak to you dated November 6, 2014. Do you see that?

A. Yes.

Q. Okay. Earlier you testified -- last week you testified that you never got a request from Pfizer asking for the patients at risk. Do you remember testifying to that?

A. I didn't recall getting one. Yes.

Q. Okay. And if you take a look down below in this document that Mr. Vatnak sends to you --

MR. COUGHLIN: Your Honor, I'd move for this to be in evidence for two reasons. One, it was -- opened the door on patient populations earlier today. It was subject to the earlier motion in limine.

But defendants moved Exhibit 994 in, which we just discussed, and this has two reasons. One, the exhibit --

THE COURT: Hold on. Number?

MR. COUGHLIN: The exhibit number is Exhibit Number 796.

THE COURT: Continue. Is it in one of the six books I have for this witness? Do we know?

MR. COUGHLIN: It's in the one I just gave you this morning.

THE COURT: I'm not sure which one that is.

Go ahead. Go ahead.

BY MR. COUGHLIN:

Q. Do you see, Mr. Auerbach --

THE COURT: You were making an explanation and I interrupted you.

MR. COUGHLIN: Okay.

The defendants had moved in information earlier about at-risk patients and various disease-free survival events that occurred. And here is Mr. Vatnak asking for patient information, at-risk patients, to be attached to the charts that Mr. Auerbach sent earlier.

When I asked Mr. Auerbach last week, he said he never got this request from Pfizer, but it is in the time frame November 6, 2014, they're asking for again the original intent population, KM plots, and then they're asking for the specific patient information that goes at the bottom of, quote, the simulated curves.

THE COURT: Response?

MS. JOHNSON: We object, Your Honor. This document contains hearsay that cannot be cured by a limiting instruction. It was covered by motion in limine number two, and the defense does not open the door by responding to information that was allowed in over objection that was itself subject to motion in limine number two.

We also would object to the characterization of the evidence that is not at issue by counsel in setting up the

exhibit.

THE COURT: When you say there's hearsay, is there any particular hearsay you're referencing?

MS. JOHNSON: Yes. The first paragraph, Your Honor, it is offered for the truth and cannot be responded to without going into the issue of motion in limine number two.

MR. COUGHLIN: Your Honor, what I'm offering this document for is for the fact that Mr. Auerbach testified that none of this at-risk patient information was requested, and this is a specific request to him by Pfizer for that information for the charts.

MS. JOHNSON: Your Honor --

MR. COUGHLIN: Mr. Auerbach testified that the charts were simulations and didn't need the patient population. This clearly shows that that's not Pfizer's understanding, so they're asking for the patient populations to be attached.

THE COURT: All right. There is a lot of information in here that constitutes hearsay information. I'm going to sustain the objection but suggest to simply ask the witness if he -- without reference to the document.

BY MR. COUGHLIN:

Q. Mr. Auerbach, does this refresh your --

THE COURT: No, that's not it. Ask him the question first.

BY MR. COUGHLIN:
Q. Mr. Auerbach, last week you testified that you don't recall a request from Pfizer for patient information for those curves?
A. So my recollection as of last week was that Pfizer had not specifically asked us to supply them with the patients at risk in the Kaplan-Meier curves. I am now reminded that they did ask for that information in -- at a later date.
Q. And you are aware that they never knew these were simulations; is that correct?
A. That is not my understanding, no.
Q. You testified earlier that you believe Pfizer was very happy with you and satisfied at the end of the day, and yet you saw Mr. Vatnak's declaration in this case where he says he did not know --
MS. JOHNSON: Objection, Your Honor.
THE COURT: Your objection is?
MS. JOHNSON: It's hearsay that --
THE COURT: It's a declaration that's in evidence?
MS. JOHNSON: It is not. You sustained an objection --
THE COURT: Sustained.
BY MR. COUGHLIN:
Q. Did you know Mr. Vatnak -- did it come to your knowledge that Mr. Vatnak, who was looking at this and making that

request, had no clue that these were simulations?

MS. JOHNSON: Objection to the characterization of excluded evidence. It's inappropriate argument.

THE COURT: Overruled.

THE WITNESS: My understanding from our discussion with him, which was in August of 2014, was that he -- my recollection is we went through with him exactly how it was performed and that they were indeed simulations.

After -- the first two years were the real data. After that was when the simulations started.

BY MR. COUGHLIN:

Q. Could you please take a look at Exhibit 486. This is an e-mail to yourself dated October 27, 2014; is that correct?

A. Correct.

Q. Okay.

MS. JOHNSON: Your Honor, you've sustained an objection to this document.

MR. COUGHLIN: Your Honor, we went past that information and here he --

THE COURT: Hold on. I don't see anything now pending before me.

MR. COUGHLIN: Okay. I would like to move for Exhibit 486 into evidence. He admits that he --

THE COURT: Hold on. 486. Any objection?

MS. JOHNSON: Objection. Hearsay. Relevance.

You've sustained the objection twice, once in the motion in limine and once last week.

THE COURT: When -- how can I find this document in the six books in front of me?

MR. COUGHLIN: It's in the book I handed you this morning, 486.

THE COURT: Okay. I must say, counsel, when there's six exhibit books in front of me of varying titles, it would be better to go to the original trial exhibits.

Okay. So this is 486, correct?

MR. COUGHLIN: Correct, Your Honor. It's certainly not hearsay. It's written by a party opponent. He's acknowledged he wrote it.

THE COURT: All right. Just a moment.

MS. JOHNSON: Your Honor, also work product was the basis on which you sustained.

THE COURT: Oh, don't -- I don't think so. I mean, the record is the record. I am not sure of that. So I have two versions, one revised, correct?

MR. COUGHLIN: That's correct, Your Honor. We would be requesting the whole version, but --

THE COURT: Okay. Didn't I allow part of this in?

MR. COUGHLIN: We talked about it and I redacted the last two sentences.

MS. JOHNSON: We talked about it, but you did not

admit either document. This might be appropriate for a conference, Your Honor. It's motion in limine number two.

THE COURT: No. No conference.

All right. We should have a conference. Let's step outside.

(Begin sidebar conference)

THE COURT: All right. As I said during the hearings on motion in limine, one of the shortfalls of doing them is you make a ruling, for example, on Pfizer because a particular issues about not retrying the Pfizer case or the implications of a dispute with Pfizer or any of that. You make the ruling, and then for different reasons Pfizer may become relevant, reasons not addressed in the motion in limine.

Now, I don't recall in reading the motion in limine any statement about the significance of Pfizer in terms of what was turned over and what wasn't, what Mr. Auerbach was saying was turned over and what wasn't. That really wasn't part of the motion in limine.

So when you cite the motion in limine, it was granted for different reasons. One of my hesitancies about motions in limine again is you spent a lot of time arguing on whether this comes within the original purpose of the motion in limine or another purpose.

When you cite the motion in limine as your

objection, it strikes me that this is for another purpose than what was cited in the motion in limine, what I decided the motion in limine based upon.

What would you say to that?

MS. JOHNSON: Your Honor, I would say that there is no way to defend against this document without talking about the Pfizer dispute, which was the point of the motion in limine.

THE COURT: Okay. Now, you have said that a lot.

MS. JOHNSON: But none in particular --

THE COURT: One at a time. We've gone back and forth about that. You haven't given me succinctly why you have to talk about all of the reasons for the dispute or even mentioned beyond the fact that there was a dispute, details of the dispute, which is what concerned me.

We've had this argument before. I'll give you one more time to tell me why you need to mention the details of dispute in defending against this. I've given you examples that you haven't given to me, examples like privilege, advice of counsel, litigation strategy that cannot be described without getting into the case.

So tell me why you have to get into the case to defend against this.

MS. JOHNSON: This one is litigation strategy.

THE COURT: Tell me why you have to mention the

litigation to get into the details of this. I even said why don't you just say it was due to other pending disputes. Why -- yes?

MS. JOHNSON: In order to defend against that, we have to tell a story.

THE COURT: No, you don't.

MR. CLUBOK: Actually, may I, Your Honor?

THE COURT: I don't know why you have to tell a story.

Go ahead.

MR. CLUBOK: It's not that it was withheld. What this is, is the night before a conference call that Pfizer is about to have with their investors, in their prior conference call an issue came up that is what sparked the litigation. The whole litigation is because in the first Pfizer call something was said. Pfizer then reacted to it. They've been now having this flurry of exchanges.

Mr. Auerbach is anticipating in this next call that the issue will come up again. We're going to be at full litigation war. He is here in a draft just to himself preparing in advance of what new claim Pfizer may make on their call tomorrow. Pfizer ends up not making the claim.

This draft, which is never -- nothing is done with this except he sends it to himself as he's preparing with the lawyers to get ready for -- in anticipation of what Pfizer --

it sits there and is never used. It stays in -- his e-mail to himself is never communicated to anyone. It never has to be used in response to an anticipated claim that he was worried Pfizer was going to make that Pfizer did not make.

This resolved the dispute. They no longer are -- they settled their differences. There no longer is any dispute after this day forward -- I guess the next day forward between the two parties.

So this whole exchange that we've now spent much time on and many other documents to continue, the way to explain away what's really going on here and the reason why some of the e-mails seem sort of cautiously written and why the Pfizer lawyers are making a lawyer's record about what supposedly wasn't delivered and why Mr. Auerbach is planning for the new claim that Pfizer is going to make, which they don't make, it's all because they're in this dispute over what information is supposed to be shared. Resolved as of the next day. That's it. That's the end of it.

So is the only possible -- first of all, we would have to do the trial within the trial and explain why Pfizer was wrong or Pfizer is making false claims.

THE COURT: All right. I'm still not seeing why that needs to be done. Go ahead.

MR. CLUBOK: Because he is preparing for a claim that he's worried --

THE COURT: Okay. Now you're repeating.

MR. CLUBOK: Yes. I apologize.

THE COURT: We should turn to the plaintiffs.

MR. COUGHLIN: Your Honor, this has nothing to do with their dispute. What it has to do with is we assert that Mr. Auerbach made those statements. From then on until the offering, he had to hide that information that he actually had from market participants, even the licensor like Pfizer.

So he dribbles out information to them. They're in here putting on information this morning, oh, then you sent them this. You sent them this. You're following up. You're trying to help them.

What does he not send them? He does not send them what's mentioned here in the second -- Pfizer has not seen the disease-free survival data, nor has Pfizer seen the Kaplan-Meier curves for the ExteNET trial.

That is crucial. That is what -- that is what Pfizer asked for from day one when they heard those false claims. Okay. What did they get? They got gobbledygook. Why? Because it fits in our case that he cannot send those to Pfizer or they'll know he's committed a fraud. Okay.

I would be afraid if I was him, you know, sending that over to Pfizer. This didn't get resolved like that next day.

THE COURT: Slow down.

MR. COUGHLIN: Mr. Vatnak has submitted a declaration here that they never -- they never knew it was a simulation, so that is a falsehood that he's put on, that they knew it was a simulation and asked for it. Okay. It goes right to him lying to even his licensor. Okay. Why? To cover up, you know, him keeping secret what's happening.

So that I think is -- it's got to come in. It's an admission by a party opponent. It goes right to the heart of our allegations. We've, you know, agreed to redact the last two sentences that he wants to sue them and reserve his rights -- a whole separate legal claim that wasn't the basis of Your Honor's motion in limine.

The whole thing should come in, but at least the first two sentences.

THE COURT: What if you asked: Were certain interested parties denied the opportunity to see the disease-free survival data or the Kaplan-Meier curves for the ExteNET trial? I know defendants will still dispute that. What if you were to ask that.

MR. COUGHLIN: He's already testified that he showed the real data in August of 2014. This completely contradicts him.

THE COURT: Don't say this. Don't you want to make a record?

MR. COUGHLIN: Yes.

THE COURT: It's up to you. Don't say this. Say 486.

MR. COUGHLIN: In 486 Mr. Auerbach types to himself that Pfizer has not seen the disease-free survival data, nor has Pfizer seen the Kaplan-Meier curves for the ExteNET trial. Last week --

THE COURT: Are you saying this impeaches his earlier testimony?

MR. COUGHLIN: Absolutely.

THE COURT: What do you say to that?

MR. CLUBOK: What we would say to that is that the only way we can explain that it does not is to say I ask just working on a potential response to a false claim that Pfizer is making. The claim that Pfizer is making --

THE COURT: Well, then --

MR. CLUBOK: If I may, Your Honor, to make my record, I'll try to do it very succinctly if I can. The claim that guy is making is that the data was so good that they weren't getting a chance to see it. They should be able to see the good data.

We have disproven that anything was hidden by showing that there is actual communications between Pfizer. That is the best evidence of what was sent. But Pfizer had been claiming that -- that Puma is hiding good data from them. That dispute gets resolved.

The plaintiffs now want to misleadingly use this to suggest that he's hiding that data. He just explained that's the theory. There is no basis for that theory. But now we are fighting shadows. We have to -- we are forced -- we're going to be asked with our limited remaining precious time to rebut a false theory that Pfizer -- that they are saying Pfizer was advancing which Pfizer ultimately withdrew, and now we have to show that it was a false theory for Pfizer and they withdrew it and we're being accused of the opposite thing in this case.

At best, this is some sort of handcuff character evidence in this case. But this particular e-mail, it's like attempted character evidence. This e-mail never leaves from his own box.

THE COURT: Is it a true statement that Pfizer has not seen the disease-free survival data? Is that a true statement?

MR. CLUBOK: No.

THE COURT: Why did your client write that?

MR. CLUBOK: Because he is loosely -- first of all, he's -- he has just heard -- actually, he -- I will make a proffer he had just heard. He's in a hotel room. He just hears that Pfizer tomorrow is going to lie and claim something about the data.

THE COURT: I don't see why that's a justification

for him to say Pfizer has not seen the disease-free survival data.

MR. CLUBOK: It is -- it is, A, that is, he writing as he's in his room trying to think about what these guys are going to say. B, there is a very hypertechnical explanation for why which we can't get into without explaining about the whole story of what Pfizer was going to be -- what we had heard that Pfizer was going to be saying or anticipating the legal response we're going to have to make.

Mr. Auerbach starts to prepare a draft response. This never gets finished, never gets sent to anyone, and it is uncommunicated internal work product in the context of a further investigation that would be impossible to explain without now going into the whole litigation.

It does not prove anything except possibly character evidence which would be inadmissible anyway.

MR. COUGHLIN: Your Honor, it proves he lied.

THE COURT: Hold on. It proved that he lied.

Now, when there's an objection and a response, I'm getting long narratives. Here I'd like a response. Impeachment. I don't know that I've ever heard that. I could be wrong. It would be great if instead of giving me long narratives, you say impeachment here. Say foundation, and I am able to rule on that instead of sorting through your long narratives. I'm just --

MR. COUGHLIN: Admission by party opponent and impeachment, Your Honor.

THE COURT: Okay. On the issue of work product, I -- I'm not seeing this as work product in this case. I'm not sure you can protect this from an unfiled piece of litigation in another matter. I'm not going on the work product issue.

403 looms large, which is essentially what you're saying when you talk about cases within cases. Since I made my previous ruling, much of this case is focused on what documents were provided and what documents were not provided.

I think this is pretty solid evidence of Mr. Auerbach's view on what wasn't provided.

MR. CLUBOK: And how is anything that is provided to -- our problem is that the whole issue of what was or was not provided to Pfizer, which they have certainly cracked the door. We had to respond. Now the door gets wider and has nothing to do with whether or not Mr. Auerbach told the truth on July 22nd in the conference call, which is what Your Honor read to the jury is what this case is about.

This secondary dispute will definitely prejudice the jury because their views about what happened in this dispute will affect their views about what's happening. It is impermissible character evidence. It is a 403 issue for us to have to get into this whole dispute when it doesn't --

THE COURT: Stop. Let me go back to the plaintiff.

How was what went on in this later dispute relevant to this case?

MR. COUGHLIN: I'm not talking about the dispute. Our theory --

THE COURT: You are talking about what went on in this later dispute. Let me ask my question again: How is what went on in this later dispute relevant to this case?

MR. COUGHLIN: Because he testified that he had told Pfizer in August of 2014 all of this information, all of the information, the ITT information and everything, and our whole case is built on the fact that he lied to the market and he could not disclose this information to somebody like Pfizer or the underwriters for the offering because they would know he lied.

He gets out the offering and then he starts to try to bring down the market. This goes to the heart of our litigation wholly and separate and apart from the Pfizer, quote, dispute. What he -- what he sent to Pfizer is bits and pieces. He cuts out the heart of the chart because he knows if they see that, they will know he lied. He is worried about that leaking out.

He does the same thing with the FDA minutes, okay, that go to the underwriters so that they don't see them and don't know. It's part of what he's doing. He's lying. He's lying here. He's lying to Pfizer. He's lying to the FDA,

and he's lying to the market.

Okay. He needs a couple hundred million dollars. He goes out to the market and gets that --

THE COURT: Okay. You have a minute or two to close.

MR. CLUBOK: It sounded like character evidence. The issue of whether to have to prove that he was not lying to Pfizer will require us to have the trial within the trial that you explained all of these arguments do go -- do not go to, the objective and subjective truth of the July 22nd statements which are proven by the documents that really were available then and the witness's testimony and the reaction by the market, this internal dispute with Pfizer had nothing to do with it.

They're just continually trying to keep cracking open the door to pile character evidence on top of character evidence.

THE COURT: Okay. I don't think it's character evidence. It relates to documents in this case. I think you can provide your rebuttal without the kind of reference to Pfizer that I have been concerned about.

I think as the facts develop in this case, I'm going to overrule the objection to the redacted version. Okay.

(End sidebar conference)

THE COURT: You move 486?

MR. COUGHLIN: Yes.

THE COURT: 486 as redacted is admitted. Go ahead.

(Exhibit 486 received.)

BY MR. COUGHLIN:

Q. Mr. Auerbach, if you could take a look in your binder -- or you can take a look on the screen right there. This is dated October 27, 2014. It states that Puma has not shared any information with Pfizer regarding the disease-free survival data from the ExteNET trial.

The primary end point of the ExteNET trial was the disease-free survival, period. Pfizer has not seen the disease-free survival data, nor has Pfizer seen the Kaplan-Meier curves for the ExteNET trial data.

That was true as of this date; isn't it?

A. I'm trying to recollect this since it is new evidence. As I recall, this is an e-mail to myself. I may have been thinking that we had not yet sent them the curves, which I believe were sent in November.

Q. Mr. Auerbach, you testified that you gave all of this information over in August 2014 when you went to New York.

A. We showed it to them, but they didn't have the material in their possession. So I think that is probably what this is referring to.

Q. It says Pfizer has not seen the disease-free. It

doesn't say it hasn't been shown.
A. Yeah. I think my recollection is that was not what I was meaning to say to myself.
Q. Or was it not --
MS. JOHNSON: Your Honor, I'm going to ask --
THE COURT: Just a moment. You'd like him to continue?
MS. JOHNSON: To be able to finish his answer.
THE COURT: You may finish your answer.
THE WITNESS: Thank you.
My recollection here is that's not what I was talking to myself about. What I was talking to myself about was that we hadn't yet sent them the three-year KM curves that we were sending them in November.
In terms of the meeting we had in August, yes, my recollection is we did show them the data. I don't believe that's what this is referring.
BY MR. COUGHLIN:
Q. So you wrote yourself a false e-mail?
A. I don't say it was a false e-mail. I would say -- if I'm writing an e-mail from me to me, the only person who needs to understand that is me. My understanding of what I was talking to myself about is that I was saying that they hadn't yet seen the data we were going to be sending them in November.

Q. Thank you, Mr. Auerbach.

If you could turn to Exhibit 1088.

MR. COUGHLIN: I don't think there's any objection to this exhibit.

MS. JOHNSON: No objection.

THE COURT: 1088 admitted.

(Exhibit 1088 received)

BY MR. COUGHLIN:

Q. Did you find it?

A. No, I didn't.

Q. Two more down.

A. Thank you. Yes.

Q. Mr. Auerbach, earlier you had a discussion with your counsel about what was required to be submitted for the nonclinical package to the FDA?

A. Yes, that is correct.

Q. Can you tell us who Erin Jones is?

A. Erin at the time worked in our regulatory affairs department.

Q. Okay. And this is a discussion about what data to include in that FDA package for your nonclinical application; is that correct?

A. May I review this, please?

Q. Yes.

A. (Witness reviewing document) Thank you. Okay.

Q. So this document -- again, who is Erin Jones? What's her position?
A. Erin worked in our regulatory affairs department.
Q. Okay. And that would be interacting directly with the FDA; is that correct?
A. That's correct.
Q. Okay. And here she sets forward why you should definitely include the clinical data to support your -- the context of your nonclinical application; is that right?
A. I believe what's stated, if we can -- can we highlight number two, please.
Q. Yes.
A. Thank you. May I read this?
Q. Yes.
A. Thank you. This is an exceptional request. Few sponsors that investigate non-IHC -- ICH S9 patient populations have been deferred carcinogenicity studies to the post-marketing setting.

So the point Erin is making is that we are making a very exceptional request, which is FDA is very, very rarely -- I'm actually not aware of any of this type in the oncology population -- allowed companies to not submit a full two-year carcinogenicity study.

So the point he is making is we are trying to put as much evidence as possible to try to sway them to allow us

to file without that data.
Q. And that's in part why you included the clinical trial date in your application, right?
A. It was in the briefing book initially, but at the meeting they would not discuss it with us.
Q. But that's not reflected in any minutes that they sent to you, right?
A. It was reflected in the meeting itself.
Q. But when they sent you the document back, they never said anything about not considering the clinical trial data; did they?
A. In the meeting itself, which took place, the teleconference, when we tried to have a discussion on clinical data, they said this is a nonclinical meeting. This is not the place to discuss clinical data.
Q. And yet when they sent you back the minutes, they quoted every significant chart or clinical data study that you had provided back in the minutes to you, correct?
A. No. I believe that was put in by us originally.
Q. Originally it was.
A. Yes.
Q. But they sent their own minutes back, right?
A. But in the FDA comments, they didn't say anything about the clinical data.
Q. They did their own minutes and they sent them back to

you in December, and they included all of your clinical trial data; isn't that correct?

A. The data we had originally put in was in the FDA's meeting minutes, but there was no commentary on it to reflect that it was discussed. The reason for that is because the clinical data was not discussed.

Q. There is nothing contemporaneous that indicates that, right, except for your word? Is that right?

A. Anyone else who was present there would remember that as well.

Q. But none of the clinical data that they included in their minutes and specifically sent back to you as their official record of those minutes, that they didn't consider that clinical data even though they kept it in the minutes or put it into their own minutes; is that right?

A. It was originally put in by Puma. It was not discussed in the meeting, so the FDA had no commentary on it, which would suggest that if they did discuss it with us, they would have put a note that said we discussed the clinical data.

Q. But they didn't. They didn't put any note at all rejecting it, saying anything about the discussion of it. You included it. It came back in their minutes to you; is that correct?

A. If the FDA had discussed clinical data with us in the meeting, there would have been a note saying that they

discussed it and what their analysis was.
Q. Let's take a look at Exhibit 773 and 491. Both have been admitted into evidence, and 491 is on the right and 773 is on the left. I put them in order in your book, Mr. Auerbach. So you can either look at the hard copy or you can look at the screen.
Exhibit 773 -- let me set up what I'm trying to ask you and understand. You testified earlier that everything, everything in these minutes that were altered was true, everything left in the altered minutes; is that right?
A. Everything that was in the Puma internal meeting notes, which is the document that was sent to Mr. Hicks, was accurate information and indeed reflected the ongoing discussions that Puma had been having with the FDA.
Q. Mr. Auerbach, you testified earlier that the first time you learned the minutes were altered was at your deposition; is that correct?
A. That's correct.
Q. You never knew about it before?
A. I was not aware that this internal meeting minutes document had existed until it was brought to my attention.
Q. How did it become an internal meeting minutes from an altered FDA document? You just made that up. There is no internal meeting minutes. There's no document like this on the server at Puma.

A. So to answer your question regarding the document being on the server, every Puma employee has their own computer. We do not have every document that is on someone's computer saved on the server. Most people just save them on their own computers.

So it's not uncommon that we're looking for a document and it's not on the server because it's on someone's personal computer.

Q. You didn't alter this document. Is that your testimony?

A. I have no recollection of altering this document, and I have no recollection of asking someone to alter this document.

Q. Mr. Auerbach, this is the most important document in this case because it goes to the underwriters --

THE COURT: Hold on. Hold on. Is there an objection?

MS. JOHNSON: Yes, Your Honor. Objection to that characterization and mischaracterization of the evidence.

THE COURT: Counsel, you know, counsel are not witnesses. Whether you think it's important --

MR. COUGHLIN: Understand.

THE COURT: Ms. Johnson, do you think this is the most important document in this case?

MS. JOHNSON: Your Honor, I think it's the least.

THE COURT: All right. Good. Let's not have

attorney comments.

MR. COUGHLIN: Okay.

THE COURT: Let's just ask questions.

BY MR. COUGHLIN:

Q. When they were doing the underwriting due diligence, they asked specifically for the FDA materials, correct?

A. That's correct. Mr. Hicks asked for that, yes.

Q. And you sent over the altered minutes; is that correct?

A. I sent over the document that the team had sent me, which was an incorrect version of the document.

Q. So you -- your testimony today is that somebody in the team sent it to you, not that you pulled it off the server yourself; is that right?

A. If I had pulled it off the server myself, then we would be able to find a version of it on the server. We have not been able to find that. The only other place it would have come from -- and typically whenever I needed a document, I would get them from --

Q. Mr. Auerbach, your counsel can go through all of that.

THE COURT: I'm going let him finish go ahead.

THE WITNESS: Thank you very much.

Whenever I usually would need regulatory documents -- because I don't have access to those documents. That part of the server is locked off to me. Whenever I would ask, need regulatory documents for any purpose

whatsoever, I would usually ask a member of the regulatory team to get them for me.

So my assumption as to what happened here was I asked a member of the regulatory team to get me copies of recent FDA communications. This was the document, the one on the right here, that was given to me. It appears to be our internal meeting notes, but it is not the official version. So it was sent in error.

BY MR. COUGHLIN:

Q. Let's take a look at it. Let's go page by page, if we could go through it.

A. Sure.

Q. If you will flip through it with me, so we would start -- so now we're on page 2 of 15. Let's go 3 of 15. So far both documents appear the same, correct? Let's go to 4 of 15. Still so far the documents appear to be the same.

Let's go to the next page. Let's go to the top two lines and pull those out for both. So in the official version which is on top, there's a difference in the numbers at the very top. In fact, the neratinib arm seems to -- on the neoplasms malignant seems to be a little higher than the placebo. Do you see that?

A. Yes, I do.

Q. Okay. So somebody changed that, what you would -- what you say internally, somebody changed the official minutes to

a different number than you had supplied the FDA; is that correct?

A. We actually looked into this in detail, and we found that this table was actually in a constantly changing mode. So we actually did find that the lower table, the 13 and 13, was in a different version of this document.

Q. In fact, that different version, however, didn't add up to 13. It added up to 14. So that's how it became 14 in the official documents, right?

A. I'm not aware of that.

Q. Okay. So let's keep going in the document. So this chart here, this is a -- this is a part of the clinical trial, right? It says it's from the safety study, study 3004, right?

A. That would appear to be correct, yes.

Q. Okay. Now, this is a clinical study chart that you say doesn't need to be in this -- in the nonclinical request, yet it is in the request, right?

A. It was put in by us. And as you saw from the e-mail earlier, it was part of our justification that we were hoping to have with the FDA as to why we should be allowed to file without the carcinogenicity data.

Q. And then somebody changed it, you're saying, internally, changed it to the 13 and the two, lowered the number so neratinib would not be above, and you're saying that became

an internal copy that was correct?
A. It may have been that they were continuously revising because they were getting updated numbers. I don't know the answer to that.
Q. You have no clue who did this?
A. All I can say is that in searching for what occurred here, we did find other versions of this table that matched the 13 and 13.
Q. Okay. Did you -- when you first testified last week about this, you said you didn't have the Word document or you were not the author of the Word document; is that right?
A. I believe that is correct, yes.
Q. Okay. When you testified at your deposition -- maybe I could take a look at -- can we play his deposition clip?
MS. JOHNSON: Your Honor, can we see it before it is published to the jury?
MR. COUGHLIN: From his deposition testimony, he testified something different earlier.
MS. JOHNSON: Your Honor --
THE COURT: You want to read from a deposition?
MR. COUGHLIN: I want to play his voice back to him. He just testified to something different.
THE COURT: Hold on. I don't need your commentary. It's not relevant about whether he testified differently. It's a party witness. Page and line, please?

MR. COUGHLIN: Page -- I believe it's 728, line 16, to to 729, line 8.

THE COURT: Any objection?

You can put it on the screen if you wish. 728, line what?

MR. COUGHLIN: Page 728, line 16, to 729, line 8.

MS. JOHNSON: No objection.

THE COURT: All right. Thank you, Ms. Johnson.

You may play.

(Portion of videotaped deposition played)

BY MR. COUGHLIN:

Q. Mr. Auerbach, now you were testifying last week in trial that you had the Word version and that you had not created the Word version and that you were the author of the later version; is that correct?

MS. JOHNSON: Objection. Mischaracterizes the testimony.

THE COURT: If it does, the witness may answer that it is not correct.

Overruled.

THE WITNESS: Thank you. That was not what my testimony was.

What my testimony was is that, as I recall, is that the pdf I was the author of because I saved it, but it does not say that I was the author of the Word document.

BY MR. COUGHLIN:

Q. So you're saying that you -- if I understand the testimony between your deposition and your trial testimony, you're saying that you keep everything on your servers at Puma that comes from the FDA in a pdf, correct?

A. That's my understanding. I don't have -- just to clarify, I don't have access to the regulatory folder. The FDA correspondence folder I don't have access to. My assumption is that it's all stored as pdf's. If it is stored as a Word document, I wouldn't know.

Q. We didn't find -- have you -- you said you did an investigation. Did you find a Word document on your servers at Puma, this Word document?

A. So, again, to reiterate what I said a few minutes ago, a lot of the documents in the company are not always stored on the server. They're stored on individual people's computers.

And especially with us having, you know, quite a bit of turnover -- this occurred in 2014, and we're five years later -- a lot of times when people leave, they take their computers with them and we oftentimes don't get them back, or they come back and our information technology, our IT department, you know, reimages them and sends them to a different employee. So we do get information lost sometimes.

Q. Okay. Let's keep going through this document.

A. Sure.

Q. Next page. The last paragraph has changed. Do you see that, Mr. Auerbach? What's taken out of that last paragraph?
A. Hang on. It looks like the DFS rates in the secondary end point paragraph.
Q. The most important information of the ExteNET study; is that correct?
A. I would not say that that is the most -- I disagree with the statement that that is the most important information in the ExteNET data.
Q. It's one of the most -- it's an important piece of information in the ExteNET trial?
A. I think there are lots of important pieces of information in the ExteNET trial. I think at ASCO, Arlene Chan probably had 30 or 40 slides worth of important information.
Q. Okay. Let's look at the next page. So the next page in the original on the left, the primary and secondary efficacy for study 3004, which is the referring to the ExteNET trial; is that correct?
A. That would be correct.
Q. And that -- that table was removed; is that correct?
A. That appears to be correct.
Q. If we flip over to the next page, the forest plots that we talked about earlier, those have been removed; is that correct?

A. That appears to be correct.
Q. Okay. If we turn over to the next page and the next page, this chart appears to be -- have been removed from the original; is that correct?
A. I -- can we go back? You're at different pages. I can't answer that.
Q. Okay. We've gotten to the end of the document without that page, without that chart. Do you see that?
A. Can you please go to the --
Q. Yes. Now go back in both.
A. Okay.
Q. Do you see those charts have also been removed?
A. Uh-huh. Yes.
Q. Okay. Let's go to -- let's go to the final question. Let's go to question number four in the original. So if we look at the top, question number four at the top, it says -- it talks about what studies have to be -- any additional studies that need to be submitted. And at the end of that question it says: And that additional SEG-1 studies are not required. Do you see the question that Puma asks?
A. Yes, I do.
Q. Okay. And in the original document, the FDA answers no; that consistent with the recommendation in ICH M-3R2, a full battery of GLP reproductive and developmental toxicology studies, i.e., fertility and early embryonic development,

embryo fetal development, and pre- and postnatal development, should be included in an NDA submission to support the proposed indication.

Do you see that?

A. Yes, I do.

Q. Okay. In the altered document, the FDA's answer is changed from yes to no. They don't agree. Also, the question has been shortened. What has been taken out there is at the end of the question, and that additional SEG-1 studies are not required. Do you see that?

A. Yes.

Q. Okay. And you have no recollection of who altered this document or why?

A. We did look into this, and what we found was that in between receiving this document and having the meeting, we sent FDA a list of all of our ongoing studies. So these are very different studies. These are not carcinogenicity studies. What these are --

Q. Mr. Auerbach, I do have a right to get an answer to that question.

A. Well --

Q. You don't know who altered this document, right?

A. I do not know who altered this document, but I can say that the information contained is accurate.

Q. The yes to no is accurate?

A. I was trying to answer that earlier and you stopped me. May I go back and answer this, please?

Q. No. I want to say, you don't know who changed the no to a yes in this document, and you're saying it was somebody at Puma?

A. Well, as I was trying to say earlier, we went back to look over the history of this and found that in the discussion with FDA, we submitted to them our ongoing SEG-1, SEG-2, and SEG-3 studies which are not carcinogenicity studies. These are, as it states in the second line up there, reproductive toxicity studies.

These are seeing whether or not the drug has an effect on a pregnant woman's ability to have a child, so reproductive toxicity. And what we found was that we had indeed submitted to FDA before this meeting took place a list of all of our SEG-1, SEG-2, and SEG-3 studies, which are three different types of reproductive toxicity studies done in rats, and they had signed off on them.

Q. Mr. Auerbach, isn't it a fact that you were the one that crossed out this so that the underwriters wouldn't know that the FDA had told you no and that you might have to do additional studies? Isn't that what happened?

A. Those studies were ongoing and/or had results. So again, that was what we found when we went and looked back. We have the list of them if you'd like to see them.

Q. Mr. Auerbach, I'll ask you the next question. Your counsel can ask you.
A. Okay.
Q. Mr. Auerbach, if you can turn to 379.
MR. COUGHLIN: I don't believe there's any objection to 379, Your Honor. I move for its admission.
THE COURT: Without objection 379 is admitted.
(Exhibit 379 received)
BY MR. COUGHLIN:
Q. Do you recognize what 379 is, Mr. Auerbach?
A. These would be the tables that are sent to me by Alvin Wong for safety.
Q. And you asked for the final validation safety data; is that correct?
A. That is correct.
Q. Okay. And then you received these tables back. And let's just take a look. If we go into 6 of 257, if we go take a look at -- if we can turn it around.
Mr. Auerbach, while you're looking at your exhibit, if you take a look at the grade three as you go across there from the diarrhea, it has the number 39.8, correct?
A. Correct.
Q. That was in the original -- that was in the original material that you received in late July 2014; is that right?
A. Do you have the original slide deck on safety, please?

Q. I do. Let me ask you this, Mr. Auerbach. If I look down on that page that we're looking at, and if I look down to the header, it says the date of this snapshot is July 7, 2014. Do you see that?

A. Yes.

Q. Okay. So that's the same -- that's exactly what the snapshot was in the Exhibit 124, the safety analysis that you received on July 18th; is that correct?

A. I -- I am assuming so. I don't have that in front of me, but I'm assuming that's correct.

Q. Okay. Let's go to the next exhibit. That would be Exhibit 254.

MR. COUGHLIN: Exhibit 254 is not objected to with a limiting instruction. It's a Stifel May 13, 2015, analyst report.

THE COURT: Without objection 254 is admitted.

(Exhibit 254 received)

BY MR COUGHLIN:

Q. Would you take a look at the top paragraph, and we'll talk about some of the numbers in that paragraph.

MR. COUGHLIN: If you can highlight that.

THE WITNESS: Yes.

BY MR. COUGHLIN:

Q. So this is a Stifel report after the abstract has been released on May 13th, 2015. It has your reported -- it says:

We expected the DFS for the Herceptin arm of the ExteNET trial to be about 86 percent suggested in the reported hazard ratio of .67 for the neratinib arm would correspond to about a 91 percent DFS in the neratinib arm. These numbers would yield a five percent absolute increase in DFS.

Do you see that?

A. Yes, I see that.

MS. JOHNSON: I'm sorry, Your Honor. Just for the record, this is subject to the limiting instruction that the parties have agreed upon.

MR. COUGHLIN: Yes, Your Honor.

THE COURT: Continue. Thank you.

BY MR. COUGHLIN:

Q. So that was via five percent delta; is that right?

A. That is what the analyst calculates, yeah.

Q. Okay. And it goes on and talks about what the actual numbers were, 91.6 and 93.9. Do you see that?

A. Correct.

Q. And see -- at the bottom it says these numbers yield an absolutely difference of 2.3 percent improvement in DFS at the expense of 40 percent grade-three diarrhea. In other words, one in 43 women -- that's the number needed to treat. Do you understand that?

A. Yes.

Q. Okay -- will see a benefit from taking a fairly

inconvenient drug for a year, and that benefit is likely non-recurrence, not survival. Do you see that?

A. Yes. That's correct.

Q. Okay. So they had been expecting a .5 percent absolute increase, which would have given you one in 20, 20 women to treat, and the actual numbers reported were actually more than double that. Do you see that?

A. Yes, I see that.

Q. Did you understand that -- were you not talking to this analyst at Stifel?

A. I've never spoken to him. He initiated coverage on the company. Stifel is a very small brokerage firm, primarily retail is my understanding. You'll notice his -- in the upper right-hand corner, you will notice his rating is hold.

So I can tell you that having been a Wall Street analyst for six years, when you have analysts who have a buy rating on the stock, they obviously want to show positive things. When you have analysts with a hold rating, they tend to take any news and immediately make it negative.

So I actually never met this analyst. At this point he initiated coverage without ever meeting me. So I -- to be honest, I don't even remember if I read this report.

Q. You had an expectation of the five percent absolute delta that we had talked about that we believed emanated from the conference call, correct?

A. That's your perception. Again, with regard to this analyst, I don't think he works anymore in Wall Street. My understanding is he does not. And I had never spoken to him before. So I didn't --

Q. Let's go to an analyst that you did speak to. Let's go to Exhibit 319, Mr. Schmidt, Eric Schmidt.

MR. COUGHLIN: I'd move for the admission of this with a limiting instruction, Your Honor.

MS. JOHNSON: No objection on that basis.

THE COURT: 319 is admitted on that basis.

(Exhibit 319 received.)

BY MR. COUGHLIN:

Q. If we go down to the last paragraph from the bottom --

THE COURT: As he is looking, let me just say 319 is not on the original exhibit list.

Go ahead.

BY MR. COUGHLIN:

Q. If we're looking at those comments, it talks about Mr. Schmidt says these results are disappointing only in that the absolute benefit of improvement in DFS is modest. Do you see that?

A. Yes, I do.

Q. Given prior comments from PBYI -- and is that you, Mr. Auerbach?

A. Yes. That would be me.

Q. You were the only one authorized at this time to speak on behalf of the company; is that correct?
A. That is correct.
Q. Okay. Investors had expectation of at least three percent absolute benefit and perhaps a benefit as high as four and five percent; is that correct?
A. So can I get some clarification, please?
Q. Sure.
A. On the last report you said that I told people it was five percent. Now you're telling me I told people it was between three and five percent; is that correct?
Q. Your counsel can ask you about those. You know Mr. Schmidt, right?
A. I knew him, yes. You'll also notice his rating --
Q. Let me ask a question.
A. Sure.
Q. Okay. He had just stopped coverage in the company; is that correct? May 5th he downgraded you?
A. He had downgraded the stock to hold basically, yes.
Q. That's right. But he attributes --
THE COURT: Excuse me one moment. I didn't get that last word. Just one moment.
He had downgraded the stock to hold basically.
Okay. Go ahead.
MR. COUGHLIN: Yes.

BY MR. COUGHLIN:
Q. You knew who he was, correct?
A. Yes.
Q. And when he downgraded the stock, he wrote you: It's been a great ride. I'm downgrading the stock -- the week before, about May 5th?
A. And I spoke with him as well.
Q. Okay.
A. And his commentary was that he had expected the company would be acquired. It was not, and he was downgrading the stock.
Q. Okay. Did you talk to him about his expectations on that day?
A. I don't talk to Southside analysts. People who write these reports are independent. What their view is, whether their expectation is we continue as an independent company, whether their expectation is we partner with someone else, or whether their expectation is the company gets acquired is their own independent view. I don't interfere with analysts' opinions.
Q. Let's take a look at Exhibit 324.
THE COURT: As we look at 324, tell me how much longer with this witness.
MR. COUGHLIN: Not a long time. Probably if we take a break right now, I'll probably cut it down and

probably be another 15, 20 minutes.

THE COURT: Why don't you plan on ending by three.

Go ahead.

MR. COUGHLIN: Okay.

BY MR. COUGHLIN:

Q. Let's take a look at the paragraph if you go to page 4 -- sorry, Your Honor. I've got to move Exhibit 324 in. Without objection, except for the limiting instruction.

THE COURT: It's in, but it's not on the original exhibit list.

(Exhibit 324 received.)

BY MR. COUGHLIN:

Q. If you take a look at the second paragraph down -- before we get to that, I wanted to ask you a question. You said that nobody had approached you and expressed any concern, discomfort, or anything else about the numbers between two and three, and four and five; is that correct?

A. That's my recollection, yes.

Q. So Mr. Schmidt didn't say anything to you on the phone or call you back after this and talk to you about the numbers going down?

A. I don't remember having a conversation with him on this.

Q. Okay. Let's go to that paragraph in the middle. It talks about our consultants were also not fans of the subset analysis PR plus, PR plus, and centrally confirmed HER2 plus

disclosed in the abstract. Do you see that?
A. Yes, I do.
Q. Okay. One of our consultants believes the subset analysis --
THE COURT: Slow down a little bit.
BY MR. COUGHLIN:
Q. One of our consultants believes the subset analysis will not be an ameliorating factor because, one, the FDA is not going to make a labeling decision based on a subset analysis. And two, in clinical practice physicians do not prescribe drugs based on subset analysis. Do you see that?
A. Yes, I do.
Q. You don't disagree with that; do you?
A. Well, the statement here appears to contradict itself.
Q. Okay.
A. May I describe that?
Q. Sure.
A. So number two says -- can we push it up a little bit on the screen so everyone can see that, please, that paragraph? Thank you very much.
So it says: Our consultants were not fans of the subset analysis because, number two, in clinical practice physicians do not prescribe drugs based on subset analyses. Right. So what he's describing is it's either all or none. I give it to everybody or I give it to nobody, and I don't

pick out little subgroups.

The last sentence says: Neratinib's use is likely to be limited to a small subset, most likely ER/PR positive, node positive disease. So there he's basically contradicting himself by saying that -- first he says in clinical practice, people either give it to everybody or they give it to nobody. They don't give it to any specific subgroup.

Then in the last sentence he says, well, actually they're going to give it to patients, but the only ones they're going to give it to are a subgroup of patients which are the ones who are ER/PR positive and node positive.

Q. So you believe that's a contradiction from number two?

A. I think that's a very direct contradiction.

Q. Somebody could disagree with you on that, right?

A. If they would like to, I would love to have that discussion.

Q. At the bottom it says on number three -- let's take a look at that. The vast majority, about 80 percent, are node negative where the drug is likely to show only a modest benefit. Do you see that, page 4? I'm talking about number three there, that second subset. Do you see that?

A. No. Can you please highlight that? Thank you.

Q. Second physician, one, two, three, four?

A. Uh-huh.

Q. I think we talked a little bit about this before. We

talked about the patient population. Were you in the courtroom for Dr. Adelson's testimony?

A. I was not here for that, no.

Q. Okay. I think she estimated that that population, the vast majority, 80 percent, are node negative. I think she testified it's about 75. You testified to something different the other day.

What's your understanding of what that -- what the overall breast cancer population is?

A. To be clear, the node negative or overall?

Q. Node negative.

A. The most published work I saw was that it was 50 percent node positive and 50 percent node negative.

Q. So if she testified to something different, you think she would be wrong --

A. Did she have a reference for that?

Q. I don't think anybody asked her.

A. Okay. I would need to see that reference.

Q. Okay. Let's flip over to Exhibit 1063.

MR. COUGHLIN: I don't believe there's any objection to Exhibit 1063. I'd move for its admission, Your Honor.

MS. JOHNSON: No objection.

THE COURT: 1063 is admitted without objection.

(Exhibit 1063 received)

BY MR. COUGHLIN:

Q. This is an exchange between you and Dr. Chan; is that correct?

A. Yes, that appears to be correct.

Q. Okay. If we take a look at the top paragraph, hi, Arlene. Can we take a look at that? This paragraph -- correct me if I'm wrong -- says: While the hazard ratio is intriguing, there are many KOLs -- and is that key opinion leaders?

A. Yes. That would be what that stands for.

Q. Okay -- who are less about HR, hazard ratio, and more about the absolute magnitude of the DFS benefit. Do you see that?

A. Yes, I do.

Q. That's why you wanted those numbers to be included in the presentation; is that correct?

A. I think that there are some KOLs who care about hazard ratios, and I think that there are some KOLs who care about absolute numbers. And since there is one presentation, I felt we needed to address both.

Q. Okay.

You testified earlier -- I'm going to have you flip to --

MR. COUGHLIN: I'm going to mark a new exhibit, Your Honor, even though we have plenty of exhibits.

THE COURT: What's the number?

MR. COUGHLIN: 1087.

THE COURT: You know, we already admitted 1088.

MR. COUGHLIN: I think I marked this before we admitted 1088. That's why it has the number one below it.

BY MR. COUGHLIN:

Q. I'd like you to flip to page 40 of 50.

THE COURT: Do you move its admission?

MR. COUGHLIN: No, I do not, Your Honor.

THE COURT: Okay.

BY MR. COUGHLIN:

Q. You testified earlier part of last week and part of today that you had information going out for a certain number of patients for at least three years. Do you remember that?

A. That's correct.

Q. Okay. And one of the things that you said is that apples to apples is comparing centrally confirmed data; is that correct?

A. That is correct.

Q. Does that compare to the HERA study? Is that right?

A. In order to compare the ExteNET data with the Herceptin adjuvant studies, that is indeed the comparison to be done.

Q. And you did a three -- and you studied the three-year curves for centrally confirmed; is that right?

A. In July of 2014, that is correct.

Q. Okay. And you knew that eventually they came back together, the arms, to 1.9 percent absolute delta, correct?

THE COURT: Hold on. I'm not sure I got the middle of that sentence. Could you read the line, Ms. Baird, beginning with, okay, and you knew.

(Record read)

THE COURT: Okay. They came back together, the arms.

BY MR. COUGHLIN:

Q. The arms came back together with an absolute -- the arms came back together with an absolute delta of 1.9 percent; is that correct?

A. So the data we were referring to before was the data cut as of July 2014. Agreed?

Q. That's the data cut that I'm referring to.

A. Yes.

Q. And you said --

A. The data you've now put in front of me, right, is dated July 17th, 2017.

Q. It goes out five years?

A. That's correct. So it's a different data set.

Q. It has -- but it has the three-year delta --

A. It has a five-year delta as well because we had a lot more data. The two, you're comparing two different data sets.

Q. And that's only a 2.2 percent, right?

MS. JOHNSON: Your Honor, I object to this line of questioning beyond the class period. There have been motion in limine rulings about data past the class period.

THE COURT: Hold on. Do you add 403?

MS. JOHNSON: Yes.

THE COURT: Sustained.

MR. COUGHLIN: I'll go back to the three-year.

BY MR. COUGHLIN:

Q. You don't dispute that you ended up with a 1.9 delta at the three-year, right?

MS. JOHNSON: Same objection.

THE COURT: Sustained.

BY MR. COUGHLIN:

Q. Mr. Auerbach, I'd like you to take a look, and you don't -- it's probably -- I don't know if it's in your binder there or not, but we talked about it yesterday, Exhibit 701. We talked about it last week, Exhibit 701.

THE COURT: Okay. That was introduced on January 17th and not admitted.

MR. COUGHLIN: That's correct, Your Honor.

BY MR. COUGHLIN:

Q. I'll give you a copy, Mr. Auerbach, if you can't find it.

THE COURT: You know, it's really hard to find

documents now. I have no idea where 701 is. I'm going to go back to the original trial books.

MR. COUGHLIN: Here's a copy, Your Honor.

THE COURT: Go ahead.

BY MR. COUGHLIN:

Q. Earlier today you testified that nobody complained to you either after the abstract or after the presentation at ASCO that your earlier comments from July were misleading. Do you remember that testimony?

A. I do not recall anyone stating that. Correct.

Q. Okay. Yet, did you receive an e-mail from Phil Gross on May 16, 2015?

A. I'm looking at this right now. Yes, I did.

Q. Okay. So you were aware that he had these feelings about what you had said earlier and what you were saying now?

Well, let me step back. Who is Phil Gross?

A. Phil Gross works at a group called Adage Capital, which was one of our investors.

Q. He was the second largest, I think, aside from you. They were the second largest shareholder in the company, correct?

A. That's correct.

Q. Had nearly a 20 percent interest, correct?

A. I thought it was lower than that, but...

Q. Okay. And he gave a report to you that he thought that

you had --

THE COURT: Just a moment.

MR. COUGHLIN: Not for the truth.

THE COURT: Ask.

MR. COUGHLIN: He stated nobody --

THE COURT: If you begin the question, did he give a report to you.

BY MR. COUGHLIN:

Q. Did he give a report to you?

A. Did Mr. Gross give a report to me?

Q. Yes.

A. No. It appears he just sent an e-mail to me.

Q. Okay. Was he reporting on what you had said before and what the actual results were?

A. He appears to be commenting on our July call.

Q. Right. And he comments about what Mr. Werber says and he comments about your responses, correct?

A. Correct.

Q. Okay.

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

MS. JOHNSON: Objection. Hearsay. Foundation.

THE COURT: Sustained.

BY MR. COUGHLIN:

Q. Mr. Auerbach, you received this document, correct?

A. Yes, that's correct.
Q. Earlier you testified that nobody -- none of the investors had complained to you about whether the earlier statements differed in any way, shape, or form from the abstract, correct?
A. I don't see anything in this that looks like it's a complaint.
Q. You don't see anything in this that -- where he lists your July --
MS. JOHNSON: Objection.
THE COURT: Sustained. You can't read from the document and -- would you focus the Court's attention? It's a one-page document. Would you focus the Court's attention on what you consider a complaint? Just, what paragraph?
MR. COUGHLIN: I will. If we go down to the answer, Alan Auerbach, paragraph, the second paragraph in.
THE COURT: Yes. All right. The second paragraph in. Just a moment.
MR. COUGHLIN: Then you go down to the highlighted or the dark area.
THE COURT: Okay. I don't see a complaint there, a complaint under these circumstances to perhaps go to impeachment. But in the dark area that begins we would anticipate, I don't see a complaint.
MR. COUGHLIN: Then he actually gives the actual

rate of --

THE COURT: Okay. Yes.

MR. COUGHLIN: That's a complaint.

THE COURT: Yes. Hold on. Hold on. This is Mr. Auerbach speaking?

THE WITNESS: No.

MR. COUGHLIN: He quotes Mr. Auerbach --

THE COURT: Hold on. This is Mr. Auerbach speaking?

MR. COUGHLIN: Yes.

THE COURT: Mr. Auerbach is complaining?

MR. COUGHLIN: No.

THE COURT: Okay. Right now the objection is sustained unless you can provide clearer evidence of impeachment.

BY MR. COUGHLIN:

Q. You didn't view this as a complaint from Mr. Gross?

A. I did not view this as a complaint from Mr. Gross.

MR. COUGHLIN: I have no further questions, Your Honor.

THE COURT: Thank you.

Let's take our break. Well timed, counsel.

We'll come back at 3:15. Remember, don't discuss the case. Don't research the case. Keep an open mind. We'll see you at 3:15.

THE CLERK: All rise.

(Open court - jury not present)

(Recess taken from 3:00 p.m. until 3:18 p.m.)

THE CLERK: All rise.

(Open court - jury present)

THE COURT: All right.

Ms. Johnson, any further questions?

MS. JOHNSON: No further questions, Your Honor.

THE COURT: All right.

The plaintiff will call its next witness, please.

MR. FORGE: Thank you, Your Honor.

Plaintiff calls Alexander Younger.

Alexander Younger, Plaintiffs' witness, sworn

THE CLERK: If you will please state and spell your first and last name.

THE WITNESS: Alexander Younger, A-l-e-x-a-n-d-e-r, Y-o-u-n-g-e-r.

DIRECT EXAMINATION

BY MR. FORGE:

Q. Good afternoon, Mr. Younger.

A. Good afternoon.

Q. Mr. Younger, could you please tell the jurors where you live?

A. I live in Norfolk in the United Kingdom.

Q. Where geographically is Norfolk located?

A. Norfolk is in the east of the country as you go up probably a hundred miles north of London.
Q. Approximately how many people live in Norfolk County?
A. Around 800,000.
Q. What is the -- could you please just describe to the jury the economy, what is it based on in Norfolk?
A. Historically, in medieval times, Norfolk was the second largest city in the United Kingdom, very much fair to say it was overtaken by the industrial revelation. So what we largely have is a large rural hinterland with an essentially agricultural economy and tourism on the coast and some manufacturing around the major city, which is Norwich.
Q. Mr. Younger, could you describe your educational background to the jurors?
A. Certainly. So I obtained my degree in rural resource management from the University of Reading.
Q. Do you have any certifications?
A. Yes. I am a qualified chart accountant through the Institute of Chartered Accountants of England and Wales.
Q. I'm going to ask you to slow down quite a bit.
A. Apologies.
Q. Would that be -- would that certification be the equivalent of a CPA in the United States?
A. I believe that's equivalent, yes.
Q. What are the qualifications to obtain that

certification?
A. So the entry qualification certainly for the certification was a degree, and then it was a three-year training contract.
Q. Meaning what?
A. So with a firm authorized to provide that training and put you through that formal examination process with the appropriate work experience, that process taking three years to obtain that qualification.
Q. What did that work experience consist of?
A. So I joined Ernst & Young. I was principally involved in their assurance practice, so the auditing both of companies public and private, and more particularly, which led to my current role in many ways, UK pension schemes.
Q. So if you could please walk the jurors through how you went from your work with Ernst & Young to working for pension schemes?
A. So --
THE COURT: Pension what?
MR. FORGE: It's called pension schemes in the UK, Your Honor.
THE COURT: Very well. Thank you for that.
THE WITNESS: Yes. So I worked for Ernst & Young for around four years. I did about a year post obtaining my qualification. I then -- I come from Norfolk originally. I

had a desire to work in the county. I had just got married. So I obtained employment with Norfolk County Council. Norfolk County Council is the administering authority of the Norfolk Pension Fund. So it's a capacity of the county council to run this pension fund as part of the local government pension scheme in the United Kingdom.

I originally joined the county council within its internal audit function. I did that role until around April, May 2004. There was then a gap in the resourcing for the pension scheme, and I moved over to work for the pension scheme, although originally on the continent to fulfill a short term gap in that resourcing. But as is often the way with these things, I've been there ever since.

BY MR. FORGE:

Q. Mr. Younger, how many beneficiaries of the Norfolk Pension Fund are there?

A. In total across all classes of member, we have around 90,000 beneficiaries currently.

Q. What types of jobs does the pension fund cover?

A. So the pension fund covers within a range of public sector employers within the geography of the County of Norfolk. That includes Norfolk County Council itself, in addition to schools, some charities, the police and fire authorities, et cetera.

Typically the jobs are for the public sector type

employment, so we have large numbers of teaching assistants in schools, large numbers of care workers. You'll also see road workers; civilian police and fire staff, not uniformed officers; and administrative functions across a range of employers.

Q. Approximately how much is the average annual pension for these beneficiaries?

A. The pensions themselves are relatively low. So in dollars, roundabout $6,000 a year. That reflects the fact that the majority of our work force are part time, teaching assistants and care assistants. Also gender wise the majority tend to be female because they tend to be occupying those roles.

Q. How is the Norfolk Pension Fund funded?

A. It is a -- well, it's a funded pension scheme in that it has a pool of assets, investments, which I believe is referred to --

Q. Slow down a little bit.

A. A pool of assets, investments which were referred to in the opening address. That pool has accumulated through the contributions of both employers and employees to the pension scheme.

Q. So what are the total assets of the pension fund?

A. So the total assets as a dollar amount are around $4 billion.

Q. That's a lot of money. What are the total liabilities of the pension fund?
A. They fluctuate with interest rates, but certainly in excess of that. Perhaps currently four and a half billion dollars. We're about to conduct our next full formal valuation of the scheme which will put a line in the sand on that number as of March 2019.
Q. And are the liabilities essentially the estimate of how much the fund is going to have to pay out in pensions?
A. Absolutely. It's a present value calculation of all those obligations, some of which may be payable 80 years from now.
Q. What is your title with Norfolk?
A. My full title is investment and actuarial services manager.
Q. So what are your principal responsibilities as a manager?
A. I look after the relationship with the fund actuary. The fund actuary is the individual responsible on a statutory basis with the measurement of those liabilities and ensuring that we have an appropriate funding plan, to make sure that they're met.

I also look after our relationship with our third-party fund managers. We don't conduct any internal fund management. All of those moneys are managed across

various asset classes through relationships with commercial entities.

Q. You mentioned that the fund is funded at least in part through contributions from employees and employers; is that right?

A. That is correct.

Q. Does the fund also depend upon returns from investments to meet its obligations?

A. That's absolutely right. As the metaphor our actuary would use, there's two levers with which to fund pensions, one of which is the cash contribution received both from employees and employers. The other is the investment returns.

Obviously if the investment returns fall up short, the burden on the contributing parties and the variable party, the employer, will increase.

Q. Do the fund investments include stocks?

A. They do, amongst a number of asset classes.

Q. Does the fund decide which individual stocks to buy on behalf of the beneficiaries?

A. No. We don't tell them decisions as an individual stock lever.

Q. How are those decisions made, then?

A. Those decisions are made in terms of portfolio construction by those asset managers that we have appointed

to run equity portfolios.
Q. How many asset managers does the fund have?
A. We have around 14 relationships that would be classified as asset managers.
Q. How are they selected?
A. So we are a public plan, so we have certain public procurement protocols, one of which is a European-wide protocol which currently exists. Whether it still will post-Brexit, I don't know, but it's called OJEU.
THE COURT: Excuse me. One moment. Gosh, I commend, Ms. Baird. I believe you said whether it exists post-Brexit, correct?
THE WITNESS: Lately, yes.
THE COURT: Thank you. Continue. Sorry for the interruption.
THE WITNESS: Apologies for speeding up a little. We have a public procurement protocol that's called OJEU. What that stands for is the Official Journal of the European Union. What it means in practice is that any public authority covered by this procurement will have to post a notice whether it's seeking to buy ten fire engines or, in our case, seeking to procure an investment manager to run a certain mandate of assets.
BY MR. FORGE:
Q. Does the fund dictate to the investment managers which

stocks to purchase?
A. No, we don't.
Q. Does the fund weigh in on which stocks to purchase?
A. No, we don't.
Q. Is the fund consulted in any way by the investment managers regarding individual stock purchases?
A. Not in the advance of those purchases, no.
Q. Does the fund allow investment managers to make purchases in U.S. markets such as the New York Stock Exchange?
A. We do, yes.
Q. Is there anything about the New York Stock Exchange and the U.S. markets that appeals to the fund?
A. I don't think it holds a particular appeal. It is obviously the largest stock market in the world. It is well regulated both at an exchange level and through federal security law.

We believe -- and I believe most academic evidence would support this -- that it's a highly efficient market.
Q. When you say highly efficient market, what does that mean to you?
A. The pricing within the market will encompass all publicly available information, and particularly --

MR. CLUBOK: Objection, Your Honor. This is expert testimony far afield of what this witness can testify to as a

lay person.

THE COURT: Sustained. You may provide further foundation and rephrase if you wish.

MR. FORGE: Sure.

BY MR. FORGE:

Q. Mr. Younger, is your impression that the New York Stock Exchange is an efficient market one of the reasons why Norfolk is comfortable with its investment managers investing in the NYSE?

MR. CLUBOK: Objection. Leading, and trying to incorporate expert testimony. Now he's just leading him through expert testimony.

THE COURT: Sustained.

BY MR. FORGE:

Q. Mr. Younger, are you comfortable with your investment managers investing in the New York Stock Exchange?

A. As a pension fund, we are, yes.

Q. Now, you mentioned it is a highly regulated market. Do you think that guarantees that the fund is not going to lose money on its investments?

A. No. Regulation guarantees that you won't lose money on investments.

Q. Has the fund lost money on individual stocks in the past?

A. Yes, of course.

Q. Approximately how many times?
A. Well, the fund has existed in its current form since 1974, so I would imagine thousands of times across individual lines of stock and with individual time periods.
Q. Throughout those thousands of times in which the fund has lost money on those investments, how many times has the fund served as a class representative in a class-action lawsuit?
A. This is the first time.
Q. Is one of the investment managers for Norfolk called Capital?
A. Yes. Capital International run one of the mandates for the fund.
Q. And for how long has Capital International been an investment manager for Norfolk?
A. Capital were funded in December 2004.
Q. Are they still an investment manager today?
A. Yes, they are.
Q. How does Capital report on performance to Norfolk?
A. So Capital will provide us with a quarterly investment report. That report will include performance. In addition, we will receive monthly accounting information which will also tally to the information we receive from our custodian bank.
Q. Is one of the stocks that Capital has purchased on

behalf of Norfolk Puma Biotech?
A. Yes, it was.
Q. Now, throughout the 14 years that -- I'm sorry. Let me back up. How many years have you been working for the Norfolk Pension Fund?
A. So I joined the same year that Capital were appointed in May 2004. So 14 years and a little bit, I suppose.
Q. Throughout those 14 plus years, have you ever come across any indication that any of the fund's investment managers would purchase the stock of a company at a time when the investment manager believed the price had been inflated by fraud?
A. No.
Q. Would that be problematic if you learned that that was the perspective of one of the fund's investment managers?
A. Yes, of course.
Q. Why?
A. Because that would suggest that the investment manager was in collusion with that company undertaking fraudulent activity, and clearly that would be to the detriment of our beneficiaries when the truth outed and the price returned to its true level.
Q. How much of the pension fund's money does Capital manage?
A. So Capital runs around ten percent of the total assets

of the fund, so something akin to $400 million.

MR. FORGE: Your Honor, at this time I would move Exhibit 14 into evidence. I don't believe there's an objection to it.

THE COURT: Without objection 14 is admitted.

(Exhibit 14 received)

BY MR. FORGE:

Q. Mr. Younger, if you could please take a look at that on either the screen in front of you or the large screen in the courtroom.

A. (Witness complies.)

Q. Do you recognize Exhibit 14?

A. I do, yes.

Q. And I'm going to focus in on the time period here with a start date of July 23rd, 2014, and a closing date of September 1st, 2015. Do you see those dates?

A. Yes, I can. Yes.

Q. Okay. And you see it lists on here Norfolk Pension Fund?

A. Yes.

Q. And it from HSBC, and it concerns Puma Biotech. Do you see that, sir?

A. I do, yeah.

Q. What is Exhibit 14?

A. So this is a report from HSBC who, as I referenced

before, are the custodian bank. This particular report has been constructed to solely show the trading activity in the U.S. stock, the ISIN number that you can see.

I'm looking at it on the left-hand side of the screen indicating that that's it. It's the trading activity of the fund within Capital's account within our custody system for the period that was given.

Q. Is Exhibit 14 organized such that the most recent trade is at the top?

A. Yes. That appears to be the case.

Q. Okay. So let's go to page 2 and see if you can confirm for me. Does it appear to indicate that the first purchase of Puma stock was on December 3rd of 2014 at a price of $192 per share and 1,100 shares purchased?

A. Yes, that does appear to be the case. That's correct.

Q. Now, if you could, Mr. Younger, please confirm for me that -- I want you to keep these prices in mind on the second page which covers purchases from December 2014 through January 9, 2015. Do you see that?

A. I do, yeah.

Q. And do you see the prices paid for those shares?

A. I can, yes.

Q. Okay. Now, the second page, let's look at the purchases continuing in January up until -- up through March 18th and the corresponding prices. Do you see that?

A. I do see --
Q. Actually through January 15, 2015. Prior to May 13th, 2015, what is the lowest price that Norfolk paid for shares of Puma Biotech? I'm going to go back to the first page.
A. 192.9 on the first page.
Q. I'm sorry. This is actually the second page with the earliest purchases.
A. Sorry. So --
Q. Is that the lowest price, $192.90?
A. Yes. That looks like it from what I've just seen there.
Q. If that's the lowest price prior to May 13, 2015, after June 1st of 2015, what is the highest price that Norfolk paid after June 1st of 2015?
A. So could I have the actual trade date? I can only see the settlement date. Thank you. So after June 1st, the most recent trade after that date, so just over $113 per share.
Q. Okay. And by August 14th of 2015, what was Puma's stock down to?
A. Well, the price of the trade on that report was 88 dollars and 56.57 cents.
Q. Now, focusing on the time period of July 23rd, 2014, through May 13th, 2015, approximately how much money did Norfolk lose on its investments in Puma stock?
A. The loss calculation we reviewed showed a figure of just over $1 million US.

Q. What does that translate to in terms of the number of pensions?

A. So given our average pension of around the $6,000 mark, so a little less than 200 pensions on an annual basis.

Q. How did Norfolk get involved in this case?

A. So just to roll back slightly, we have two firms appointed to monitor our portfolios for class-action settlements. One is the guys in the room, Robbins Geller. The other is BR&B, Barrack Rodos & Bacine.

What they're doing initially is simply checking that our custodian has filed all claims on settled cases. We, like many large institutional investors, have received settlements across a number of investments.

I guess the best known would be Enron, WorldCom, Tyco perhaps, but generally there are large number of settlements in any given year. The history of custodian banks certainly going back five or six years was that they did not always file for those moneys.

So we have two appointed firms who have been monitoring to make sure they do, and they work with us and the custodians to make sure that all filings are made in the appropriate time period.

The second service that they both perform for us is to review that portfolio and identify where we may have losses where potentially there is evidence of fraud or other

nefarious activity other than the normal market move in stock. We accept normal market moves.

What I would typically mean is if there's very sharp movements, if there's been a very sharp upward movement followed by a very sharp downward movement, they will certainly be looking at the circumstances of that. If they find something in those circumstances, they will bring that to our attention.

Q. Did Norfolk apply to be the representative of the class in this case?

A. We did, yes.

Q. Was Norfolk appointed to be the class representative?

A. We were, yes.

Q. As class representative, what have your duties involved?

A. So our duties has been the oversight of the litigation through the action of the attorneys and ensuring that it is conducted in the best interests of the wider class whose potential losses would clearly be a multiple of those that I've identified for ourselves.

Q. Does that oversight extend at all to any of the factual investigation of the case?

A. The factual investigation insofar as it relates to Norfolk we can comment on directly. What we have also seen is the investigation and discovery undertaken by the appointed attorney in this case, Robbins Geller.

Q. Does Norfolk's role involve actually performing any of that factual investigation involving the allegations of the case?
A. No, it does not.
Q. Does Norfolk's role involve formulating any of the legal theories in the case?
A. No, it does not. We would be unqualified to do so.
Q. Were you deposed in connection with this case?
A. Yes, I was.
Q. And did you testify on behalf of the class when you did that?
A. I testified on behalf of Norfolk County Council.
Q. Did Norfolk County Council produce documents in this case?
A. I believe we produced all documents that have been requested.
Q. And are you here today testifying on behalf of Norfolk Council?
A. I am, yes.
Q. Are you here also on behalf of the class?
A. I am, yes, as representative of the lead plaintiff.
Q. Did you fly out from England to testify here today?
A. I did, yes.
MR. FORGE: Thank you.
No further questions, Your Honor.

THE COURT: Cross.

MR. CLUBOK: At great risk, Your Honor, can I approach with a binder?

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. CLUBOK:

Q. Good afternoon, Mr. Younger.

A. Good afternoon.

Q. Mr. Younger, you and I had never met before last week when you came here for this case, correct?

A. I don't believe so, no. I may have seen you at an earlier hearing actually. That could possibly have been the case.

Q. Okay. By the way, what you did there -- it was an irrelevant question, but I'm just going to raise it now because the judge raised it before. I asked a negative question and you gave a negative answer. So we had that double negative problem. If I catch you doing that, it -- I said we've never met before, and I think you said no.

Sometimes that may happen. If it does, I will try my best to say it's true, sir, that you and I never actually met until next week, to try to make sure that if the answer is no, that's fine. But if the answer is yes, we'll just try to clear up the record. Okay?

A. I will try my hardest to avoid it.

Q. That one was my fault. So if we get it wrong, I will try to fix it. If I hear it -- and I'm not asking that to make you change your answer. I just want to make sure the answer is correct for the record.

A. That's fine.

Q. Thank you.

Now, sir, you are here to represent Norfolk County Council, correct?

A. Yes, in its capacity as administering authority of Norfolk Pension Fund.

Q. And your job is currently the investment and actuarial services manager, right?

A. That's correct.

Q. As part of that job, you have been tasked as the Norfolk employee who is responsible for managing the operation of this litigation on behalf of Norfolk, correct?

A. Yes, the day-to-day management of it.

Q. And the reason you were selected out of the folks who work at Norfolk is because you're the person there most knowledgeable within Norfolk about the issues in this lawsuit and Norfolk's positions in this lawsuit, correct?

MR. FORGE: Object. That is compound.

THE COURT: Is your microphone on?

MR. FORGE: It is, Your Honor, I apologize. I would object as it's compound.

THE COURT: Sustained. Pull the microphone over your way. It's got a long cord.

BY MR. CLUBOK:

Q. Sir, you're the person at Norfolk most knowledgeable about the issues in this lawsuit from Norfolk's perspective, correct?

A. That's correct, yes.

Q. And you're also the person at Norfolk who is the most knowledgeable about the positions that Norfolk is taking in this case; is that correct?

A. Could you define positions there? Do you mean a stock position or do you mean a legal position?

Q. I mean a legal position, the legal theories that Norfolk has agreed to allow to be advanced in this case. Out of the folks at Norfolk, you would be the most knowledgeable about which positions or which legal claims you have chosen to bring here; is that fair?

A. Yeah. I mean, I am the most familiar with the case in terms of we're a public body, a formal signoff has to come through our democratic process. So was I qualified? Yes, would be my answer to that question.

Q. Well, certainly it's you who are tasked with, for example, reviewing pleadings prior to them being filed in this case, correct?

A. Certainly I may undertake the initial review. If

necessary, I would discuss them with my colleagues.
Q. Now, setting aside your litigation role, we're going to turn back to your day-to-day investment role. As part of your job duties, I think you testified that you are responsible for looking after or overseeing those outside investment advisors that you have outsourced the investment-making decisions to, correct?
A. Yes. We would describe them as outside investment managers, yeah. But terminology aside, that is correct.
Q. Within Norfolk, your direct supervisor, the person you report to, is Glenn -- I think I'm pronouncing this right -- Cossey, C-o-s-s-e-y?
A. That's correct, Glenn Cossey. His first name is with a double N.
Q. Okay. Mr. Cossey. And he is the chief investment manager. That's his title at Norfolk, correct?
A. That is the title he holds, yes.
Q. And your ultimate boss, in other words, his boss, is a woman named Nicola Mark who is the head of the pension fund, correct?
A. That's correct, yes.
Q. And Mr. Cossey and Ms. Mark still hold those positions today just like they did in 2014 and '15, correct?
A. That is correct, yes.
Q. Now, sir, you talked a little bit about your educational

background. It's fair to say you have no formal training in biotechnology, correct?

A. I would make no such claim.

Q. And you certainly have no training in the development of cancer drugs or what it takes to do that for a company, correct?

A. Again, I would make no such claim.

Q. So it's correct?

A. Sorry. Could you repeat? It's correct that I have no experience of developing cancer drugs.

Q. Correct.

A. I have no experience of developing cancer drugs.

Q. And no experience in understanding what it takes for a new company, for a developmental biotechnology company to develop a new cancer drug, correct?

A. No experience of that, no.

Q. Let's talk about what you do know about, which is Norfolk Pension Fund. I'd like to show you -- well, first of all, we're going to look at Exhibit 9 --

MR. CLUBOK: -- which I believe, Your Honor, has not been objected to. I'd like to offer it into evidence.

THE COURT: Without objection 9 is in.

(Exhibit 9 received)

BY MR. CLUBOK:

Q. Mr. Younger, Exhibit 9 is Norfolk Pension Fund's annual

reports and accounts for 2014 to 2015, which covers the time period ending March 31st, 2015; is that correct?

A. That is correct, yes.

Q. You recognize this document?

A. Yes. We see it every year.

Q. And you would be very familiar with the contents of this document?

A. I would be familiar with the contents generally but bearing in mind it's an annual document. So if you ask me about a specific number, I'll have to look to that number.

Q. Okay. Well, let's do that. Let's look at page 57 if we can. This shows the --

A. Sorry. I'm not there yet.

Q. Please take your time.

A. Thank you.

Q. Page 57 shows the number of financial numbers that relate to the pension fund, but I want to refer your attention specifically to the figure at the top which says total investment assets.

A. So midway down the page; is that correct?

Q. I'm sorry. Midway down the page, yes.

A. So the figure for March 15 of just under 3 billion sterling?

Q. Yes.

A. Yep.

Q. And you just said a word that I just want to make sure we address right now. You said just under 3 billion sterling. That's 3 billion what we call pounds or English pounds?
A. That would be 3 billion English pounds, yes.
Q. And to translate that into dollars, the value of that in dollars sort of fluctuates based on the exchange rate between the pound and the U.S. dollar, correct?
A. That is absolutely correct, both because some of those underlying assets are denominated in dollars, and then equally some are denominated in other countries. So should you then undertake a dollar conversion, there would be a considerable variance. And that will change year on year as the dollar and the British pound move against each other.
Q. And roughly in this time period, the dollar is a little under a $1.50 -- or, the pound was worth a little less than $1.50; is that correct?
A. I don't have that figure committed to memory, but I'm clearly aware there's been a weakening versus the British pound -- sorry, I was about to say sterling -- since that period. So that would sound realistic.
Q. That in March of 2015 the conversion rate was approximately one pound to $1.50 US; is that right?
A. Well, as I said, I don't have that figure committed to memory. I don't retain exchange rates over a long period,

but the figure sounds realistic. So I can work with it.
Q. And so just rounding, and realizing it is a rough approximation, approximately 3 billion pounds, sterling, in March of 2015 would have equaled approximately $4.5 billion in U.S. money, correct?
A. That's correct. You times that figure out by one and a half.
Q. And so you had your deposition taken about a year ago. By that time the value of the pound had fallen pretty significantly as compared to the value of the dollar, correct?
A. That is correct, the political events in the UK having influenced that.
Q. Actually you blamed both Brexit and the election of Donald Trump to that decline, correct?
A. I think the election of Mr. Trump introduced a strong dollar policy. I don't know if I blamed Mr. Trump for that. I think I just came up with reasoning as to why that would be the case. And clearly Brexit had a very negative impact on sterling. The two together, and I don't know what measure, but it came to that impact.
Q. Fair to say that the relative strength of the dollar, that increase you attributed to the policies of Donald Trump and the impact of Brexit, correct?
A. I think they were two of the prime drivers.

Q. And that meant in real dollars that the value of the fund dropped by something like $300 million just because of the fluctuation in the currency rate; isn't that right?
A. I'm not sure we're particularly concerned with the value of the fund in dollars because our liability is sterling denominated. So we don't report in dollars. So we come up with a dollar figure for these purposes, but we don't -- nowhere in our accounts is there a dollar figure. None of our liabilities are paid in dollars.
Q. Understood. On direct examination you answered questions in dollars, so that's why I've started there.
A. I was asked to provide approximate answers in dollars, which I did.
Q. Correct. So now I'm following up on that. In dollars the value of the fund dropped by several hundred million dollars just because of currency fluctuations, nothing to do with specific investments; is that correct?
MR. FORGE: Your Honor, I'm going to object as compound.
THE COURT: Rephrase.
BY MR. CLUBOK:
Q. Isn't it true that you attributed several hundred million dollars in drop in dollars in the value in the fund as expressed in dollars to currency fluctuations?
A. I think I attributed the move in the sterling dollar

exchange rate. Whether I attributed a dollar figure drop to the total value of the fund when converted to dollars, I don't recall.

Q. Well, let's go back to pounds, then. By the time of your deposition, which was about a year ago, the value of the fund in pounds had actually increased from roughly 3 billion pounds to about three and a half billion pounds; is that correct?

A. That is correct, yes.

Q. So if the dollars were kept constant -- I'm sorry. If the exchange rate had been kept constant, another way to think about that would be that, and I'm doing quick math here, the value in dollars if it stayed at that 1.5 to 1 exchange rate, 3.5 billion sterling would have been worth more than $5 billion US but for the currency fluctuation; isn't that correct?

A. It would depend how far the movement in the upward valuation of the fund was itself determined by our conversion back from those dollar denominated assets. And I haven't got those figures to hand, so I truly don't know the answer to that.

Q. Fair to say that 3.5 billion times 1.5 is approximately 5.25? Is that true?

A. Well, I can do the math, yes. But the point I was making was that that figure itself, that sterling figure, is

itself a conversion of certain dollar assets. So if you do one leg of the calculation, you have to have done the first leg, so in that sterling number what was being impacted or not by a dollar move. I'm sorry. I don't mean to be disrespectful, but I think it's --

Q. Understood. Regardless, the gains were over 500 billion pounds between those two time periods, correct? I'm sorry, 500 million pounds, correct? From --

A. Sorry. In the sterling denominated AUN between those two dates, yes, that's correct.

Q. Now, sir, let's talk about how your investments were doing in March of 2015. I want to refer you to page 4 of Exhibit 9, which you I think still have in front of you.

Again, this is the Norfolk Pension Fund annual report and accounts for the year ending March 31st, 2015. I want to refer you to the bottom paragraph on page 4. We're going to blow that up. It says: Over the last year the Norfolk Pension Fund's assets have increased by nearly 300 pounds while paying pension benefits to our members of 120 million pounds.

Maybe I left out a million there. It's the assets increased by 300 million pounds while you were paying pension benefits of 120 million pounds; isn't that right?

A. You spotted a typo in there, but, yes, that figure is the increase we referred to, the difference between 2.9 and

2.6.

Q. And you were telling the truth here in this annual report, correct?

A. Of course.

Q. So for that year, this is just the value of the fund, had increased by 300 million pounds while you were paying out about 120 million pounds in pension benefits, correct?

A. That is correct, yes.

Q. In fact, that was about a 13 percent return for that year over the prior year, correct?

A. Yes. Their one-year investment return as stated in the report was 13 percent.

Q. And it's fair to say you were head of all the benchmarks you had set for yourself in terms of your investing goals for that year, correct?

A. Over three and five years, as it states there, we were, yes.

Q. Well, let's talk about the investment managers that you worked with to help you get these kinds of returns. Look at page 22 if you would.

A. Just a moment.

Q. And as you're getting there, I'm going to just blow up on the screen towards the bottom of page 22 where it refers to the external investment managers who managed the fund's assets during this time frame. You list out 12 different

professional investment managers that you were working with to manage your balances then, correct?

A. That is correct.

Q. And amongst those it includes Goldman Sachs Asset Management, correct?

A. They are one of the listed managers.

Q. It includes Fidelity?

A. That's correct.

Q. Includes Wellington?

A. That is correct.

Q. But I see that one it does not include is Cowen, who we've heard a little bit about in the course of this proceeding. They were not one of your investment advisors, correct?

A. No, clearly not. They're not listed.

Q. That's correct that Cowen was not one of your investment advisors?

A. It is correct that Cowen were not an investment manager, the term that we use there, during that period.

Q. In 2014 to 2015, you were not working with Cowen, correct?

A. No, we were not working with Cowen.

Q. And Cowen is the company that employed Mr. Eric Schmidt, who Mr. Auerbach was asked a little bit about?

A. I believe that to be the case.

Q. You also at the time didn't retain an investment advisor called Leerink, correct?
A. We did not.
Q. And Leerink is the company that employed someone name Howard Liang, who is one of the people who asked the questions on that call, correct?
MR. FORGE: Your Honor, I'm just going to object as to foundation regarding which investment managers employ which analysts.
THE COURT: Sustained unless you want to develop more.
BY MR. CLUBOK:
Q. Do you know who Howard Liang works for?
A. I believe you just stated he works for Leerink.
Q. Do you know who Yaron Werber works for?
MR. FORGE: Again, Your Honor, I'm just going to object for a lack of personal knowledge.
THE COURT: He can ask, do you know who he worked for. You may answer that yes or no.
THE WITNESS: I can't recall.
BY MR. CLUBOK:
Q. Do you know who Yaron Werber is?
THE COURT: Same thing. Yes or no.
THE WITNESS: I believe he's an analyst.
THE COURT: No. No. Hold on. Your answer is yes?

THE WITNESS: Yes.

THE COURT: All right.

Do you want to ask him how he knows?

MR. CLUBOK: Yes.

BY MR. CLUBOK:

Q. Do you know what connection, if any, he has to this case?

A. I believe he's a biotech analyst that covered Puma Bio.

Q. In fact, he's the one who asked that very first question that's been the subject of a lot of the claims that you heard your counsel make in opening statement, correct?

A. Yes.

Q. Yaron Werber works for Citibank, and Citibank is not one of your investment advisors during this time period, correct?

MR. FORGE: Your Honor, again I'm just going to object as to the --

THE COURT: Just object.

MR. FORGE: Lack of foundation, Your Honor.

THE COURT: Sustained unless you want to develop a background.

BY MR. CLUBOK:

Q. Is Citibank one of your investment advisors during the time period?

A. They were not an investment manager for the fund during the time period.

Q. One firm you did work with, though, was a company called Capital International, correct?
A. That is correct.
Q. If I call them just Capital through the course of my questioning, is that okay?
A. Yes.
Q. I will say, just so there's no confusion, that my understanding is -- and you can answer if you know this, or if you say you don't know, that's fine. Let me ask it this way: Are you aware that Capital International is an affiliate or a subsidiary of an entity that's known as Capital Group?
A. That's correct, the Capital Group being a large US-based fund manager.
Q. Okay. If I -- unless there's a meaningful difference, I will just call it Capital throughout my questioning, okay?
A. Of course.
Q. So you had this relationship with Capital going back at least about ten years prior to this 2014-2015 time period, correct?
A. That's correct, yes.
Q. You said I think that at the time Capital was entrusted with managing about 10 percent of your total assets or roughly 300 million pounds at the time?
A. That would have been correct. I believe there's a

disclosure in this annual report if you wanted the exact number.

Q. Now, Exhibit 13, if I may turn your attention to that.

MR. CLUBOK: Your Honor, it's another exhibit that I believe there's no objection to, and I would move to admit it.

THE COURT: Without objection Exhibit 13 is admitted.

(Exhibit 13 received.)

BY MR. CLUBOK:

Q. Exhibit 13 is actually a document that says Capital Group on it, and it is a document that has in the upper left corner investment review, Norfolk Pension Fund, 23 September 2014. Do you see that?

A. I do, yes.

Q. And it's true, sir, that this is a document that was prepared in connection with a meeting that representatives of Capital had with representatives of Norfolk, correct?

A. That's correct.

Q. And if we can turn to the very next page, it identifies meeting participants as Martyn Hole, but then it also has a fellow named Philip May, correct?

A. That's correct.

Q. And at the time Philip May was the person you referred to as the relationship manager between Norfolk and Capital

Group, right?
A. He was, yes.
Q. Philip May also happens to be the husband of the current prime minister of the United Kingdom, Theresa May, correct?
A. That's correct. So at the time we're talking about here, she was home secretary.
Q. Okay. But Philip May wasn't the person making individual investment decisions as far as you understood, correct?
A. No. Philip May is the relationship manager, so he looked after the relationship with Norfolk as he did for a number of institutional customers. So that would involve making sure meetings and information were available or received and that generally we were happy with the service.
Q. With Philip May as your relationship manager at Capital, you pretty much got anything you needed from them in your opinion, correct?
A. Capital are a well-resourced, professional organization. So, yes, we did.
Q. So if you could turn to page 8. I'm sorry. It's listed as page 6 in the bottom right corner of the presentation. I believe technically it may be page 8 of the exhibit.
MR. CLUBOK: For the record it's a page that is entitled the Capital system working in partnership with Norfolk.

BY MR. CLUBOK:
Q. Do you see that page?
A. Yes, I do.
Q. And there's a number of pictures, and it says the Norfolk Pension Fund team. And it lists Mr. May as the relationship manager and then several other individuals with their pictures, correct?
A. That's correct.
Q. And one of the portfolio managers listed from Los Angeles on the right there is a woman named Darcy Kopcho, correct?
A. That's correct.
Q. Now let's turn to page 16 if we can.
A. (Witness complies.) Is that Capital's numbering, or is that 14?
Q. I appreciate it.
A. I equally can't see.
Q. I understand. On Capital's numeric numbering system, it was slide 14.
A. Thank you.
Q. You bet. And it's entitled Global Equity Research Portfolio, and there's a number of individuals at Capital that are identified, all of whom are at your disposal and help work with you on your investments, correct?
A. I don't believe I would use the phrase they were at our

disposal. They were amongst the individuals within the Capital team running these moneys.

Q. Okay. And one of those individuals was a woman named Skye Drynan, correct?

A. That's right, at the bottom of that schematic.

Q. And by the way, it notes there that Skye Drynan had been with Capital for six years at that point and 15 years in the industry, correct?

A. That's the disclosure.

Q. All right.

Now, during this time period it's correct that Capital was given full discretionary authority to buy and sell stocks on behalf of Norfolk's behalf, correct?

A. It was a discretionary portfolio where they were making the stock sale and purchase decisions.

Q. Is that a yes?

A. That's a yes.

Q. So you talked a little bit on direct about the purchases that were actually made, and I think you testified that the very first purchase made by Norfolk or made by Capital on behalf of Norfolk was December 3rd, 2014?

A. I believe that was the case. I was referencing the document in front of me, but, yes.

Q. Let's put that document, Exhibit 14, back up just to remind you. This was the document that Mr. Forge at Robbins

Geller who examined you in direct put up. Am I correct, is this the document that he put up?

A. This is the document, yep.

Q. This was a bank statement from HSBC, which is the bank that was entrusted to hold your stocks during this time period, correct?

A. It's a record of securities trades, yes.

Q. I think in response to Mr. Forge's questions, you referred to the bottom of page 2. This goes in reverse chronological order, so you have to go to page 2 to get the earliest date. He referred you to the first date down there. And just on the left side, the date, he showed you December 1st, 2014. Do you remember that?

MR. CLUBOK: Can we blow that up?

BY MR. CLUBOK:

Q. He said -- he pointed to that and he said -- well, on December 3rd, he said that's the first date of purchase of stock. Remember you were asked that?

A. Yes.

Q. But do you see below that, and we have it here and maybe we can expand the whole row. There's something that says receive free, and that's December 1st, 2014. If we could just expand the bottom rows, the bottom couple rows.

You see on December 1st, it says receive free, and then it has 3,300. It's an eye test, but that's a period

after that. It's not 3 million. It's 3,300 dot 0000. Do you see that?

A. I can see that, yes.

Q. Now, you said that the first stock that you bought or that Capital bought on your behalf was December 3rd. How did you get 3,300 shares of stock free on December 1st?

A. Typically in custody reporting, and I think there's also a deliver free item further up on the first page, there will be adjustments to the stock account which can arise in custody systems.

I don't know specifically what that one was, but I think that's probably what that item is. What it does not appear to be is a cash purchase because, as you've attested, there seems to be zero consideration.

Q. Did Norfolk purchase -- strike that.

Did Capital on Norfolk's behalf purchase any stock in Puma prior to December 3rd, 2014, as you testified on direct?

A. I believe that's the reporting adjustment. I believe the first from the report cash purchase was that December 3rd trade date.

Q. Is that a no to my question?

A. It's -- can you repeat the question, please?

MR. CLUBOK: I'll ask the court reporter to repeat the question, if I may.

(Record read)

THE WITNESS: No. The first purchase was December the 3rd, looking at the report.

BY MR. CLUBOK:

Q. And that 3,300 is just a bookkeeping error or bookkeeping artifact?

A. That is my belief.

Q. Okay. I'd like to show you --

MR. CLUBOK: Well, I'd like to refer to Exhibit 18, Your Honor, which has not been objected to. I'd like to move for its admission.

THE COURT: Without objection 18 is in evidence.

(Exhibit 18 received)

BY MR. CLUBOK:

Q. We're putting up Exhibit 18. Now, 18 is a document that was produced by Capital. And if you look in the bottom right, you see something what's called a Bates number. That's a control number in litigation -- the bottom right if we can, the very bottom right. Yep. It says CII-00001. That means it was the very first page of documents produced by Capital in response to requests made in the course of this litigation. Okay?

A. Yep. Absolutely.

Q. Now, if we look at the top of this document, it's entitled -- if we can blow it up -- trade blotter, July 22nd,

2014, to May 29, 2015. Do you see that?
A. I can read that, yes.
Q. By the way, you were here for the opening statement, correct?
A. Yes.
Q. You were here when the judge gave instructions about the class period in this case?
A. I was, yes.
Q. You're aware that that is the alleged class period in this case, July 22nd, 2014, to May 29, 2015; correct?
A. I believe it's July to May period, yes. I believe it's a July to May period, yes.
Q. Those particular dates, correct?
A. I don't know the specific dates for those, no.
Q. Okay. Let's look at the trade blotter that Capital produced, and if we can look at the first few trades. Do you see on the left where it says 10/02/14? Do you see that?
A. Yes, I can.
Q. And there's a column that has MGRINIT. And it says SYD. Do you see that?
A. I can read that, yes.
Q. And then it has buy next to it. Do you see that?
A. You're coming over a little bit; is that right, not next to it? You're coming over to the highlighted buy. Yep. I can see that, yes.

Q. A few columns over.

MR. CLUBOK: If we could expand that whole row so we can see that whole row, not just the left columns, please.

BY MR. CLUBOK:

Q. And you have a hard copy, so feel free to see whatever is easier to see, either the hard copy or the screen.

A. Yeah.

Q. What we have here is a row that indicates on October 2nd, 2014, buy. And then in the column entitled SHRPARAMT, it says 200. Then it has a stock price. Again, the date October 2nd, 2014. Do you see all that?

A. I can see that, yes.

Q. Okay. Now, let's expand downward the rows so we capture the entire period before December 3rd, 2014.

THE COURT: Now, I need to stop you for just a moment, not because of the time. Did the lights go out briefly?

MR. CLUBOK: Briefly.

MR. COUGHLIN: Briefly.

THE COURT: Okay. For some reason it stopped my computer. It did not stop Ms. Bredahl's computer. Ms. Baird, did it affect you at all? Okay. You looked at me.

So for some reason my computer is the only one affected. I really wanted to make sure we're getting a

record. It did it twice and I stopped twice.

All right. With that, continue.

MR. CLUBOK: Thank you, Your Honor.

BY MR. CLUBOK:

Q. We've expanded on the screen all of the rows with dates prior to December 3rd, 2014, and you can see there if you look at the column, it has the denominated numbers in hundreds. And you worked -- I'm going to do math. If I'm wrong, you can catch me. But 200 plus 200 is 400, plus 400 is 800, plus 800 is 1,600, plus 600 is 2,200, plus 300 is 2,500, plus 800 is 3,300 or 3,300, right?

A. I believe that math is correct.

Q. And for all of those rows, there's an indication of buy, and there's a price, and there's dates that range from October 2nd to October 9th, 2014; correct?

A. I believe that's the date range.

Q. And if you turn back to your bank records where you testified that that 3,300 number was just an artifact or just a bookkeeping issue --

A. I think I speculated on that, yes. I said I didn't know, but my guess was.

Q. Okay. Well, now that you've seen -- and maybe we can put the two documents side by side. Fair to say that it appears that actually Norfolk had purchased 3,300 shares in Puma stock beginning as early as October according to these

records, correct?
A. I don't know because I'm not familiar with the Capital trade blotter. That's a Capital document, so I can't comment on it.
Q. Fair to say that you're not familiar enough with the dates that Norfolk purchased Puma to know whether or not that 3,300 that's supposed -- that you said you speculated was received free was actually purchases made by Capital on your behalf?
A. I think I said I don't know.
Q. All right. Well, let's go back to Exhibit 18, the trade blotter. We looked at the top of the trade blotter. I want to look at the part of the trade blotter that is -- and I'm sorry. It's an eye test for me as well. The very end of it that ends five fourteen, the last few trades.

These are the last few trades that are identified on this trade blotter that was supposed to identify all the trades in the class period. You can see the very last two trades have the initials DBK. Do you see that?
A. I can see that.
Q. Do you recognize those to be the initials of Darcy Kopcho, that person that we identified before when we were going through your list?
A. I mean, I know her initials would be DK. I'm not familiar with what her middle name is, so I'd be making an

assumption.
Q. Just so the record is clear, the first few transactions, the ones in October, just to remind you, those had the initials SYD, which are the initials of Skye Drynan. Did you know that?
A. I obviously know her initials SD. Where they get the Y from, I don't know.
Q. Now, you've actually met Darcy Kopcho in person, correct?
A. I don't believe I've met her in person. I met her via video conference.
Q. Okay. You worked with her via video directly, correct?
A. Yes. She has met myself alongside our trustees at investment review.
Q. She's also met your boss and your boss's boss?
A. So Glenn and Nicola we're referring to here?
Q. Yes.
A. They attended that meeting, yes.
Q. All right. Let's turn now to Exhibit 10.
MR. CLUBOK: Exhibit 10, Your Honor, I believe is also unobjected to.
I'd like to move it into admission.
THE COURT: Exhibit 10 is admitted without objection.
(Exhibit 10 received.)

BY MR. CLUBOK:

Q. Exhibit 10 is a document dated October 2004. This is the investment management agreement between Norfolk and Capital, correct?

A. Bear with me.

Q. I should say this was the original agreement?

A. Yes, this is the original agreement. From time to time variations will be made by a side letter. So they're appointed in the autumn with funding in December. But from time to time this agreement would then be adjusted by side letter when perhaps we were changing a benchmark or perhaps fee-level discussions.

Q. Let's look at page 4, section 2.2. Actually if we could just quickly look at 2.1. I know you testified about this, but here it is in writing where it says the client, meaning Norfolk, has appointed the manager, meaning Capital, as investment manager of the client's assets.

Do you see that?

A. I can see that, yes.

Q. Okay. For 2.2 it says that Norfolk is giving Capital full discretion to, quote, invest the assets comprising the portfolio at such times and in such securities as it considers are in the best interest of the client in accordance with the Guidelines, Capital G, correct?

A. I think the first part of your, quote, Norfolk shall

give full discretion, where are you reading?
Q. I'm sorry. That's why I put the quote in the middle.
A. Yes. Apologies. The phrase starting the manager shall is there, yes.
Q. And this is, you understood, the legal language that reflected the discretion that was being given to Capital, correct?
A. Well, I'm not an attorney. But, yes, my practical understanding is that's the discretion, that they will be making stock selection decisions on our behalf.
Q. And Norfolk is relying on Capital to make decisions in the best interest of Norfolk?
A. Norfolk should be acting in a fiduciary basis for us.
Q. I'm sorry?
A. Norfolk should be acting on a fiduciary basis for us, i.e., making financial decisions in our best interest.
Q. I think you meant to say Capital?
A. Sorry, Capital. Apologies. Long day, and I flew in yesterday.
Q. I totally understand. I'm only asking you to say it again for a clear record.
A. So Capital are acting as a fiduciary, i.e., making financial decisions in the best interest of the Norfolk Pension Fund.
Q. And Norfolk is relying on them to do that properly,

correct?
A. Yes.
Q. Now, Norfolk, however, does set Guidelines, with the capital G, that they have to abide by, correct?
A. All of our managers will have investment guidelines within their investment management agreement.
Q. So it's not like you just say, hey, do absolutely whatever you want. It's pick individual stocks but within a certain set of guardrails or guidelines that you give them that you expect them to follow, correct?
A. Absolutely. So that might say within certain public markets or against certain benchmarking. We might also say you're not to hold more than five percent of a given name, something like that. Risk management.
Q. And you also might give them general advice about, for example, whether they should invest in socially responsible companies? That's one of the guidelines that you offer, correct?
A. I don't think we tell them to invest in socially responsible companies. What we require our managers to do is engage with companies on corporate governance aspects.
Q. You expect your investment advisors to directly engage with senior management at the companies they want to invest in, correct?
A. Well, we expect our managers to be managing

appropriately.

Can I clarify something from you when you're asking that question? Are you asking are they engaging on environmental, social, and governance matters? Or are you asking them as part of their investment thesis that they are meeting with management where possible?

Q. The latter.

A. We would expect them to meet with management where possible.

Q. And you would expect your investment managers to meet with top management of the companies they invest in, correct?

A. We would expect them to reach out and engage with those companies where possible.

Q. Okay. Now, given this discretion and the general guidelines, fair to say that before Norfolk -- I'm sorry. I did it myself.

Strike that. Let me start over.

Fair to say that before Capital decided to make any particular purchase in Puma stock, they didn't have to give you advance notice, correct?

A. That is correct.

Q. So if it was October and they for whatever reason thought it was a good time to invest in Puma, they could just do that and you had given them full authority on your behalf?

A. That would be correct for any company in their

portfolio.
Q. But it is the case that they reported after the fact those investments they had made on your behalf, correct?
A. Well, they report it, but those trades are within our custody system anyway. Those assets are held in safe custody by our custodian bank.
Q. Okay. So let's get back to that. They're giving you -- from Capital's perspective, even though they don't have to get advance permission, they do give you at least -- they give you regular reports on the assets they have purchased on your behalf, correct?
A. We will see monthly accounting reporting.
Q. And even if they didn't do that for some reason, your bank continuously lets you know what investments your investment advisors have put you into, correct?
A. We can see all of the trades and the holdings in realtime from the custodian.
Q. And this was true during the class period. In realtime you could see exactly what investments you were being put into by Capital, correct?
A. That's correct.
Q. Now, throughout the entire class period, Norfolk never told Capital that it disagreed even after the fact with any decision it had made to purchase Puma stock; is that correct?
A. That wouldn't be our role based on the discretion we've

granted them. But, no -- sorry. I don't know which negative -- that is correct. We would not have told Capital in the same ways we would with any other holding in the portfolio why you purchased that holding.

Q. My question is much simpler. With respect to Capital specifically and transactions in Puma during the class period, it's true that you never objected in any way even after the fact, correct?

A. We have never given a view to a manager, including Capital's purchase of Puma Bio, on any individual stock purchase decision.

Q. And that continued even after the class period. Even after the class period, it's fair to say that you never told Capital in words or substance as it was making additional purchases in Puma stock that you objected to those purchases; is that true?

A. The class was obviously formulating. We did not directly discuss the matter with Capital at that point.

Q. So is that a yes to my question?

A. That's a yes.

Q. All right.

THE COURT: Let me ask, how much longer with this witness?

MR. CLUBOK: I have approximately 35 minutes, I believe, maybe 40.

THE COURT: Will there be recross?

MR. FORGE: Approximately 90 seconds, Your Honor.

THE COURT: All right.

Sir, I'm afraid we need to see you tomorrow.

THE WITNESS: Absolutely.

THE COURT: Would you like me to wear my white wig? All right. We'll skip the wig. We'll see you tomorrow. Thank you.

Ladies and gentlemen, 9:00 tomorrow. Remember, don't discuss the case. Keep an open mind. Don't research the case.

THE CLERK: All rise.

(Open court - jury not present)

THE COURT: You can step down. Thank you.

All right. Everyone, be seated. I don't want to go longer than five. Let's look at the first overall view. Shouldn't plaintiffs be referred to as a plural -- I'm sorry. Yeah. What do we think about that? Should plaintiffs be a plural or a singular?

MR. GRONBORG: We've been referring to it as a plural, Your Honor.

THE COURT: What does the defense say?

MS. SMITH: That's fine with us.

THE COURT: Okay. So I'm not sure all the instructions comply with that. All the instructions need to

refer to plaintiffs as a plural.

Next, looking at instructions -- well, the parties agree to joint instruction number one. That's good.

Moving to plaintiffs' instruction number two, this goes to the issue reflected in the bench memos and elsewhere that the issue of omissions comes up. I am inclined to allow the plaintiffs to proceed on an omissions basis.

Going from memory, I think the plaintiffs oddly said at one point in the summary judgment this wasn't about omissions. I'm not sure why you said that, but I think everywhere else they have been consistent, in the pleadings, in their briefings, though the defense understandably started to contest that.

So I am inclined to allow instructions on omissions. Let me turn to the defense and hear what their argument is. Am I right that it was mentioned once in the summary judgment, or where are we on that? I know you fight it in your trial brief, et cetera, as you should, but I'm inclined to allow omissions to be go forward.

Who would like to argue that? Because I am prepared to make that as a conclusive decision right now.

MS. SMITH: Thank you, Your Honor. This case has never been pled as an omissions case.

THE COURT: I understood the pleadings did have it as an omissions case. So are we in disagreement on that?

MS. SMITH: We are in disagreement on that, Your Honor.

THE COURT: Then let's turn to the plaintiff.

Did you plead it as an omissions case?

MR. GRONBORG: We did, Your Honor.

THE COURT: Where?

MR. GRONBORG: I can cite to you the paragraphs that are in the briefing that we provided. So I will find --

THE COURT: That's my recollection when I looked it up.

MR. GRONBORG: I think we cited to paragraph 92.

THE COURT: Of the complaint?

MR. GRONBORG: 95-B of what was the amended operative complaint.

THE COURT: Okay. So, counsel, you said it wasn't, but he's giving me paragraphs, and my understanding is it was pled.

Where are we on that?

MS. SMITH: Yes, Your Honor. I apologize. I don't have the complaint in front of me, so I can't look at those paragraphs. But --

THE COURT: Well, I did.

MS. SMITH: So a little bit of history here. So originally in this case the plaintiffs had identified the press release as one of the operative statements that was

challenged. As to that particular statement, plaintiffs' theory had been that the press release was incomplete because it didn't disclose additional information. That is more in the nature of an omissions although it was never pled as a pure omissions case. The only statements that were made --

THE COURT: Oh, no, no, no. Let's be very careful with our language. Do you think anyone here is suggesting that it was alleged as a pure omissions case and not an affirmative misrepresentation case as well?

MS. SMITH: We are not saying plaintiffs are alleging this is a pure omissions case.

THE COURT: And no one ever did, so I'm not sure why you said that. I don't want to be confused here. Let's be on the same wavelength. It's never been an issue of a pure omissions case.

Go ahead.

MS. SMITH: Your Honor, we agree. This has never been an issue of a pure omissions case. Therefore, the portions of the jury instructions that relate to omissions are not appropriate --

THE COURT: But you're repeating everything. Let me cut to the chase. I think the plaintiffs have established an omissions case. That would mean your statement about the jury instruction doesn't really apply. Your argument should be that this is not an omissions case. That's what I need to

hear.

You first suggested they didn't plead it. Yeah, they did. So where are we? Feel free, anyone that wishes to speak. Again, I'll make the statement. There was one statement in the summary judgment papers where I don't know why, but plaintiffs said it wasn't an omissions case.

But they have since -- they never amended their pleadings and their papers -- but since then have been consistent that it's an omissions case. So let's address the question of whether this is an omissions case.

MR. CLUBOK: My understanding of their theory was that the press release contained material omissions because it did not include the various pieces of information that they thought the press release should include.

When we won summary judgment on the press release, that is when the omissions dropped out. My understanding --

THE COURT: Very fine argument. What is the plaintiffs' response?

MR. GRONBORG: I can cite you to seven different paragraphs in the complaint, none of which are tied to the press release. Our pleading all along has been that there were both false statements and omissions. Statements that were made on the conference call omitted the true facts about the ExteNET trial.

MR. CLUBOK: What paragraphs?

MR. GRONBORG: I'm happy to cite to you all of the paragraphs in the complaint again. It's also in the brief you have.

THE COURT: Okay.

Mr. Clubok, response?

MR. CLUBOK: Since Mr. Gronborg offered to cite the paragraphs, I would ask the Court if we can take him up on his offer.

THE COURT: I think he did a moment ago. Do you want to cite further?

MR. GRONBORG: I'm happy to read them out again.

THE COURT: Folks, gosh, this seems to me stuff you could have been talking about in your meet and confer. I mean, they ought to have been -- the plaintiffs should have told you their paragraphs, and you could have had a debate about it. But now let the plaintiff look up the paragraphs and provide them.

MR. GRONBORG: And we did provide these previously.

THE COURT: To who? Where?

MR. GRONBORG: We provided it during our discussions, and we provided it to the Court in our briefing on this issue.

THE COURT: Yeah. I'm thinking. Yeah. Go ahead.

MR. GRONBORG: Paragraph 92, paragraph 95-B, paragraph 101, paragraph 103, paragraph 105, paragraph 106,

paragraph 110, paragraph 112, are all ones that explicitly discuss omissions. The case is about false statements and omissions.

MR. CLUBOK: If I may, Your Honor, I think -- I did it very quickly -- every single one of those paragraphs that has the word omissions is simply a boilerplate recitation of the word omissions. If that satisfies a pleading standard for omissions, every single material misrep case is an omission.

There's no specific facts alleged that talk about the specific omissions. This is a fraud case. We have to have specifics about what --

THE COURT: Okay. Now, it's funny. Let me just say, defense argument has moved from the complaint doesn't reference omissions to the complaint references omissions as boilerplate, which of course would be a 12(b)(6) motion.

So now well into the trial, you're saying this isn't an omissions case because of inadequate allegations, correct?

MR. CLUBOK: No, Your Honor.

THE COURT: Oh, that wasn't correct?

MR. CLUBOK: That's not what I'm saying.

THE COURT: Wait. Hold on. How did I get that wrong? I thought you specifically said they were boilerplate, they were inadequate, and therefore they would

apply across the board in these kinds of cases. Boy, I thought I accurately repeated your argument. I'm sorry I have it wrong.

Restate your argument based on the insufficient complaints, because I just did not understand that exchange at all. What did I miss?

MR. CLUBOK: It's my fault for not being clear. It's a compound response to that question. As far as I understand, the only factual reference to an omission in the complaint is alleged omissions in the press release. There are then various paragraphs that just in boilerplate refer to omissions without alleging a specific omission from the conference call.

Your Honor read a neutral statement to the jury which alleged the complaints about certain statements that are alleged to be misstatements. I did not hear then nor have I heard omissions that are -- that have been adequately alleged with respect to those alleged misstatements unless it is the case that by operation, every single misstatement is necessarily an omission.

If that's what we're dealing with, then I guess I understand the plaintiffs' argument.

THE COURT: Plaintiffs' response? I sure did hear -- I sure did hear you talk about inadequate pleadings. The only thing is you combined it with the specificity on the

item that was cut during summary judgment.

MR. CLUBOK: Yes, and --

THE COURT: No. It's time for the plaintiff to speak.

MR. CLUBOK: Okay.

MR. GRONBORG: Your Honor, it's not a boilerplate complaint. It specifically identifies omissions. It is not --

THE COURT: What specific omissions did it identify?

MR. GRONBORG: It specifically identifies the facts that were known by the defendant that were either misstated or omitted from all of the statements. And that includes the July 22nd conference call, and it specifically lays out what those facts are.

THE COURT: Based on that, I'm going to take another look at it, but I'm leaning towards the plaintiff. This is something I want the sides to talk about before we begin at 9:00 o'clock tomorrow.

Okay. That goes to plaintiffs' instruction number two. On plaintiffs' instruction number three, I would be inclined to add, as requested by the defendants, the word justifiably, the word justifiably before relied. We can talk more about that.

On plaintiffs' instruction 4.1, I do not believe

defendants have provided a compelling basis to depart from the model instructions.

Would the defense wish to comment on that right now? I'm not making a final ruling, but that's my notion. And I note that often the defense makes a statement that isn't in the model rules, and then there's a string cite. In this short period of time, I don't have time to read each of those cases and see how they apply to your arguments.

Now, the string cite often includes pin cites, but it's really a task for me to go through your string cites. I'd rather wish to fall back on the notion that I'm going to stick with the model instructions unless good cause can be shown.

So I'm inclined to give plaintiffs' instruction 4.0.

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

THE COURT: Uh-huh.

Okay. Then on defendant's instruction number five regarding opinion, I'm inclined not to give it. I don't think it made its way into the model instructions, and I don't see any reason why I should add it.

Anything you want to say on that at this point?

MR. CLUBOK: Your Honor, there's been Supreme Court precedents since, including Omnicare, very recently that lays

out very clearly --

THE COURT: So your argument is -- let's be clear. Your argument is that Omnicare, the wisdom of Omnicare was not before the instructions committee? Did you hear me?

MR. CLUBOK: I'm sorry.

THE COURT: Your argument is that the wisdom of Omnicare was not before the instructions committee; is that right?

MR. CLUBOK: I believe -- I'm told that they footnote referenced Omnicare. I'm not sure if it was --

THE COURT: If they referenced Omnicare, then their opinion appropriately reflects Omnicare unless you convince me that it doesn't. Where would I be wrong on that?

MR. CLUBOK: Well, Your Honor, I think the Ninth Circuit has also ruled in the cases we cite in 2017. I'm not sure the model instructions takes those into account. I will say with all due respect on this one, the Supreme Court was quite clear about the rule with respect to opinions. The statement that Mr. Auerbach made, with all due respect --

THE COURT: You don't have to say with all due respect. Look, you don't have to say with all -- let's just get it right here.

MR. CLUBOK: I do have respect for them, but I think they got it wrong. If they have ignored Omnicare or if they purported to follow it and it does not include these

instructions, they are misstating the law according to the Supreme Court and as interpreted by the Ninth Circuit since.

THE COURT: Okay. The on the basis of what I was saying, I would not give instruction number five, on defense instruction number five.

On plaintiffs' instruction number five, I would give the plaintiffs' instruction but replace the fourth paragraph with the third paragraph of defendant's instruction number six. That gets kind of complicated, but on plaintiffs' instruction number five, I would replace the fourth paragraph with the third paragraph of defendant's instruction number six.

MR. GRONBORG: We're fine with that, Your Honor.

THE COURT: Then as to defendants number 7 through 11, I would not give that. I believe they expand on the definition of knowledge and provide a defense-favorable nuance. So at this moment I'm inclined not to give 7 through 11.

All right. On defendant's number 13, delegation to investment authority, I don't believe that was based on the model instructions, and I don't see a reason to give it beyond the model instruction.

On defendant's instruction number 15, I believe it is redundant and not well enough supported by controlling authority. So those are just some general views. We'll get

into this in much more depth, but it's approaching five. I want you to talk further about the instructions between now and 9:00 tomorrow.

And it probably looks like we'll have to do all our work on this Thursday morning, which probably means a pretty early start for argument Thursday morning and then the parties assigning the duties of producing a set that models the rulings we make on Thursday morning. Okay. That's where we are.

One other thing. I don't think I've done this in this case, which is a surprise, because I usually do it in cases. While the parties are discussing settlement -- I'm sorry. While the parties are discussing jury instructions, bring up the issue of settlement. I know you are now in warrior mode.

I certainly understand that and recollect that, but sometimes in the middle of warrior mode you can take a deep breath and make jaw-jaw rather than war-war. Looking at our English friend, that is allegedly Churchillian, but it's not. Anyway, talk settlement before 9:00 tomorrow.

Anything else?

MR. COUGHLIN: Your Honor, we have a depo clip that remains in dispute, I think, but maybe not. Darcy Kopcho, are we all settled? We're going to each waive the objections that remain?

MR. CLUBOK: There's one fundamental objection to this Darcy Kopcho. There was a series of questions where effectively the questioner said, hey, assume that there was a counterfeit FDA document. If that were true, wouldn't you think X, Y, Z? And it was a whole series of questions where they were asked to assume facts that were not in evidence but that were suggested to be true by the lawyer.

And then the fact witness who is a party opponent, they are indistinguishable under the law from -- as the investment manager, from the plaintiff. They were then led to give answers saying, yes, if that were true, I'd have questions. Or, gee, if it was a counterfeit document, I'd have concerns.

It is objectionable on many levels.

THE COURT: Start with?

MR. CLUBOK: Start with leading. Second of all, assumes facts not in evidence. Foundation. Prejudicial. Reflects arguments of counsel. Incorporated into a question -- all of those arguments.

THE COURT: I'll take your prejudicial to mean the prejudice aspect of 403, keeping in mind that 403 goes to timing but it also goes to prejudice.

You know, what happened to the age-old incomplete hypothetical or improper hypothetical? It sounds to me like --

MR. CLUBOK: I left that one off, Your Honor. I should have said that --

THE COURT: People don't seem to say that.

MR. CLUBOK: They don't say that enough.

THE COURT: But the argument, improper hypothetical, rather raises all the issues you discussed, I think.

MR. COUGHLIN: Your Honor, we didn't call this witness. They called this witness under 611, that this witness would not fall under a party opponent. This witness was no longer even employed when she was deposed.

THE COURT: Hold on. Would you -- could you make a 611 argument as to adversity, an adverse witness?

MR. CLUBOK: We absolutely could. The --

THE COURT: What would you base your adverse witness argument on?

MR. CLUBOK: We would base it because an investment manager with full discretion under the law is not just an agent, but the law -- that's the jury instruction. We understand you may not allow for a jury instruction, but it certainly states the proper law for investment manager, which is that you must treat them as if they were made directly by the plaintiff, investment decisions by the investment advisor with full discretion. You treat their knowledge and their admissions as one with the party providing agency. That is

the law as we understand it, Your Honor.

THE COURT: Okay. I don't think it's enough to establish 611 diversity based on what you've said. I don't know if you saw hostility. It's not enough for me to determine they are adverse merely from their position.

Okay. It's now 5:00. These are kind of difficult questions.

Are all the other issues on that transcript resolved?

MR. COUGHLIN: I think they are, Your Honor.

MR. CLUBOK: They are, Your Honor.

THE COURT: Okay. Then when would you be using this transcript?

MR. COUGHLIN: We could be using it as early as tomorrow afternoon.

MR. CLUBOK: No, Your Honor. That's in our case, I believe, and we will not use it until Thursday. We're not going to hustle to use it, so we'll have time.

THE COURT: Okay. Well, as always with transcripts, the earlier you can give them to me, the better, because I have meetings the next two evenings and I'll find a place to put it in. Even if you want to give me the transcript now and have me read it and think about it, I would.

You heard all the objections. Your 611 argument

goes to adversity, hostility, et cetera. I think I'm -- I was ruling in your favor on that basis.

MR. COUGHLIN: Yes.

THE COURT: But that goes to it being a leading question. And there were quite a lot of other objections being made, and it could be confusing. But hypotheticals, inappropriate settings can be appropriate.

So we'll see you all tomorrow at 9:00. Have those talks.

MR. CLUBOK: We will. Thank you, Your Honor.

THE COURT: See if you can clarify the jury instructions making our job easier on Thursday morning, and raise the issue of settlement.

MR. CLUBOK: Yeah. And with respect to the deposition, frankly given the timing, we'll probably cut it down significantly anyway.

THE COURT: Okay. Good. Thanks.

(Proceedings adjourned at 5:01 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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