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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS
LP, et al.,

CIVIL ACTION NUMBERS:

Plaintiffs/Counterclaim-
Defendants,

-vs-

14-cv-03547-RMB-KMW

SAGENT PHARMACEUTICALS, INC.,
Defendant/Counterclaim-Plaintiff.

ASTRAZENECA PHARMACEUTICALS
LP, et al.,

Plaintiffs/Counterclaim-
Defendants,

-vs-

14-cv-05539-RMB-KMW

GLENMARK GENERICS, INC., USA,

Defendant/Counterclaim-Plaintiff.

15-cv-00615-RMB-KMW

Mitchell H. Cohen United States Courthouse
One John F. Gerry Plaza
Camden, New Jersey 08101
July 14, 2016

B E F O R E:

THE HONORABLE RENÉE MARIE BUMB
UNITED STATES DISTRICT JUDGE
AND A JURY

United States District Court
Camden, New Jersey

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Certified as true and correct as required by Title 28,
U.S.C., Section 753.

/s/ Theodore M. Formaroli, CSR, CRR

United States District Court
Camden, New Jersey

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1 THE DEPUTY CLERK: All rise.
2 (OPEN COURT, July 14, 2016, 9:08 a.m.)
3 THE COURT: Good morning.
4 RESPONSE: Good morning, Your Honor.
09:08AM 5 THE COURT: Have a seat.
6 Okay. Are we ready to continue with the deposition
7 testimony?
8 MS. PIROZZOLO-MELLOWES: Yes, we are, Your Honor.
9 THE COURT: Ms. McCleskey, come forward.
09:09AM 10 MR. FREITAS: Yes, Your Honor.
11 (Laughter.)
12 THE COURT: Good morning.
13 MR. FREITAS: Good morning.
14 THE COURT: Okay. Whenever you're ready.
09:09AM 15 MS. PIROZZOLO-MELLOWES: We left off at Page 140 of
16 the transcript.
17 THE COURT: Yes, thank you.
18 MS. PIROZZOLO-MELLOWES: And Ms. Waldron continues
19 the questioning on behalf of defendants.
09:09AM 20 (Deposition read as follows:)
21 Q. Let's get back to the documents you kept when you were at
22 the Lombardi Cancer Center.
23 Did I understand you to say that you did keep
24 laboratory notebooks?
09:09AM 25 A. Yes.

1 Q. Did you have any raw data of any kind?

2 A. It was in the laboratory notebooks.

3 Q. It would be pasted in the lab notebooks?

4 A. Why do you think raw data would not be on the same piece
09:09AM 5 of paper as the lab notebook?

6 Q. Actually, I don't know one way or the other. I want to
7 know what your particular procedure was.

8 A. Well, most of the time, you're writing the laboratory
9 notebook. If you get, like, a printout or something, then you
09:09AM 10 would paste that in the laboratory notebook.

11 Q. Got it. Did you keep anything on the computer?

12 A. Yes.

13 Q. What did you keep on the computer?

14 A. Well, remembering that computers were not as good as they
09:10AM 15 are now, when I got data, I would have to enter it into the
16 computer, like, into a graphing program, for instance, and
17 then it would draw the graph and I would print the graph. But
18 the -- but the data in the computer was the same as in my --
19 hopefully, as in my lab notebook.

09:10AM 20 Q. You didn't create, say, Word files and keep them on a
21 computer?

22 A. Oh, yes, but that's not data.

23 Q. Okay. I see. What type of information or documents, if
24 any, would you have saved on a computer?

09:10AM 25 A. The drafts of the paper, the -- after I entered the data

1 to make a graph, that would be saved, of course, but it would
2 be the data from the lab notebook that I entered. So it's,
3 like, a copy and -- and also the graphics file, picture a
4 graph. I don't know how you would say that, but the graph
09:10AM 5 itself, I guess you would say, that was saved to the computer.
6 But I also, of course, printed it.

7 Q. Do you have knowledge as to whether anyone in your group
8 had documents saved to a computer that had originated from
9 AstraZeneca?

09:11AM 10 A. I don't have knowledge about anybody else in my group
11 except me.

12 Q. Did you have any documents originating from AstraZeneca
13 that related to Ms. McCleskey 1998 saved to a computer?

14 A. Are you speaking about data?

09:11AM 15 Q. Anything. For example --

16 A. Saved to a computer?

17 Q. Yeah, like a statement of proposed investigation --

18 A. Oh, no --

19 Q. -- sample requests?

09:11AM 20 A. -- no, no.

21 Q. Did you have data that originated from AstraZeneca saved
22 to a computer?

23 A. No.

09:11AM 24 Q. Did you have any binders or personal notebooks separate
25 from your lab notebooks in which you kept information

1 regarding McLeskey 1998?

2 A. I had binders with the tumor data, the tumor measurements
3 in pictures of mice.

4 Q. Any other places where you would have had information
09:11AM 5 related to McLeskey 1998, that we haven't talked about?

6 A. No.

7 Q. Now, you mentioned, if I understood you correctly, I
8 believe you testified that you destroyed your technical
9 documents related to McLeskey 1998 in the beginning of

09:12AM 10 June 2014; is that right?

11 A. Correct.

12 Q. What did you mean by "destroyed?" How did you destroy
13 them?

14 A. I just threw them in the trash.

09:12AM 15 Q. Just a regular trash bin?

16 A. Yeah.

17 Q. Where was this trash bin?

18 A. At my school.

19 Q. What school?

09:12AM 20 A. The University of Maryland School of Nursing.

21 Q. Do you know what happened to the documents after you
22 threw them in the trash bin?

23 A. No.

24 Q. When you left Lombardi Center and took your technical
09:12AM 25 documents with you, was it your understanding that that was

1 okay by the rules, by Lombardi's policies?

2 A. I didn't have any understanding about that.

3 Q. Did you know what document retention policies Lombardi
4 would have had in place at the time?

09:12AM 5 A. No.

6 Q. When you -- I'll just say "you" to start, and then we
7 will be talking about Lombardi Center. When you got a
8 document on a project, say, a certificate of service or MSDS
9 or something like that, what did you do with it? Where was
10 something like that kept?

09:13AM

11 A. I don't know what a certificate of service is.

12 The -- we were required to keep MSDSs in the notebook
13 in the lab for all chemicals that we had in the lab, so that's
14 what we did.

09:13AM

15 So MSDSs would be kept in the laboratory notebooks,
16 correct?

17 (Reading stopped.)

18 MR. FREITAS: I apologize.

19 THE COURT: Ask it again.

09:13AM

20 MS. PIROZZOLO-MELLOWES: You have to read -- he
21 inadvertently reread the question.

22 THE COURT: Yes.

23 (Deposition read as follows:)

09:13AM

24 Q. So MSDSs would be kept in the laboratory notebooks,
25 correct?

1 A. No, not in -- not where we had the data. We had separate
2 notebook for MSDSs.

3 Q. MSDSs had their own notebook?

4 A. That's correct.

09:13AM 5 Q. What about certificates of analysis?

6 A. Didn't usually keep those.

7 Q. They're -- why not?

8 A. Didn't feel that we needed them.

09:14AM 9 Q. Who retained custody of documents as they came in on the
10 McLeskey 1998 project?

11 A. I don't know what you're talking about, what documents.

12 Q. Do you recall how samples got shipped into the facility,
13 whether, say, they went to a mailroom or a specific sample
14 depository?

09:14AM 15 A. They went to the mailroom.

16 Q. And then that -- that would happen?

17 A. The mail people would bring them to us.

18 Q. Would you then keep the samples in your lab?

19 A. Yes.

09:14AM 20 Q. And did I understand you correctly that at the time you
21 were a postdoc in Dr. Kern's lab, you were not aware of the
22 policies and procedures that Lombardi Center had in place with
23 regard to retention of documents; is that right?

09:14AM 24 A. Not only was I not aware of anything they had in place, I
25 was not aware if -- whether they had anything in place.

1 Q. If you received ancillary paperwork with samples, such as
2 a certificate of analysis or something like that, what would
3 you have recorded the receipt of that document --

4 (Reading stopped.)

09:15AM 5 THE COURT: "Would you."

6 (Deposition read as follows:)

7 Q. Would you have recorded the receipt of that document in
8 your laboratory notebook?

9 A. No.

09:15AM 10 Q. Did Lombardi require you to make copies of anything and
11 send them on to a document repository or anything like that?

12 A. No.

13 Q. To your knowledge, were the documents that you were
14 keeping in your lab the only copies?

09:15AM 15 A. As far as I knew.

16 Q. Are you aware of whether copies were ever made of your
17 laboratory notebooks?

18 A. I think not.

19 Q. Who had access to your laboratory notebooks besides you?

09:15AM 20 A. Dr. Kern.

21 Q. Anyone else?

22 A. Well, the other people in the lab would have, had they
23 wanted it, but I don't know that they ever did --

24 (Reading stopped.)

09:15AM 25 THE COURT: So could have.

1 MR. FREITAS: Pardon me.

2 (Deposition read as follows:)

3 A. Well, the other people in the lab could have had they
4 wanted it, but I don't know what they ever did -- that they
09:15AM 5 ever did.

6 Q. In the conversation that you just referred to, when you
7 communicated with Mr. Trock, what did you discuss with
8 Mr. Trock?

9 A. He -- I think he, I don't remember a whole lot about the
09:16AM 10 conversation, but he said that he had been just about to
11 discard the data from -- from this paper when they called.

12 Q. When who called?

13 A. The -- the lawyers that were doing the Teva thing, Mary
14 Burke and company.

09:16AM 15 Q. I'm sorry. I believe you just said, "Mary Burke did not
16 ask me not to destroy documents."

17 A. She did not say, Don't destroy documents. When she said
18 that, I do not know.

19 Q. Mary Burke never told you to preserve your documents
09:16AM 20 related to McLeskey 1998?

21 A. Correct.

22 Q. Did anyone Mary Burke worked with ever tell you not to --
23 tell you that you must preserve your documents related to
24 McLeskey 1998?

09:16AM 25 A. No.

1 Q. Now, I believe you said earlier that you recall speaking
2 with three people at AstraZeneca, Dr. Wakeling, Dr. Vose, and
3 a third person whose name you don't remember; is that correct?

4 A. Correct.

09:16AM 5 Q. Do you recall approximately how many times you spoke with
6 Dr. Wakeling?

7 A. Twice.

8 Q. Was this via telephone or by some other means of
9 communication?

09:17AM 10 A. Telephone.

11 Q. Who called who?

12 A. I called him.

13 Q. Both times?

14 A. Yes.

09:17AM 15 Q. Why did you call Dr. Wakeling?

16 A. The first time I called to get him to send me the drug
17 and find out how to administer it to mice. The second time I
18 called to tell him we had used the drug he sent the first time
19 and that I needed more drug.

09:17AM 20 Q. Did Dr. Wakeling require you to fill out any paperwork or
21 do anything in writing before you received samples of drugs?

22 A. Not me.

23 Q. Did he require that someone fill out some sort of
24 paperwork before samples would be shipped?

09:17AM 25 A. I don't know.

1 Q. What did Dr. Wakeling tell you in response to your
2 request that you wanted AstraZeneca to send you samples of
3 drugs?

09:17AM

4 A. He told me that I should give it to the mice as it
5 outlined in this paper and that he would ship it.

6 Q. Basically, an okay-I'll-take-care-of-it type thing?

7 A. Um-hum.

8 Q. How many times did you speak with Dr. Vose?

09:18AM

9 A. Once -- that -- assume that he was not the second -- the
10 person I don't know who it is, but --

11 Q. Right.

12 A. -- I know I spoke with him once.

13 Q. Did you ever communicate with Dr. Wakeling in writing
14 either by e-mail or letter?

09:18AM

15 A. Not that I recall.

16 Q. Okay. So you said you spoke with Dr. Vose once; is that
17 right?

18 A. Um-hum.

19 Q. Was this on the phone?

09:18AM

20 A. Yes.

21 Q. Did you ever have any written communications with him?

22 A. Not to my -- not that I remember.

23 Q. On the one incident -- one instance that you did speak
24 with Dr. Vose, who called who?

09:18AM

25 A. I called him.

1 Q. Why did you call Dr. Vose?

2 A. Because Dr. Wakeling told me to call him to get
3 preformulated drug.

09:18AM 4 Q. Do I understand that you talked to Dr. Wakeling about
5 receiving powdered ICI 182,780 and Dr. Vose about obtaining
6 preformulated ICI 182,780?

7 A. At separate times.

8 Q. I'm just trying to understand. I think I understand the
9 -- that you talked to these guys about two different things.

09:19AM 10 Do I understand correctly that you talked to
11 Dr. Wakeling about receiving powdered ICI 182,780?

12 A. Correct.

13 Q. And then do I understand correctly that you talked to
14 Dr. Vose about receiving the preformulated ICI 182,780?

09:19AM 15 A. Much later.

16 Q. Much later? That's a good point.

17 Do you recall approximately when, or do you recall the
18 approximate dates on which you talked to Dr. Wakeling?

19 A. No.

09:19AM 20 Q. Year?

21 A. I don't know.

22 Q. But you know you talked to Dr. Vose much later. What do
23 you mean by "much later?"

09:19AM 24 A. When I talked to Dr. Wakeling initially, then he sent me
25 the drug, then we used the drug in mice and also in *in vitro*

1 studies and we used it all up. So I don't know how long that
2 took, but I would say a matter of months, anyway, maybe a
3 year. Then we needed more drug so I called Dr. Wakeling
4 again, that's when he told me to call Dr. Vose.

09:20AM 5 Q. And the powdered ICI 182,780 would have been what you --
6 what was dissolved in ethanol and then spiked into the peanut
7 oil?

8 A. Correct.

9 Q. When you spoke to Dr. Vose, what did he tell you about
09:20AM 10 shipping you samples of preformulated 182,780?

11 A. He said he would.

12 Q. Did he say anything else?

13 A. Not to my remembrance.

14 Q. Did he require that you do anything before he sent the --
09:20AM 15 sent the files of preformulated ICI 182,780?

16 A. No.

17 Q. Do you know whether anyone in your lab had to complete
18 any type of paperwork before AstraZeneca would send the lab
19 preformulated 182,780?

09:20AM 20 A. I do not know.

21 Q. Who would know?

22 A. Possibly Dr. Kern.

23 Q. Okay. And now the third person that you spoke to, was
24 this before or after you talked to Dr. Vose?

09:21AM 25 A. After.

1 Q. Who called who?

2 A. I called him.

3 Q. Did you have any communications in writing with this
4 third person?

09:21AM 5 A. No.

6 Q. And what was the purpose of calling this third person?

7 A. I wanted to find out what the -- what was in the drug
8 because I was getting ready to publish a paper. I was getting
9 ready to write the paper, actually.

09:21AM 10 Q. And what did he tell you?

11 A. He told me --

12 Q. Do you recall the words he used?

13 A. No.

14 Q. But he told you all of the excipients and their
09:21AM 15 percentages?

16 A. He told me what's in the paper: 10 percent ethanol,
17 10 percent benzyl benzoate and 10 percent benzyl alcohol
18 brought to volume with the castor oil.

19 (Reading stopped.)

09:21AM 20 MS. PIROZZOLO-MELLOWES: Your Honor, I think there
21 was a mistake in reading that.

22 THE COURT: It's -- no, the court reporter took it
23 down correctly, that's fine.

24 (Deposition read as follows:)

09:21AM 25 Q. You don't recall whether or not he specified the units of

1 measure?

2 A. I do not recall.

3 Q. How did you know to contact this third person?

4 A. I called the number that was -- that I had been given for

09:22AM 5 Dr. Vose.

6 Q. And somebody else answered?

7 A. I don't know if it was somebody else or if it was

8 Dr. Vose.

9 Q. So there -- you're saying -- if I'm understanding you

09:22AM 10 correctly, you believe it's possible that it was Dr. Vose that

11 told you the makeup of the formulation but you're not sure?

12 A. Well, it was whoever answered the phone. That's all I

13 can say about it.

14 Q. I see. But you called Dr. Vose's direct line?

09:22AM 15 A. Yeah. I called the same number I had called previously

16 to speak with Dr. Vose.

17 Q. Who gave you Dr. Vose's phone number?

18 A. Dr. Wakeling.

19 Q. Who gave you Dr. Wakeling's phone number?

09:22AM 20 A. I don't remember.

21 Q. Do you recall generally how you knew to call Dr. Wakeling

22 that he was the person to call?

23 A. Either Dr. Lippman or Dr. Kern told me, but I don't know

24 who or when or anything.

09:23AM 25 Q. But do I understand you correctly that you -- with regard

1 to this third person, that it was a man?

2 A. Yes.

3 Q. When you called Dr. Vose the first time, or when you
4 called Dr. Vose, how did you know it was him that answered the
09:23AM 5 phone?

6 A. I don't remember.

7 Q. But you feel confident that you were speaking to Dr. Vose
8 the first time?

9 A. Well, I certainly believed that I was.

09:23AM 10 Q. At the time, did you believe that the third person that
11 you were talking to was Dr. Vose?

12 A. I don't recall what I believed.

13 Q. What do you believe today?

14 A. I don't believe.

09:23AM 15 Q. You have no idea who you talked to?

16 A. Right.

17 Q. Did you send AstraZeneca drafts of the study protocol
18 that you were going to follow for the research described in
19 McLeskey 1998?

09:23AM 20 A. No.

21 Q. Did you ever provide your lab notebooks or raw data to
22 AstraZeneca?

23 A. No.

24 Q. Did you record when you received samples from AstraZeneca
09:23AM 25 in your laboratory notebooks?

1 A. I don't recall.

2 Q. What was your general practice with regard to recording
3 receipt of samples at the time you were postdoc in Dr. Kern's
4 lab?

09:24AM 5 A. I would unpack them and if they needed refrigeration, I
6 would put them in the refrigerator or the freezer as
7 appropriate.

8 Q. Did you have a separate practice as to what you would
9 record about the samples received?

09:24AM 10 A. No.

11 Q. Was it your understanding from the beginning of your
12 postdoc in Dr. Kern's lab that AstraZeneca was the source of
13 182,780 or was that something you learned later in time?

09:24AM 14 A. At the beginning, I had no idea there was such a thing as
15 182,780.

16 Q. How did you come to find out that? How did you come to
17 find out that AstraZeneca would supply 182,780 to the lab?

18 A. I'm not sure.

19 Q. What do you -- what is your best recollection?

09:24AM 20 A. We had meetings of all the researchers, the breast cancer
21 researchers and it may have come up at that, one of those
22 meetings.

23 Q. From the Lombardi side of things, not the AstraZeneca
24 side of things, but from the Lombardi side of things, was
09:25AM 25 procuring samples as simple as calling and asking for them, or

1 was there an internal protocol that had to be followed first?

2 A. I was not aware of an internal protocol.

3 Q. Do you know how long it took in between the time you
4 talked to Dr. Wakeling and the time that you received the
09:25AM 5 powdered ICI 182,780?

6 A. I think it was a matter of weeks.

7 Q. Do you recall how long it took from the time you talked
8 to Dr. Vose to then receive the preformulated ICI 182,780?

9 A. Probably about the same.

09:25AM 10 Q. And you personally do not recall filling out any forms or
11 signing anything in regard to samples, correct?

12 A. Correct.

13 Q. I want to make sure we're absolutely on the same page.

14 So before you started, at any time, did you send

09:25AM 15 AstraZeneca a statement of proposed investigation forms?

16 A. No.

17 Q. Do you know whether or not Dr. Kern had sent AstraZeneca
18 a statement of proposed investigation forms?

19 A. No.

09:25AM 20 Q. No, you do not know, or no, he did not?

21 A. No, I don't know.

22 Q. Did you fill out any other forms for AstraZeneca before
23 you started your work on McLeskey 1998?

24 A. No.

09:26AM 25 Q. Do you know whether anyone else in your group filled out

1 any other forms for AstraZeneca?

2 A. I don't know.

3 Q. Before starting the work on --

4 A. I don't know. I know nothing.

09:26AM 5 Q. Did you personally ever request any samples from
6 AstraZeneca in writing?

7 A. No.

8 Q. Okay. So you received powdered ICI 182,780 from Dr. Alan
9 Wakeling, correct?

09:26AM 10 A. Correct.

11 Q. Did Dr. Wakeling send the powdered samples directly to
12 you?

13 A. I don't recall. I got them, but I don't remember who
14 they were addressed to.

09:26AM 15 Q. You don't have a specific recollection of whether they
16 came directly to you or whether Dr. Kern gave them to you?

17 A. I opened the package, or I got the package. I don't know
18 if I got the package from a mailman or from Dr. Kern. I don't
19 know.

09:27AM 20 Q. Okay. But you opened the package?

21 A. Yeah.

22 Q. Do you recall approximately when that was when you opened
23 the package?

24 A. No.

09:27AM 25 Q. Was it in 1997?

1 A. Oh, no. It was way before that.

2 Q. Way before that? So 1996, 1995?

3 A. It was before 1993.

4 Q. Before 1993?

09:27AM 5 A. Yes.

6 Q. How was the powder sample packaged? Was it in a -- a
7 bottle or -- how did it arrive, do you recall?

8 A. I think it was just in a little jar.

09:27AM 9 Q. Would the receipt of that sample have been logged in the
10 lab?

11 A. No.

12 Q. Now, if I understand you correctly, Dr. Wakeling gave you
13 information on administration of the drug, correct?

14 A. Correct.

09:27AM 15 Q. Did Dr. Wakeling send you instructions on how to
16 formulate the 50-milligram per milliliter concentration of
17 ICI 182,780 and ethanol and peanut oil?

18 A. He didn't send them to me, no.

09:28AM 19 Q. Did he send you instructions regarding making the
20 formulation?

21 A. No.

22 Q. How did you know to do that?

23 A. He told me over the phone.

09:28AM 24 Q. Okay. So Dr. Wakeling told you how to administer it, and
25 he also told you how to make the formulation that's recorded

1 in McLeskey 1998 concerning ethanol and peanut oil?

2 A. Exactly.

3 Q. And you testified earlier, I think, that you were

4 actually the person that had actually dissolved the

09:28AM 5 ICI 182,780 in ethanol and then spiked it into the peanut oil?

6 A. Correct.

7 Q. Why did you use a concentration of 50-milligrams per

8 milliliter?

9 A. Because that's what Dr. Wakeling said to do.

09:28AM 10 Q. Dr. Wakeling did not discuss any sort of confidentiality

11 with you --

12 A. No.

13 Q. -- when -- when you spoke with him?

14 A. No --

09:28AM 15 Q. Sorry, it needs to be verbal.

16 A. Sorry, no.

17 Q. If you'll turn to Page 698 of Exhibit 5, do you see a

18 paragraph headed, the title Drugs, and then about seven lines

19 down, we see the lined sentence for the experiments depicted

09:29AM 20 in Figure 1, B and C, 50-milligram per milliliter

21 preformulated drug in a vehicle of 10 percent ethanol, 15

22 percent benzyl benzoate, 10 percent benzyl alcohol brought to

23 volume by castor oil was supplied by B.M. Vose, Zeneca

24 Pharmaceuticals.

09:29AM 25 Do you see that?

1 A. Yes.

2 Q. Is this the preformulated drug that we were just
3 discussing that you procured via telephone conference with
4 Dr. Vose?

09:29AM 5 A. Yes.

6 Q. Approximately when did you receive the preformulated
7 ICI 182,780 from Dr. Vose?

8 A. All I can tell you is it was before 1993.

9 Q. The preformed -- both -- you received both the powdered
09:29AM 10 ICI and the preformulated ICI before 1993. Is that what
11 you're saying?

12 A. Yes.

13 Q. How do you know that it was before 1993?

14 A. In 1993, I received a faculty appointment, and then I was
09:30AM 15 no longer a postdoc. And at that point, the animal
16 experiments were done.

17 Q. Were you the person that opened the package of the
18 preformulated ICI 182,780?

19 A. Yes.

09:30AM 20 Q. Do you recall how many preformulated samples were sent to
21 you?

22 A. No.

23 Q. Do you recall if those samples were in vials?

24 A. No.

09:30AM 25 Q. How were -- how were the preformulated samples packaged?

1 A. I don't recall.

2 Q. What documentation accompanied the preformulated
3 ICI 182,780?

4 A. I don't recall.

09:30AM 5 Q. Do you recall whether or not there was documentation
6 included with the preformulated ICI 182,780?

7 A. I don't recall.

8 Q. If you wanted to try to remember, who would you talk to?

9 A. Nobody. I mean, I -- there's nobody. I think it's lost
09:31AM 10 to posterity.

11 Q. So do I understand correctly that at the time you
12 received the preformulated ICI 182,780, you did not know what
13 excipients were present in the formulation -- in that
14 formulation?

09:31AM 15 A. Correct.

16 Q. Did you have an understanding that the preformulated
17 ICI 182,780 could not be used in humans?

18 A. Nothing we had in our lab could be used in humans.

19 Q. Were you given specific instructions from AstraZeneca
09:31AM 20 that it should not be used in humans?

21 A. I don't recall.

22 Q. Turning back to Page 698 in the drug section again, you
23 see the text that says, In a vehicle of 10 percent ethanol, 15
24 percent benzyl benzoate, 10 percent benzyl alcohol brought to
09:31AM 25 volume with castor oil.

1 Do you recall who actually wrote that text?

2 A. I did.

3 Q. Did you test or analyze the formulation in any way?

4 A. No.

09:31AM 5 Q. Were you told that the preformulated ICI 182,780 that you
6 received should not be administered intramuscularly?

7 A. I was told to administer it subcutaneously to my --

8 Q. When the person who answered Dr. Vose's phone gave you
9 the excipients present in the preformulated ICI 182,780, were
09:32AM 10 you sworn to secrecy?

11 A. No.

12 Q. Why did you want to include those details in McLeskey
13 1998?

14 A. That's how I was instructed to write a paper when I was
09:32AM 15 in my predoctoral, was to include such things.

16 Q. Have you searched your personal files for all documents
17 relating to either the powdered ICI 182,780 received or the
18 preformulated ICI 182,780 that you received?

19 A. I don't have any personal files about this.

09:32AM 20 Q. Did I understand you correctly that you do not recall
21 whether or not the person that answered Dr. Vose's phone told
22 you that the percentages were in weight to volume or
23 volume-to-volume?

24 A. I do not recall.

09:33AM 25 Q. Did you assume that the percentages were either in weight

1 to volume or volume-to-volume?

2 A. I don't think I ever thought about it one way or the
3 other.

09:33AM

4 Q. Have you thought about it since McLeskey 1998 was
5 published?

6 A. Yes, but I have no basis for knowing which way it was.

7 Q. So as you sit here today, you don't know whether or not
8 the percentages were in weight to volume or volume-to-volume?

9 A. I do not know.

09:33AM

10 Q. So what did you mean when you said "These studies
11 indicate that estrogen independence may be achieved"?

12 A. I meant that in our engineered model, we achieved
13 estrogen-independent tumor growth in mice through engineering
14 the cell to express in FGF.

09:33AM

15 Q. So in the context of your experiment, you wanted to use
16 the aromatase inhibitors and ICI 182,780 to shut down any
17 remaining estrogen that might have been present?

18 A. Yes.

09:34AM

19 Q. And you wanted to shut down any remaining estrogen so
20 that you could isolate or investigate the estrogen independent
21 cell growth; is that right?

22 A. Well, we wanted to demonstrate that cells as -- when
23 injected into mice to form tumors, were not affected by -- by
24 different ways of shutting down the estrogen pathway.

09:34AM

25 Q. So you used the aromatase inhibitors to shut down the

1 estrogen pathway so you could demonstrate that the hormonal
2 independent cancer cells were not affected and continued to
3 grow; is that right?

4 A. Continued to make tumors --

09:34AM 5 Q. Continued to make tumors.

6 A. -- and grow as tumors.

7 Q. And the same thing -- so you used the ICI 182,780 to act
8 as a pure antiestrogen, shut down any estrogen receptors so
9 that you could see if the estrogen-independent cells would

09:35AM 10 continue to grow?

11 A. Correct. As tumors --

12 Q. As tumors?

13 A. -- in -- in mice.

14 The reason I keep saying that is, of course, we can

09:35AM 15 grow cells in tissue culture, but I wasn't talking about that.

16 I'm talking about mice.

17 Q. Okay. So in order to study the hormonal-independent

18 cells, you wanted to deliberately target any remaining

19 estrogen production or any remaining estrogen receptors first;

09:35AM 20 is that right?

21 A. Correct.

22 Q. And the reason that you used the aromatase inhibitors in

23 the ICI 182,780 to shut down the remaining estrogen is because

24 they target the body's estrogen differently than tamoxifen

09:35AM 25 does; is that right?

1 A. Correct.

2 Q. Okay. At the time you were using the ICI 182,780,
3 because you understood that it would interrupt estrogen-based
4 pathways?

09:35AM 5 A. It would inactivate the estrogen receptor.

6 Q. Are you saying -- you keep directing me to the fact that
7 this was -- these experiments were done in mice.

8 Are you saying that this work has no applicability to
9 human subjects?

09:36AM 10 A. I don't know of any applicability to humans.

11 Q. The title says Cross-Resistant *in Vivo*.

12 What does "cross-resistant *in vivo*" mean?

13 A. "Cross-resistant" means that the cells formed big tumors
14 even in the face of the ICI 182,780, or the aromatase
09:36AM 15 inhibitors. And "*in vivo*," refers to the fact that we used
16 mice or an animal to test it. *In vitro* would be, like, cell
17 culture.

18 Q. So what does "cross-resistant" mean here? Resistance to
19 several different types of drugs?

09:36AM 20 A. It means also resistant.

21 Q. So it's basically saying resistant to several types of
22 drugs?

23 A. Yes.

24 Q. So this -- okay.

09:37AM 25 Now McLeskey 1998 was published in the Journal of

1 Clinical Cancer Research, correct?

2 A. Correct.

3 Q. And you were the person that determined whether or not
4 you wanted to cite references in McLeskey 1998?

09:37AM 5 A. Me and Dr. Kern.

6 Q. Did you keep laboratory notebooks from your lab when --
7 when you -- you were at Georgetown?

8 A. Of course.

9 Q. What happened to those lab notebooks?

09:37AM 10 A. I brought them to Maryland with me and then when I was
11 getting ready to retire, I threw them away.

12 Q. With the rest of the documents?

13 A. Mm-hmm.

09:37AM 14 Q. Going back to the preformulated samples that you received
15 from Dr. Vose, if I understand you -- understood you
16 correctly, you thought that you had received the samples
17 before 1993.

18 A. Yes.

09:37AM 19 Q. Is it possible that you received them in the first
20 quarter of 1993?

21 A. I don't think so, but I don't know really.

22 Q. You don't know for sure one way or the other?

23 A. Well, we had finished the animal experiments by the time
24 I got my faculty appointment.

09:38AM 25 Q. When exactly did you get your faculty appointment?

1 A. I believe it was July 1st, 1993.

2 Q. Okay. So you knew -- you think you received the samples
3 before July 1, 1993?

09:38AM 4 A. Well, you know, the experiments with the tumors were
5 several months ago, several months long. So it had to have
6 been quite a bit before July.

7 Q. Okay. So you do or do not think it's possible that you
8 received the samples in early 1993?

9 A. I don't know.

09:38AM 10 Q. Okay. When you were talking to the unnamed person that
11 answered Dr. Vose's phone, did you ask who you were talking
12 to?

13 A. I don't recall.

14 Q. But you do recall that you talked to Dr. Wakeling twice?

09:38AM 15 A. Yes.

16 Q. And you do recall that you were the one that called him
17 both times?

18 A. Yes.

09:38AM 19 Q. And you do recall that he gave you instructions on how to
20 make the peanut oil formulation?

21 A. Yes.

22 Q. And you do recall that he gave you instructions on
23 administration of the formulation?

24 A. Correct.

09:39AM 25 Q. And he's the person that told you to talk to Dr. Vose

1 about the preformulation -- preformulated ICI 182,780?

2 A. Yes.

3 Q. And you remember calling Dr. Vose regarding the
4 preformulated drug, correct?

09:39AM 5 A. Yes.

6 Q. Okay. But you don't remember whether there was a label
7 on the preformulated drug vials that you received, correct?

8 A. I'm sure there was, but I don't remember one.

9 Q. You don't recall whether there was any paperwork that you
09:39AM 10 received with the samples?

11 A. I don't recall.

12 Q. You can't remember the name of the person that told you
13 the identity of the formulation?

14 A. No.

09:39AM 15 Q. But do you remember that the person did not tell you to
16 keep the formulation secret, correct?

17 A. Yes, I remember that.

18 Q. You don't remember anything else in particular that he
19 said?

09:39AM 20 A. No.

21 Q. After you finished the experiments that are reflected in
22 McLeskey 1998, was there any preformulated drug left over?

23 A. I don't remember.

24 Q. If there had been drug left over, what would you have
09:40AM 25 done with it?

1 A. Discard it.

2 Q. How?

3 A. Down the sink probably.

4 Q. You don't recall any specific instructions from

09:40AM 5 AstraZeneca to return any unused material?

6 A. No.

7 Q. When you talked to Dr. Wakeling about the ethanol peanut
8 oil formulation, did he say anything other than tell you the
9 order of the steps?

09:40AM 10 A. Not that I recall.

11 Q. Did he tell you anything about the development of the
12 formulation within AstraZeneca?

13 A. No.

14 Q. I recall asking you about AstraZeneca, and I recall

09:40AM 15 asking you about O'Melveny & Myers. I just want to make sure
16 we're clear.

17 Did anyone at any time ever tell you to preserve your
18 documents that related to McLeskey 1998?

19 A. No.

09:40AM 20 Q. Did I understand you correctly that you were not privy to
21 any sort of confidentiality agreement between AstraZeneca at
22 Lombardi, correct?

23 A. Correct.

24 Q. Dr. Wakeling is the person that informed you of the
09:41AM 25 existence of the preformulated drug?

1 A. Correct.

2 Q. Dr. McLeskey, may I direct your attention to Exhibit
3 No. 9, that is the declaration of Sandra McLeskey, Ph.D.?

4 A. Yes.

09:41AM 5 Q. And feel free, of course, to review the declaration.

6 My question is, is there anything sitting here today
7 that you wish to change or correct in this declaration?

8 A. No.

9 (Reading stopped.)

09:41AM 10 MS. PIROZZOLO-MELLOWES: The questioning now
11 continues by Ms. Pensabene and I'll play the part of
12 Ms. Pensabene.

13 THE COURT: Okay. Well, as long as -- as long as the
14 record is clear who is doing the questioning.

09:41AM 15 So maybe Mr. Rizzi you should do it, so the court
16 reporter knows that when you're speaking, it's Ms. Pensabene.

17 MR. RIZZI: Of course, Your Honor.

18 THE COURT: Page 210.

19 (Deposition read as follows:)

09:42AM 20 Q. Dr. McLeskey, at the time you were doing that research
21 that led to the paper of Exhibit 5, I think it is, was that
22 early in your career as a -- as a researcher?

23 A. Yes.

09:42AM 24 Q. Okay. And at that time, were you experienced with
25 dealing with pharmaceutical companies?

1 A. No.

2 Q. Was Dr. Kern the head of the lab you worked in at
3 Lombardi Cancer Center at Georgetown?

4 A. Yes.

09:42AM 5 Q. And was he your boss?

6 A. Yes.

7 Q. And what was Dr. -- and was Dr. Lippman the head of the
8 Cancer Center?

9 A. Yes.

09:42AM 10 Q. And was Dr. Lippman Dr. Kern's boss?

11 A. Yes.

12 Q. Back at the time that you were doing this research that
13 we've been talking about, were you familiar with the
14 statements of proposed investigations or forms or material
09:42AM 15 transfer agreements?

16 A. No.

17 Q. Okay. Who in the lab at that time would have signed a
18 statement of material -- of proposed investigation or a
19 material transfer agreement with regard to samples with

09:43AM 20 AstraZeneca?

21 A. It would either have been Dr. Kern or Dr. Lippman.

22 Q. Okay. You would not have done so?

23 A. No.

24 Q. Okay. And at the time, did you -- let me back up.

09:43AM 25 Did you have one way or another -- do you know one way

1 or another whether there was a statement of proposed
2 investigation or material transfer agreement with AstraZeneca?

3 A. I did not know.

4 Q. At the time, did you ever consider whether there was a --

09:43AM

5 some kind of an agreement or a statement of proposed
6 investigation or material transfer agreement with AstraZeneca
7 regarding samples?

8 A. I did not.

9 Q. Why not?

09:43AM

10 A. It just didn't occur to me.

11 Q. Okay. When you first called for samples, did you tell

12 Dr. Wakeling that you were calling from Dr. Lippman or

13 Dr. Kern's group?

14 A. I -- yes -- well, I don't know what I said, but I'm sure

09:44AM

15 I said something like that.

16 Q. When -- when you first called for samples, did you

17 understand whether Dr. Lippman or Dr. Kern had a preexisting

18 relationship with AstraZeneca?

19 A. I knew that Dr. Lippman knew.

09:44AM

20 Q. Now, once you got the preformulated ICI 182,780, was it

21 -- did you understand that its use was restricted to animals?

22 A. That's all I did was animals.

23 Q. Could you have used the preformulated ICI 182,780 in

24 people?

09:44AM

25 A. No.

1 Q. Could you have sent the preformulated ICI 182,780 to
2 anyone in the public to use?

3 A. No.

09:44AM 4 Q. Was it your understanding that the use of the
5 preformulated sample was restricted to use in the Georgetown
6 laboratory in animals?

7 A. I don't know how to answer that. That was -- that was
8 what I was going to use the drug for.

09:44AM 9 Q. Well, did you think that -- that you could give it to
10 anyone else to use in research in people?

11 A. No.

12 Q. Was the animal work in your laboratory publicly
13 available?

14 A. Not until it was published.

09:45AM 15 Q. Could members of the public have access to your
16 laboratory notebooks before they were -- before the paper was
17 published?

18 A. No.

09:45AM 19 Q. Did you send the manuscripts or the draft of Exhibit 5 to
20 AstraZeneca anyone at AstraZeneca to review?

21 A. No.

22 Q. Was sending the manuscript or draft of Exhibit 5 to
23 AstraZeneca to review have been your responsibility at the
24 time?

09:45AM 25 A. No.

1 Q. Okay. When you called to ask for the formulation did you
2 tell anyone at AstraZeneca that you planned to publish the
3 formulation?

4 A. I said I was preparing a manuscript.

09:45AM 5 Q. Did you ask anyone at AstraZeneca permission to publish
6 the formulation?

7 A. No.

8 Q. Okay. I just want to ask a couple of questions about the
9 laboratory notebooks and materials that I know you said you
09:45AM 10 destroyed when you retired. Did AstraZeneca own those
11 laboratory notebooks that you described?

12 A. No.

13 Q. Did AstraZeneca have control over those laboratory
14 notebooks?

09:46AM 15 A. No.

16 Q. Could anyone at AstraZeneca have told you what to do with
17 your laboratory notebooks?

18 A. No.

19 Q. When you destroyed the -- threw away the laboratory
09:46AM 20 notebooks, were -- were you aware that the litigation with
21 Teva was over?

22 A. Yes.

23 Q. At the time you threw away the laboratory notebooks, did
24 you know about this litigation?

09:46AM 25 A. No.

1 Q. Did you learn about the litigation after you threw away
2 the notebooks?

3 A. Yes.

09:46AM 4 Q. Did you view -- with regard to the two different
5 formulations of ICI 182,780 in your paper, did you view the
6 ICI 182,780 in peanut oil and the preformulated ICI 182,780 as
7 interchangeable?

8 A. Yes.

09:46AM 9 Q. In your work did you do any pharmacokinetic analysis of
10 the drugs that you used in the paper at Exhibit 5?

11 A. No.

12 Q. Did you do any blood level analysis of the drugs you used
13 in the work that you did in the paper at Exhibit 5?

14 A. No.

09:47AM 15 Q. In your work at Exhibit 5 did the ICI 182,780 have any
16 effect on tumor growth or the metastasis of tumors?

17 A. No.

18 MR. RIZZI: That's the end of Ms. Pensabene
19 questioning.

09:47AM 20 THE COURT: Thank you.

21 (The examination is continued by Ms. Waldron.)

22 Q. But your testimony is that you believe that AstraZeneca
23 has paid you less than \$10,000 to date; is that correct?

24 A. Correct.

09:47AM 25 Q. Yeah -- let's -- actually, that's a really good point.

1 Let me rephrase my question. Do you currently understand that
2 in the late nineties at the time you were doing your postdoc,
3 Dr. Ellis was doing clinical trials related to fulvestrant?

4 A. I did.

09:47AM 5 Q. When did Dr. Ellis come to Georgetown?

6 A. I'm not sure, but it was in the late nineties I think.

7 Q. Did the person who gave you the information about the
8 formulation understand that you were asking in connection with
9 publishing McLeskey 1998?

09:48AM 10 A. I told him that I was preparing the manuscript.

11 Q. I believe you testified earlier that you believed that
12 your current consultancy with O'Melveny & Myers began in June
13 of 2014; is that correct?

14 A. Yes.

09:48AM 15 Q. Do you know the date that you signed the agreement with
16 O'Melveny & Myers?

17 A. No.

18 Q. Do you know if it was late or early June?

19 A. It was not early June.

09:48AM 20 Q. Did the consultancy you had with regard to the Teva
21 litigation ever formally expire?

22 A. I don't know.

23 Q. Are you aware of being formally released from that
24 agreement?

09:48AM 25 A. No.

1 Q. Do you have any reason to believe that it didn't
2 continue -- continue on?

3 A. I'm under the impression that it did not continue.

4 MS. PIROZZOLO-MELLOWES: That concludes the reading.

09:48AM 5 I'd like to offer into evidence the exhibits that
6 were referenced --

7 THE COURT: Yes.

8 MS. PIROZZOLO-MELLOWES: -- in the transcript. They
9 are DTX-545, DTX- 546, DTX-547, DTX- 548, DTX- 22, DTX- 552.

09:49AM 10 THE COURT: Mr. Prugo, any objections?

11 MR. PRUGO: I'm not sure what all the exhibits are,
12 your Honor, so.....

13 THE COURT: They are in the binder. So two of them
14 are the subpoenas, I don't know that they have any evidentiary
09:49AM 15 value.

16 MR. PRUGO: No, I agree.

17 THE COURT: The other are her declarations and
18 responses.

19 MR. PRUGO: No problem there, your Honor, that can go
09:49AM 20 into evidence. That's DTX-0552 to -- the McLeskey
21 declaration, sure.

22 THE COURT: What about DTX-547?

23 MR. PRUGO: That seems to be another subpoena, your
24 Honor. There is no evidentiary value of the subpoena.

09:50AM 25 THE COURT: Those are the responses and objections.

1 MR. PRUGO: Well, if the subpoena doesn't go in -- I
2 guess we would maintain the objections. But, frankly, if we
3 haven't objected to the testimony, then I don't really see the
4 relevance of the objection to the subpoena.

09:50AM 5 THE COURT: DTX-547 is not a subpoena.

6 MR. PRUGO: My apologies, your Honor. No problem
7 with that exhibit.

8 THE COURT: Okay. So 547 and 552 are in evidence,
9 545, 546 are not in evidence.

09:50AM 10 And 22 is in, is it not?

11 MS. PIROZZOLO-MELLOWES: I believe it is.

12 THE COURT: DTX-22 is in, is it not?

13 MR. PRUGO: Yeah, that's already in, your Honor. I
14 believe that's already in.

09:50AM 15 MS. PIROZZOLO-MELLOWES: And DTX-548, additional
16 responses.

17 THE COURT: Yes. Any objection?

18 MR. PRUGO: Oh, of course not, no.

19 THE COURT: Okay in evidence.

09:51AM 20 (DEFENDANT EXHIBITS DTX-545, 546 AND 548 WERE RECEIVED IN
21 EVIDENCE)

22 MS. PIROZZOLO-MELLOWES: That conclude McLeskey.

23 We would like to read an additional transcript of Dr.
24 Francis Kern.

09:51AM 25 THE COURT: Okay. And are you playing the role Dr.

1 Kern?

2 THE COURT: Okay, when everybody is ready.

3 (THE DEPOSITION OF DR. FRANCIS G. KERN WAS READ BY MS.

4 PIROZZOLO-MELLOWES INTO THE RECORD)

09:52AM 5 MS. PIROZZOLO-MELLOWES:

6 Q. Could you please state your full name for the record?

7 A. Francis Gerard Kern.

8 Q. Where do live?

9 A. I live in Highland Park, New Jersey.

09:52AM 10 Q. Do you understand that you are under oath today?

11 A. Yes, I do.

12 Q. Is there any reason that you cannot provide full and
13 honest testimony today?

14 A. No, there is not.

09:52AM 15 Q. Would it be okay with you if I call Exhibit 3 "McLeskey
16 1998?"

17 A. Fine.

18 Q. Did Dr. Gellert ask you anything about the samples that
19 your lab received from AstraZeneca?

09:53AM 20 A. I don't know if it was Lisa or Dr. Gellert who answered
21 those -- asked those particular questions. I don't know the
22 direct question that -- that addressed what you have just
23 asked, but I think it became apparent that, yes, it was all
24 about us receiving some samples to accomplish this work.

09:53AM 25 Q. What did you tell Dr. Gellert about your lab's receipt of

1 the samples from AstraZeneca?

2 A. That it was 20 years ago, I didn't remember too much
3 about it.

09:53AM

4 Q. Just to make sure I understand, did I understand you
5 correctly that you only talked to Dr. Gellert one time on the
6 phone?

7 A. Correct.

8 Q. Did you ever meet with Dr. Gellert in person?

9 A. No.

09:53AM

10 Q. Can you please tell me what your duties are, what's that
11 mean?

12 A. I am the head of the oncology scouting. We do search and
13 evaluation of any licensing opportunities, partnering
14 opportunities, the academic medical centers to acquisitions of
15 company, biotech companies. So it spans that range, scouting
16 making recommendations as to who should be a partner or who
17 should be -- you know, who we should license from, who we
18 should acquire.

09:54AM

19 Q. Going back now to Georgetown, approximately how long were
20 you at Georgetown?

09:54AM

21 A. I left in '97.

22 Q. Have you ever done any formulation work?

23 A. Not personally, no.

24 Q. Do you consider yourself a formulator?

09:54AM

25 A. No.

1 Q. I assume this means you have not formulated any
2 parenteral drugs?

3 A. Personally myself? No.

09:54AM

4 Q. Did you have access to Dr. McLeskey's laboratory
5 notebooks and data?

6 A. Access? I guess I could ask to see them if I wanted to,
7 so in that sense I had access, yeah.

8 Q. Just to be clear, you never had copies of Dr. McLeskey's
9 notebooks or data underlying the McLeskey 1998?

09:55AM

10 A. No.

11 Q. When the lab received documentation, say with samples,
12 how would those documents have been kept in your lab?

13 A. You know, it's hard to say back in 1993, or -- I guess it
14 was just put in a file and put in a file cabinet.

09:55AM

15 Q. Do you have any specification recollection of your
16 procedures?

17 A. No.

18 Q. Who was in charge would you say, was in charge of the day
19 today activities concerning the research that led to McLeskey

09:55AM

20 1998?

21 A. I was.

22 Q. Would you say you directed the research?

23 A. Yes.

24 Q. What were your duties as they pertained to the research?

09:55AM

25 What does it mean to direct the research?

1 A. You know, you'd meet maybe not daily but at least weekly
2 with Dr. McLeskey, go over the data that had been generated
3 the last week, make suggestions as to what new experiments
4 should be performed.

09:56AM 5 Q. Who came up with the ideas for the research that led to
6 McLeskey 1998?

7 A. Again, it's a long time ago, so generally I came up with
8 the ideas for the lab, for what was going on in that lab.

9 Q. How did you decide what drugs you would study or what
09:56AM 10 drugs you would include in the research?

11 A. Relating to this paper or --

12 Q. Yeah. Let me take a step back.

13 How did you decide which drugs you would study in
14 relation to McLeskey 1998?

09:56AM 15 A. We had earlier found that transfection of this particular
16 growth factor, okay, into these breast cancer cells that
17 originally required estrogen for their growth made them
18 resistant to a drug called tamoxifen. Tamoxifen also has what
19 are called estrogenic actions. Even though it functions
09:56AM 20 primarily as antiestrogen, it may -- it has some agonistic
21 effects to the estrogen receptors.

22 THE COURT: Agonistic.

23 A. Agonistic effects to the estrogen receptors. Others had
24 shown that growth factors similarly could simulate the type of
09:57AM 25 agonistic effect on a estrogen receptor. We wanted to probe

1 into the question of whether the mechanism by which this
2 particular growth factor caused this resistance to this drug
3 tamoxifen was through this accentuating the agonistic effects
4 of tamoxifen. So we approached that question by using this
09:57AM 5 pure -- what's called pure antiestrogen, the ICI 182,780,
6 because that causes degradation of the estrogen receptor. So
7 if you could show that the cells could still grow in the
8 absence of estrogen when they had been treated with this drug,
9 that meant that the estrogen receptor was gone, okay, and
09:57AM 10 consequently they had bypassed the need for the estrogen
11 receptor signaling in this particular breast cancer cell.

12 Follow?

13 Q. Generally speaking, I think.

14 A. Okay.

09:58AM 15 Q. So, to hit the highlights, do I understand that you knew
16 that tamoxifen had partial agonist activity?

17 A. Right.

18 Q. But ICI 182,780 was a pure antiestrogen?

19 A. Right.

09:58AM 20 Q. And you knew that ICI 182,780 would cause degradation of
21 the receptor?

22 A. Right.

23 Q. When did you learn about the resistance of ICI 182,780?

24 A. Hard to tell. You know, early nineties, probably.

09:58AM 25 Q. To the best of your recollection, how did you find out

1 about ICI 182,780?

2 A. I, you know. I knew -- there were a lot of experiments
3 in the literature on precursor to this 162 something, 464,
4 perhaps. Was it 464?

09:58AM 5 Q. That sound right. I'm not sure either.

6 A. So, you know, there was a lot of publications on that. I
7 don't know how we became aware that that had been replaced,
8 you know, with 182,780. But when we started this work, we
9 wanted to get as close as we could to a drug that would

09:59AM 10 eventually make, or more likely to make its way to the clinic.

11 Q. When did you start this work? When was the origin?

12 A. You know, my guess it was probably in 1993. And we
13 published a paper in 1993 showing that tamoxifen resistance in
14 cancer research with FGF 4 transfected breast cancer cells, so
09:59AM 15 it was a continuation of that work. So my guess is 1993,
16 around there.

17 Q. How did you first procure ICI 182,780 from AstraZeneca?

18 A. Yeah. I'm not clear on that.

09:59AM 19 Q. Was there already ICI 182,780 in the lab when you
20 started?

21 A. I don't think so. You know, others at the Lombardi
22 Cancer Center may have been using it for other experiments. I
23 would assume, you know, that we would have had to request it,
24 the compound, for our particular experiments, you know. But
10:00AM 25 like I said, it was a long time ago. I noticed that Bob Dixon

1 is an author on this paper. You know, he had much better
2 relations with Alan Wakeling and with the two people who gave
3 us the aromatase inhibitors, you know. It could have been
4 either I requested it or he requested it, you know, but I'm
10:00AM 5 pretty sure that he had to have made that particular request
6 for these particular experiments.

7 When I moved to Southern Research I did make a
8 separate request to Zeneca, I believe, at the time, you know,
9 and I had to fill out their forms and describe the experiments
10:00AM 10 that I was going to perform at Southern Research. So that's
11 what's making me think we had to do something similar when we
12 were at the Lombardi Cancer Center.

13 Q. During the telephone call in late August with Ms.
14 Pensabene, AstraZenica's representative, Arthur Mann and
10:01AM 15 yourself, were you asked about whether you had any documents
16 pertaining to McLeskey 1998?

17 A. I believe so.

18 Q. What did you say?

19 A. I said I didn't think so.

10:01AM 20 Q. Did you look for documents at that time?

21 A. At that time?

22 Q. Yes.

23 A. No. I mean, I looked on a few thumb drives that I had
24 around from -- but they were actually from another -- another
10:01AM 25 job, you know. Nothing was on those.

1 Q. Were you specifically asked to look for documents at that
2 teleconference?

3 A. I don't recall.

4 Q. Have you ever before read the subpoena that's marked as
10:01AM 5 Exhibit 2? Have you ever received a request from AstraZeneca
6 or any of AstraZeneca's representatives requesting documents
7 related to McLeskey 1998?

8 A. No.

9 Q. Have you ever been told by AstraZeneca or any of its
10:02AM 10 representatives not to destroy any documents you had related
11 to McLeskey 1998?

12 A. No not to destroy? I was never told that, no.

13 Q. Okay. So you only talked to Dr. Gellert at one time?

14 A. Right.

10:02AM 15 Q. Dr. Gellert asked you about your recollection of
16 receiving samples from AstraZeneca?

17 A. I don't know if it was Dr. Gellert or Lisa.

18 Q. What did you say on this telephone conference regarding
19 your recollection about receiving samples from AstraZeneca?

10:02AM 20 A. That we must have received them. I wasn't sure. I think
21 I said at the time I wasn't sure who was responsible at that
22 time.

23 Q. Did you talk about whether or not you had a
24 confidentiality agreement with AstraZeneca?

10:02AM 25 A. I believe we did.

1 Q. Did you have a confidentiality agreement with AstraZeneca
2 in the early nineties?

3 A. Well, confidentiality or material transfer?

10:03AM

4 Q. Well, let's start with confidentiality. Did you ever at
5 anytime enter into a confidentiality agreement with
6 AstraZeneca?

7 A. I don't recall. I don't know.

8 Q. Well --

10:03AM

9 A. Material transfer, or whatever, you know, they -- they
10 tend to call it. I don't know.

11 Q. Okay. Did you ever sign anything titled "confidentiality
12 agreement?"

13 A. I don't recall doing so.

10:03AM

14 Q. Do you have any reason to believe -- you have no reason
15 to believe that you did sign a document entitled
16 "confidentiality agreement?"

17 A. I have no reason to believe that I did not either. So,
18 yeah, I -- I just don't recall.

10:03AM

19 Q. You currently do not possess any copies of any
20 confidentiality agreements that you signed with AstraZeneca,
21 correct?

22 A. I do not.

10:03AM

23 Q. Do you have any documentation indicating that you signed
24 anything called a "confidentiality agreement" with
25 AstraZeneca?

1 A. I do not.

2 Q. Now, you've referred to a material transfer form. Did I
3 understand you correctly?

10:04AM

4 A. Usually It's called a material transfer agreement, an
5 MTA.

6 Q. Okay. In your words what is an MTA? What are you
7 referring to?

10:04AM

8 A. You are asking a company for, you know, a portion of a
9 compound that is generally a proprietary compound not publicly
10 available, that you are asking them for a sample to allow you
11 to perform some laboratory experiments.

12 Q. Can you say with certainty that you signed a material
13 transfer agreement with AstraZeneca in relation to McLeskey
14 1998?

10:04AM

15 A. With certainty? No, I can't say with certainty.

16 Q. You don't currently possess any copies of material
17 transfer agreements that you signed with AstraZeneca in
18 relation to McLeskey 1998, correct?

19 A. I do not.

10:04AM

20 Q. I will confess I barely remember where we just left off.
21 I believe you said that you did not have your own personal lab
22 notebooks or data relating to McLeskey 1998; is that right?

23 A. Um-hum.

10:05AM

24 Q. And did not copy for yourself Dr. McLeskey's laboratory
25 notebooks or data; is that correct?

1 A. That's correct.

2 Q. So, your edits and contributions continued after you left
3 Lombardi Center; is that correct?

4 A. For this particular paper? Yes.

10:05AM 5 Q. So, McLeskey 1998?

6 A. Right.

7 Q. Am I correct then that you would have had some sort of
8 documentation related to McLeskey 1998 with you at SM?

9 A. It would have been at Southern Research.

10:05AM 10 Q. At Southern Research with you?

11 A. Maybe an electronic version of the file, yeah.

12 Q. While you were at Lombardi Center did it have a
13 specification document retention policy?

14 A. I don't know.

10:05AM 15 Q. You were not made aware of a specific document retention
16 policy while you were at Lombardi?

17 A. I don't recall whether I was or not.

18 Q. As you sit here today, you don't recall a particular
19 document retention policy at Lombardi?

10:05AM 20 A. I don't recall one, no.

21 Q. Do you recall whether or not there were any rules or
22 restrictions on documents that you could take outside of
23 Lombardi, say to your new job?

24 A. I don't recall there being any, no.

10:06AM 25 Q. Did I understand you correctly that you directed the

1 research that led to McLeskey 1998, correct?

2 A. Correct.

3 Q. And I believe you said that you managed the day-to-day
4 activities; Is that right?

10:06AM 5 A. To the extent possible, yeah, I guess, right.

6 Q. Were you responsible for designing the studies described
7 in McLeskey 1998?

8 A. Probably, yes.

9 Q. Were you the primary individual responsible for actually
10:06AM 10 conducting the research described in McLeskey 1998?

11 A. No.

12 Q. Who was?

13 A. McLeskey -- well, I mean the other authors had
14 contributions but the primary was McLeskey.

10:06AM 15 Q. What was Dr. Sandra McLeskey's role in procuring samples
16 from AstraZeneca relating to McLeskey 19898?

17 A. I'm not sure she had a role.

18 Q. Do you have any personal knowledge as to if Dr. Sandra
19 McLeskey procured samples from AstraZeneca related to McLeskey
10:07AM 20 1998?

21 A. Personal knowledge? I do not. I mean, you said that I
22 had told her -- or may have told her to go talk to Vose and, I
23 don't know, whoever, Vose and Wakeling, and it's possible that
24 I may have done that, right.

10:07AM 25 Q. As you sit here today do you have a recollection of

1 instructing Dr. McLeskey to do that?

2 A. I do not have a specific recollection, but it was
3 25 years ago.

10:07AM

4 Q. Do you think it is possible that you told Dr. McLeskey to
5 call Drs. Wakeling and/or Vose?

6 A. It's possible, yeah.

7 Q. At the time that McLeskey 1998 was being researched and
8 drafted, could you describe the general process within your
9 group for submitting documents for publication to a journal?

10:07AM

10 A. General process? It depends on who the first author was
11 and their capabilities with English. So Sandra was certainly
12 very capable with English, so she would have written the first
13 manuscript. She would have -- you know, the first draft. I
14 would have read the first draft and would have made editorial
15 changes, content changes, suggestions. Generally it was
16 between the two, first author and a senior author, that would
17 discuss this and then eventually would get to the rest the
18 authors.

10:08AM

19 Q. In this case those two people would have been Dr.
20 McLeskey and yourself?

10:08AM

21 A. Right. You know, it's also possible Dr. El-Ashry, who
22 has a very good command of English, would have written the
23 sections of the receptor binding assays.

10:08AM

24 Q. Did you personally submit a draft of McLeskey 1998 to
25 AstraZeneca before it was publish?

1 A. I don't have a recollection of doing so.

2 Q. Do you believe at the time -- did you believe that you
3 needed to submit drafts of McLeskey 1998 to AstraZeneca before
4 it was published?

10:09AM

5 A. Yeah. Now that I think about it, it's usually -- it's
6 typically with MTA that they will want to see the data that's
7 been generated with the compound before publication, so -- but
8 it's quite possible, given the lapse of time that occurred
9 between the time of the manuscript, the material was acquired,

10:09AM

10 who was responsible for acquiring that material and the time
11 when the manuscript was submitted that it just slipped my mind
12 that that was an obligation.

13 Q. So you have no recollection of telling Dr. McLeskey that
14 she should submit a draft to AstraZeneca; is that right?

10:09AM

15 A. I have no recollection of doing so.

16 Q. Did anyone from AstraZeneca ever contact you about
17 McLeskey 1998 after it was published?

18 A. No. Well, beyond the phone call.

19 Q. In August of 2015?

10:09AM

20 A. Right.

21 Q. Has anyone from AstraZeneca ever told you that McLeskey
22 1998 violated any confidentiality provisions with AstraZeneca?

23 A. No.

24 Q. Were there ever any penalties or reprimands imposed upon
25 you by AstraZeneca for publishing McLeskey 1998?

10:10AM

1 A. No. For publishing?

2 Q. For publishing McLeskey 1998?

3 A. No.

10:10AM

4 Q. To your knowledge were there ever any penalties or
5 reprimands imposed upon the Georgetown Lombardi Cancer Center
6 as a result of publishing McLeskey 1998?

7 A. Not to my knowledge.

8 Q. You said that you edited McLeskey 1998 before it was
9 published, correct?

10:10AM

10 A. Right.

11 Q. At that time did you have any qualms about publishing the
12 formulation data in McLeskey 1998?

13 A. I did not.

14 Q. Did anyone from AstraZeneca?

10:10AM

15 THE COURT: Mr. Rizzi?

16 MS. PENSABENE: I'm sorry. I think you just
17 interrupted the witness.

18 MS. PIROZZOLO-MELLOWES: I'm sorry.

10:10AM

19 A. Right. I mean at the time I thought it was probably just
20 something that was a formulation for animal studies.

21 Q. Did anyone from AstraZeneca ever specifically tell you to
22 keep the formulation secret?

23 A. No.

10:11AM

24 Q. Am I correct that you do not have any documentation
25 showing that you entered into a confidentiality agreement with

1 AstraZeneca?

2 A. You are correct.

3 Q. Am I correct that you do not have any documentation
4 showing that you signed a material transfer agreement for
10:11AM 5 AstraZeneca?

6 A. You are correct.

7 Q. Am I correct that you have no paperwork pertaining to the
8 samples you received from AstraZeneca; is that correct?

9 A. You are correct.

10:11AM 10 Q. But again, you are not the person that actually procured
11 of the samples that led to McLeskey 1998; is that correct
12 will?

13 A. I don't know if I was or was not, right.

14 Q. Do you have any reason to doubt that it was Dr. McLeskey
10:11AM 15 that procured the samples from AstraZeneca?

16 A. I don't think she procured the samples, it was either
17 myself or Dr. Dixon, right.

18 Q. So, at the time that the research leading to McLeskey
19 1998 was being done, you had no knowledge of Dr. McLeskey
10:12AM 20 calling Alan Wakeling; is that correct?

21 A. I don't recall. You know, I would probably had -- had to
22 have been -- it would have either had to have been myself or
23 Dr. Dixon who signed the forms, right? It could have been we
24 told her, call up Dr. Wakeling and see, you know, if he'll
10:12AM 25 send this to us.

1 Q. So you are saying if there was a form signed it would not
2 have been Dr. McLeskey?

3 A. Right.

10:12AM

4 Q. But do you have any reason to doubt that Dr. McLeskey did
5 call Dr. Wakeling to procure samples of ICI 182,780?

6 A. I have no personal knowledge that she did, but she could
7 have, yes.

8 Q. Do you have any reason to doubt that Dr. McLeskey called
9 Dr. Vose for preformulated ICI 182,780?

10:12AM

10 A. Again, I have no personal knowledge that she did, but
11 it's quite possible that she did.

12 Q. Did you have any particular restrictions on Dr. McLeskey
13 as far as her communications with AstraZeneca?

14 A. No.

10:13AM

15 Q. Did you give Dr. McLeskey any specific instructions
16 regarding the confidentiality or secrecy of the samples
17 received from AstraZeneca?

18 A. Confidentiality? I'm not sure what you mean by that.
19 Samples aren't confidential.

10:13AM

20 Q. What do you mean?

21 A. Well, I mean information is confidential but samples
22 themselves, so I -- I don't quite understand your question.

23 Q. Did you ever give Dr. McLeskey any specific instructions
24 about keeping her work at Lombardi Center confidential?

10:13AM

25 A. I don't know if I gave her specific instructions, it's,

1 you know, sort of implied that you don't publicly announce
2 your work until it's published or ready for presentation.

10:13AM

3 Q. Did Dr. McLeskey -- let me take a step back. At the time
4 you were doing the research leading to McLeskey 1998, did you
5 know the components of the preformulated ICI 182,780 received
6 from the lab, received from AstraZeneca?

7 A. No, I don't think so. No. No reason for me to know.

8 Q. Can you turn to Exhibit 3, which is a copy of McLeskey
9 1998.

10:14AM

10 A. The paper?

11 Q. Yeah. Okay. So in the journal page 698 --

12 A. Right.

13 Q. -- which is marked SAN.FUL 641, the second column there's
14 a paragraph headed "drugs."

10:14AM

15 A. Right.

16 Q. Do you see that?

17 A. Yeah.

18 Q. Seven lines down we see the sentence: For the
19 experiments depicted in Figure 1 B and C 50 mg per mL

10:14AM

20 preformulated drug in a vehicle of 10 percent ethanol,
21 15 percent benzyl benzoate, 10 percent benzyl alcohol brought
22 to volume with castor oil was supplied my B. M. Vose,
23 AstraZeneca Pharmaceuticals?

24 A. Right.

10:14AM

25 Q. Do you see that?

1 A. Right.

2 Q. Did I read that correctly?

3 A. Yes, you did.

4 Q. Do you know where the information that the preformulated
10:15AM 5 drug, 10 percent ethanol, 15 percent benzyl benzoate and
6 10 percent benzyl alcohol brought to volume with castor oil --

7 A. I have no personal knowledge of where that information
8 came from.

9 You know, at the time I probably assumed it was
10:15AM 10 information that was provided when it was provided to us.
11 That would have been my logical assumption when reading this.

12 Q. So, am I correct that you did not tell Dr. McLeskey not
13 to publish the details of the formulas, correct?

14 A. Correct.

10:15AM 15 Q. At some point we mention the phrase "the research
16 beginning." To the best of your recollection, when did you
17 begin the research that led to McLeskey 1998?

18 A. Well, like I said, I assume it was following original
19 publications on this kind of -- line of work that appeared in
10:15AM 20 Cancer Research in 1993. So, around that time.

21 Q. 1993/1994?

22 A. '92, '93, '94, in that range probably.

23 Q. Do you think it's possible that your lab received the
24 samples that are discussed on page 698 of McLeskey 1998 in the
10:16AM 25 first quarter of 1993?

1 A. Do I think it's possible? Yeah, it's possible.

2 Q. Do you think it's possible that those samples were
3 received by your lab in the second quarter of 1993?

10:16AM 4 A. You know, I don't -- I don't know. I -- you know, I
5 can't tell if it's first quarter, second quarter. I can't
6 tell if we, you know, ran out of stuff or needed to get more,
7 you know, right.

8 Q. We've already discussed that on page 698 of McLeskey 1998
9 it states that preformulated drug in a vehicle of 10 percent
10 ethanol, 15 percent benzyl benzoate and 10 percent benzyl
11 alcohol brought to volume with castor oil was supplied by B.
12 M. Vose.

13 A. Right.

14 Q. Do you have any reason to doubt that those particular
15 samples were received by your lab in early 1993?
10:17AM

16 A. I have no reason to doubt that, no.

17 Q. Were you aware that it ws AstraZeneca or one of its
18 predecessors that was supplying ICI 182,780?

19 A. Yeah. One of its predecessors probably at the time.

10:17AM 20 Q. Do you believe that this research was important at that
21 time?

22 A. Yes.

23 Q. Why was it important?

24 A. You know, it showed that growth factors could get around
10:17AM 25 the need for estrogen receptors in a cell line that was

1 originally dependent on estrogen.

2 Q. McLeskey 1998 was published in the Journal of Clinical
3 Cancer Research; is that right?

4 A. Um-hum.

10:17AM 5 Q. To your understanding, who are the people that read the
6 Journal of Clinical Cancer Research?

7 A. In 1998? So, it's Volume 4, so it was a relatively new
8 journal. People engaged in what's called translational
9 research, I guess you would say.

10:18AM 10 Q. Just so I understand, I guess, the structure with the
11 Lombardi Cancer Center, am I correct that Dr. McLeskey was a
12 postdoc, you were her supervisor and Dr. Lippman was your
13 supervisor in some way?

14 A. Yeah, I guess you could put it that way.

10:18AM 15 Q. To your knowledge after McLeskey 1998 was published did
16 AstraZeneca ever contact any of your coauthors regarding
17 McLeskey 19698?

18 A. Not to my knowledge.

10:18AM 19 Q. Do you have a specific recollection of filling out any
20 particular forms for AstraZeneca before you started your work
21 on McLeskey 1998?

22 A. No specific recollection.

10:18AM 23 Q. Dr. Kern, I know we have been talking about samples a lot
24 today, but I know I didn't actually ask you about the receipt
25 of the samples themselves. Were you actually the person that

1 received the physical samples from AstraZeneca relating to
2 McLeskey 1998?

3 A. I don't know for certain but it's quite possible I was.

10:19AM

4 Q. Do you have any recollection of what the packaging looked
5 like for the preformulated ICI 182,780 that was received?

6 A. No.

7 Q. Do you recall if there was any documentation that
8 accompanied the samples of the preformulated ICI 182,780?

10:19AM

9 A. There usually is but, you know, a packing slip at least.
10 Right?

11 Q. Do you have any specific recollection of what was
12 included with the samples?

13 A. No.

10:19AM

14 Q. What is your best recollection of the documentation that
15 was accompanying the preformulated ICI 182,780 samples?

16 A. My best recollection is no recollection at this point.

17 Q. So am I correct that you don't know if the Lombardi
18 Center received a certificate of analysis with the
19 preformulated drug samples?

10:19AM

20 A. Yeah, I don't know. I do not know if they did or not.

21 Q. Am I correct that you do not know if the Lombardi Center
22 would have received MSDS sheets with the preformulated drug
23 samples?

24 A. Usually that comes with it, yeah, an MSDS sheet.

10:20AM

25 Q. An MSDS sheet for each excipient?

1 A. I don't know. I don't -- I don't know what's on the MSD
2 sheet, yeah.

3 Q. At the time McLeskey 1998 was published, did you have an
4 understanding of whether those percentages were in
10:20AM 5 weight/volume or volume to volume?

6 A. Weight/volume or volume to volume, I think they're all
7 liquids, so probably would have been volume to volume.

8 Q. Do you know one way or the other?

9 A. I mean, looking at it, I would say they're liquids, so
10:20AM 10 it's volume to volume. I'm not sure about benzyl benzoate,
11 whether that's a liquid or --

12 Q. Did you test the samples yourself?

13 A. No.

14 Q. And as I understand you earlier, that you do not consider
10:21AM 15 yourself a formulator; is that correct?

16 A. That's correct, right.

17 Q. Have you had any formulation classes?

18 A. No.

19 Q. When vials containing preformulated ICI 182,780 were
10:21AM 20 received at Lombardi Cancer Center, would they have been
21 logged or recorded in some way?

22 A. I -- I don't know.

23 Q. And did I understand you correctly earlier that you never
24 talked to anybody at AstraZeneca regarding the components of
10:21AM 25 the preformulated ICI 182,780 received by Lombardi Cancer

1 Center?

2 A. That's correct.

3 Q. And you're not paying for any of the lawyers that are
4 here representing you, right?

10:21AM 5 A. No.

6 Q. And neither is Daiichi?

7 A. Not that I know of.

8 Q. You had referenced earlier, I think, something called an
9 MTA.

10:21AM 10 A. MTA, material transfer agreement.

11 Q. And I think you referenced one specifically in connection
12 with some work you did at Southern Research -- at SRI,
13 Southern Research Institute?

14 A. Right, yes.

10:22AM 15 Q. Now, were you referring to a specific MTA that you
16 recall?

17 A. Yes.

18 Q. Was that with AstraZeneca?

19 A. That was. Well, I don't know if it's Zeneca.

10:22AM 20 Q. When I say AstraZeneca, I mean any predecessor.

21 A. Right.

22 Q. Have you seen that particular MTA recently?

23 A. No.

24 Q. You haven't seen it?

10:22AM 25 A. No.

1 Q. What made you recall that?

2 A. Just when the issue came up, I remembered that I did
3 contact Vose in order to get more compound because I needed it
4 to continue the work, once I moved institutions.

10:22AM 5 Q. This was after you had moved to SRI?

6 A. Right.

7 Q. So you recalled specifically making a request to
8 Dr. Vose?

9 A. Right.

10:22AM 10 Q. Has anyone shown you actual -- you an actual material
11 transfer agreement that you entered into with --

12 A. No.

13 Q. -- AstraZeneca?

14 A. No.

10:23AM 15 Q. In that laboratory at that time, in let's just say '93 to
16 '98 time frame, approximately how many other research projects
17 were going on at that time?

18 A. In?

19 Q. In your laboratory.

10:23AM 20 A. In my laboratory, four or five, in that range, something
21 like that.

22 Q. And these were all projects that you were responsible
23 for?

24 A. Yeah. You know, each postdoc kind of had a project, so
10:23AM 25 yeah.

1 Q. You may have answered this before, but there was no --
2 for people who worked in the Cancer Center or in your lab,
3 there was no confidentiality, general confidentiality
4 agreement they had to sign in order to do work in the lab?

10:23AM 5 A. I don't recall, no.

6 Q. Would you say it was sort of a collaborative environment
7 at the time in terms of sharing --

8 A. Yes.

9 Q. -- information with colleagues?

10:24AM 10 A. Yes.

11 Q. So you would discuss with colleagues projects you were
12 working on, you would share what you were working on?

13 A. Yeah.

14 Q. Prior to the research -- sorry, let me back up.

10:24AM 15 Throughout the course of your career, just roughly, on
16 how many occasions do you recall, in connection with research
17 you were doing, making a request for a drug, whether from
18 AstraZeneca or anybody, in order to conduct research?

10:24AM 19 A. Not too often. A lot of -- I mean, a lot of times,
20 things were commercially available, and that's sort of the
21 first preference, so you don't have to go through that type of
22 paperwork. So, you know, I've had people approach me for cell
23 lines, where we would have to send them Georgetown's MTA.

24 Q. Okay. Going in the other direction?

10:24AM 25 A. Going in, mostly going in the other direction, yeah.

1 Q. Okay. Well, so you're saying it wasn't a regular
2 occurrence that you would enter into an MTA in order to obtain
3 a drug for you to conduct research?

4 A. No, I don't think so, no.

10:25AM

5 You know, we would ask for plasmids. Again, we would
6 have to ask for an MTA for those from other academic
7 laboratories.

8 Q. Specifically, with regard to McLeskey 1998, I'm not sure
9 the record was clear. Maybe you weren't asked.

10:25AM

10 Approximately for how many years did the research go
11 on?

12 A. For this particular paper?

13 Q. Yes.

10:25AM

14 A. Hard to estimate, but, you know, my guess is it started
15 around '93, '94, in that range, and went to the time that it
16 was finally accepted, which was November, '97, I think.

17 Q. So you believe that for that entire time, there was
18 research going on towards this?

19 A. Related to this paper, yeah.

10:26AM

20 Q. And during that time, is it fair to say that you would
21 discuss with colleagues the nature of that research?

22 A. Yeah, it would be fair to say that.

23 Q. And you didn't understand that there was any prohibition
24 or restriction on you doing that, did you?

10:26AM

25 A. Not within the Lombardi Cancer Center, certainly, there

1 was no -- no restriction.

2 Q. Before the paper was published, in that time frame that
3 the research was going on, did you give any talks or report
4 progress to anyone?

10:26AM 5 A. You know, it's possible some of this work may have been
6 presented at the annual meeting of the AACR as a poster or
7 possibly as a talk. I just don't recall.

8 Q. Okay.

9 A. There would be records of abstracts with those people.

10:26AM 10 Q. Approximately what time frame are you talking about?

11 A. Same time frame. Well, it would be before it was
12 published, yeah.

13 Q. What is the AACR?

14 A. American Association of Cancer Research. That's most
10:27AM 15 likely where it would have been presented, if it was.

16 Q. And is it fair to say that when you undertook to begin a
17 research project at Lombardi, you would do so with the hope
18 and expectation that the work results in a publication?

19 A. Yes.

10:27AM 20 Q. And that's true with McLeskey 1998?

21 A. Yes.

22 Q. Sorry, just going back to relationship with Ms. Pensabene
23 and her first, which is O'Melveny and Meyer, for the record.

24 Is there an actual engagement agreement in place between you
10:27AM 25 and O'Melveny?

1 A. No.

2 Q. When did O'Melveny actually start representing you in
3 connection with this case?

10:27AM

4 A. I think after Arthur -- after the subpoena was delivered,
5 Arthur sent me an e-mail saying that Lisa had offered to
6 represent me, and I think that -- the day after I received the
7 e-mail, the day I received -- I forget which document here --
8 the request for documents subpoena.

10:28AM

9 Q. Before that, did you have any reason to believe that you
10 needed counsel in connection with the subpoena?

11 A. No, I guess not.

12 Q. Did Mr. Mann explain to you or provide you any
13 information as to why O'Melveny was offering to represent you
14 in this case?

10:28AM

15 A. No.

16 Q. Going back to the Lombardi Center when you were there.
17 Was there any control on access to the actual facility
18 starting in 1993?

19 A. Control on access to?

10:28AM

20 Q. To the building.

21 A. To the building? The doors were locked, yeah.

22 Q. Well, was --

23 A. Certainly, the animal facilities were locked up.

24 Q. Where the animals were?

10:28AM

25 A. Yeah.

1 Q. So the animals couldn't get out?

2 A. Well, so other people couldn't get in.

3 Q. No animals, human or otherwise, okay.

4 Who actually had access to the lab itself? Did you

10:29AM

5 have to be a employee or somebody working for the Cancer

6 Center to be able to get into the building?

7 A. Yes. I mean, you know, students could be -- come down

8 because there was -- the faculty at their offices in the

9 proximity of the laboratories.

10:29AM

10 Q. So if you were a student of undergrad or the medical

11 school --

12 A. We had some undergraduates who were working in the

13 laboratories, right.

14 Q. Was there some sort of special ID issued to those

10:29AM

15 students so they could get access to the laboratory?

16 A. I don't think so, but I don't recall.

17 Q. Beyond student ID, was there any other ID that had to be

18 shown to get access to the lab?

19 A. Yeah, I just don't recall. I'm fairly certain that there

10:29AM

20 were guards there, right. You know, so anybody just coming on

21 and off the street would have difficulty going down into the

22 laboratories.

23 Q. There was no ID issued by the Cancer Center itself that

24 you needed to get into the Cancer Center lab?

10:30AM

25 A. I don't recall there being so.

1 Q. Before making the request to AstraZeneca for the samples
2 that were used in McLeskey 1998, did you have any prior
3 dealings with AstraZeneca in terms of requesting samples for a
4 research project?

10:30AM 5 A. No.

6 Q. And since that time, you referenced the occasion at SRI?

7 A. Right.

8 Q. Any others besides that?

9 A. I don't think so, no.

10:30AM 10 Q. At any time when you working on the project, McLeskey
11 1998, did you have any understanding that you would not be
12 able to publish the results of the work?

13 A. No. I mean, I thought I had freedom to publish the work.

14 Q. During the time you were working on this project, which
10:30AM 15 is described in McLeskey, 1998, did you have any understanding
16 that there was any restriction on publishing the formulation
17 of ICI 182,780 in any publication resulting from the work?

18 A. Okay. Yeah, I would say if I were -- if I was the one
19 that signed the MTA, I probably would have understood that
10:31AM 20 they wanted to see the paper, the manuscript, before it was
21 submitted, right. That would have been the only limitation
22 that I would have been aware of, right. And I think in there,
23 they usually would have said they're not going to block
24 publication, the publication itself, right, yeah.

10:31AM 25 Q. Okay. So the only -- and, again, you have no

1 recollection of actually signing anything in connection with
2 this particular project, do you?

3 A. No.

10:31AM

4 Q. You're saying hypothetically, if you had, the only
5 restriction you were aware of --

10:32AM

6 A. I think what I said was it was probably either me or
7 Dickson, we signed that form. If it was Dickson, I might not
8 have been aware of limitation. If it was me, I would have
9 read those terms and, you know, would have been aware of that
10 limitation.

11 Q. And what terms specifically?

12 A. You know, usually, there's -- when a company gives you
13 something that's not publicly available yet, they'll ask to
14 see the manuscript before you submit.

10:32AM

15 Q. And that was the only restriction you might have been
16 aware of?

17 A. Correct.

10:32AM

18 Q. Okay. And, again, you have no knowledge that the
19 manuscript or any version of the manuscript was sent to
20 AstraZeneca?

21 A. I have no knowledge that it was.

22 Q. Let me ask you this. So, I know you looked at this
23 before and you saw that it was submitted originally --

24 A. July 3rd.

10:32AM

25 Q. '97.

1 A. Yeah.

2 Q. What's your best understanding as to when a first draft
3 would have been prepared, I believe you said probably by
4 Dr. McLeskey?

10:32AM 5 A. Two to three months previous, probably. That would be my
6 estimate. Could have been earlier, little earlier, in that
7 range.

8 Q. So, for the work at SRI, you said you do recall there was
9 an MTA.

10:33AM 10 A. Yeah.

11 Q. And you do recall that the MTA obligated you to provide a
12 manuscript to AstraZeneca.

13 A. I don't recall that.

14 Q. You don't recall that?

10:33AM 15 A. No.

16 Q. So you're not sure if there was an obligation?

17 A. Not at that time.

18 Q. But if there was, it didn't happen?

19 A. Yeah. Somebody screwed up.

10:33AM 20 Q. Was there any other occasion, besides the two we have
21 talked about at Georgetown and SRI, where you received
22 material potentially under an MTA from AstraZeneca?

23 A. No, I don't think so.

10:33AM 24 Q. Well, throughout the course of your career, do you have a
25 recollection of any occasion where you sent a draft manuscript

1 to a drug supplier?

2 A. Throughout my career? No, I guess not.

3 Q. Well, wasn't your objective to clearly convey to the
4 research community the work you did; is that fair? That was
5 part of the purpose of the paper, no?

10:34AM

6 A. That's correct, right.

7 Q. And the formulation is there, right? So the formulation
8 is there for what it's worth?

9 A. The formulation is there, right. Somehow or other, we
10 got that information.

10:34AM

11 Q. And isn't it fair to say that if any of the authors
12 thought that it was important to be more explicit in
13 describing the formulation for purposes of conveying that
14 research, then that would have been done in the paper?

10:34AM

15 A. I -- I'm, you know, fairly certain that we felt we met
16 our obligation for materials and methods section.

17 Q. And that you had clearly conveyed to the research
18 community what the formulation was?

19 A. That we had clearly relayed to the research community
20 what the formulation was?

10:34AM

21 Q. Yes.

22 A. You know, like I said previously, at the time I didn't
23 really know what a formulation was, to tell you the truth.

24 Okay? So it's -- this is information that was conveyed to us
25 and, you know, that's what we put into the paper.

10:35AM

1 Q. And you were the one who was ultimately responsible for
2 signing off on the final version of the paper, right?

3 A. Yeah.

10:35AM

4 Q. You didn't have any reason to believe when you read it
5 and signed off on the final version -- you read it carefully,
6 didn't you?

7 A. Yeah.

10:35AM

8 Q. And you didn't have any reason to believe that there was
9 anything unclear or incomplete about the description of the
10 formulation?

11 A. I had no reason to believe that.

10:35AM

12 Q. Sorry. You didn't have any reason to believe that the
13 description of the formulation would in any way prevent
14 researchers in the field from making full use of the results
15 that were -- that you were publishing?

16 A. No, I didn't have any reason to believe that.

17

18 MS. PIROZZOLO-MELLOWES: That concludes Dr. Kern's
19 testimony.

10:35AM

20 THE COURT: Okay.

21 (The read in concluded.)

22 MR. RIZZI: Your Honor, the next witness is a live
23 witness.

24 THE COURT: Okay.

10:36AM

25 MS. PETERSON: Dr. Mehta.

1 THE COURT: Thank you. You may step down.

2 MR. RIZZI: Can we take a short break?

3 THE COURT: Yes, why don't we take a five-minute
4 break. Okay?

10:36AM 5 THE DEPUTY CLERK: All rise.

6 (A recess was taken at 10:36 a.m.)

7 THE DEPUTY CLERK: All rise.

8 THE COURT: Okay. Be seated.

9 MS. PENSABENE: Your Honor, I understand that there
10 was a question about PTX-6, 7 and 8. They are the prosecution
11 histories.

12 THE COURT: Are they in evidence?

13 MS. PENSABENE: The parties have agreed that they
14 should be in evidence. Happily, I can say the parties have
10:54AM 15 agreed.

16 THE COURT: That's nice to hear.

17 So what are the document numbers? 6, 7, and 8?

18 MS. PENSABENE: PTX-6, 7, and 8.

19 THE COURT: Okay.

10:54AM 20 MS. PETERSON: And I think there is a corresponding
21 set of exhibits on JTX-6, 7, and 8 as well. They were
22 produced -- one set was produced by the plaintiff and one set
23 was produced by the defendants.

24 THE COURT: Yes. So which are the exhibits coming
10:54AM 25 in?

1 MS. PETERSON: I think we should agree's it's the JTX
2 numbers since that's the joint list.

3 MS. PENSABENE: That's absolutely fine, Your Honor.
4 They are the certified file histories that come from the
10:54AM 5 Patent Office.

6 THE COURT: Okay. So JTX-6, 7, and 8 are in
7 evidence.

8 MS. PENSABENE: Yes. Thank you, your Honor.

9 THE COURT: Okay.

10:54AM 10 (JOINT EXHIBITS JTX-6, JTX-7, AND JTX-8 WERE RECEIVED IN
11 EVIDENCE.)

12 THE COURT: Okay.

13 MS. PETERSON: The defendants call Dr. Mehta to the
14 stand.

10:54AM 15 THE COURT: Okay. Come forward.

16 THE DEPUTY CLERK: Good morning.

17 THE WITNESS: Good morning.

18 THE DEPUTY CLERK: If you could please take a step in
19 the witness stand, place your left hand on the Bible and raise
10:55AM 20 your right hand.

21 (DIVYESH MEHTA, HAVING BEEN DULY SWORN/AFFIRMED, TESTIFIED AS
22 FOLLOWS:)

23 THE WITNESS: I do.

24 THE DEPUTY CLERK: Can you please state and spell
10:55AM 25 your full name for the record.

1 THE WITNESS: Divyesh Mehta.

2 THE DEPUTY CLERK: Will you please spell it.

3 THE WITNESS: Divyesh, D-I-V-Y-E-S-H, Mehta,

4 M-E-H-T-A.

10:55AM 5 THE DEPUTY CLERK: Thank you.

6 THE COURT: Okay. Doctor, have a seat, make yourself
7 comfortable.

8 THE WITNESS: Thank you.

9 THE COURT: Please speak loudly into the microphone,
10 please. Okay.

11 MS. PETERSON: May I proceed?

12 THE COURT: You may.

13 (DIRECT EXAMINATION OF DIVYESH MEHTA BY MS. PETERSON:)

14 Q. Good morning.

10:56AM 15 A. Good morning.

16 Q. Can you please start by introducing yourself to the
17 Court.

18 A. My name is Dr. Divyesh Mehta. I am a medical oncologist
19 and licensed to practice medicine in the State of Arizona.

10:56AM 20 Q. And do you hold any other titles?

21 A. I am the chief of oncology services at the Maricopa
22 Integrated Health Services, which is the County Hospital for
23 Phoenix, Arizona.

24 Q. Anything else?

10:56AM 25 A. I'm also professor of medicine at the University of

1 Arizona, College of Medicine in Phoenix.

2 Q. And can you tell us a little bit about your educational
3 background?

4 A. So I graduated in 1971 from Baroda, India.

10:56AM 5 I came to the United States in 1972. Before that, I
6 had done a year of internship in India and another internship
7 in Chicago, a residency in internal medicine, and then a
8 fellowship at the University of Illinois in Chicago, in
9 hematology and oncology.

10:57AM 10 Q. And are you currently a practicing physician?

11 A. Yes, I am.

12 Q. In what areas do you practice?

13 A. I practice in hematology and oncology, specializing in
14 breast medicine.

10:57AM 15 Q. And you mentioned hematology. What is that?

16 A. Hematology is diagnosis and treatment of blood diseases,
17 including blood cancer.

18 Q. And what portion of your clinical practice is devoted to
19 oncology and, in particular, the treatment of breast cancer?

10:57AM 20 A. It has varied over the last 15 years.

21 While I was in Chicago, from 2003, most all of my
22 clinical practice was breast cancer.

23 When since coming to Phoenix, Arizona in 2011, 60
24 percent of what I see are breast cancer; the rest is assorted
10:57AM 25 tumors and some blood conditions which I also see.

1 Q. And how many breast cancer patients have you treated over
2 the course of your career as a clinician?

3 A. The number must be in thousands.

4 Q. And how many patients do you see a month?

10:58AM 5 A. At the moment I see about ten new breast cancer patients
6 a month, and maybe 30 to 50 patients in follow-up or in
7 hormonal or chemotherapy.

8 Q. And what other prior academic positions have you held?

9 A. So, I was assistant professor of medicine in -- from late
10:58AM 10 '70s to 1985.

11 I was associate professor of medicine in Chicago from
12 2003 to 2011. And during that time, I was also the chair for
13 the Division of Hematology and Oncology at the University of
14 Illinois, and I was also the director of clinical oncology
10:59AM 15 services, which means I ran the chemotherapy services for the
16 University Hospital for the entire program.

17 Q. And what did you do during the time period from 1985 to
18 2003?

19 A. So I returned to India to my hometown, where I graduated
10:59AM 20 from and where I grew up.

21 I set up a practice as well as I set up three tertiary
22 care hospitals which would provide cancer care. I set up a
23 breast clinic, and I also set up a mammography unit for -- one
24 of the first in Western India.

10:59AM 25 One of the problems we found when we did that was that

1 most breast cancers came late in India because there were no
2 mammographies, and women would come with a lump that had
3 spread. And so we tried to introduce mammography, and we
4 learned that women were somewhat shy and not really trusting
10:59AM 5 that this would not be photographed or something, and they
6 were worried that there would be man technicians, so we began
7 an education program of why it was important, how it was done.
8 And by that time, we started to educate people to get that
9 done. So that was in the initial part of my return to India.

11:00AM 10 Besides starting a hormonal and chemotherapy treatment
11 program for breast cancer patients, I was involved in getting
12 diagnostic setups going.

13 And then I set up ICON.

14 Q. And what is ICON?

11:00AM 15 A. So ICON, I-C-O-N, stands for Indian Cooperative Oncology
16 Network. This is a cooperative group, a mentoring group, we
17 set up in Mumbai, and the whole idea was this: There were
18 lots of patients who could benefit from new drugs, but they
19 had no funds to access them.

11:00AM 20 There were a hundred plus physicians in India treating
21 all kinds of cancer, including breast cancer. They did not
22 know how to put these patients on trials.

23 And there were drug companies and universities across
24 the world who wanted large number of patients for their
11:01AM 25 trials.

1 So we became the fulcrum that brought the pharma and
2 the universities to the physicians and the patients.

3 We also then had to set up education programs, so we
4 set up programs for doctors to be able to do good clinical
11:01AM 5 research, human rights and research, consenting. We focalized
6 what was there, being floated between the drug companies and
7 the doctors, and we monitored it was ethically and
8 transparently carried out.

9 So this was basically a process that started in mid
11:01AM 10 '90s and now it's in full force. It's become a force that has
11 linked up 300 different institutions in India and covers a
12 population of about 750 million people. So now they have
13 access to modern drugs, and the doctors have access to modern
14 methods of research.

11:01AM 15 Q. And over the course of your career, have you engaged in
16 any clinical research activities associated with the treatment
17 of cancer?

18 A. So, we just finished a study on impact of HPV in triple
19 negative breast cancer.

11:02AM 20 THE COURT: In what?

21 THE WITNESS: HPV is an infection that is present on
22 female cervix, and it seems to be responsible for cancer of
23 cervix, certain genital cancers, lung cancer, and ENT cancers,
24 and we had a feeling that it may be linked to the last kind of
11:02AM 25 breast cancer, which is triple negative cancer, the ER

1 negative, the PR negative, the HER2 negative, the most
2 difficult to treat breast cancer.

3 And we wondered, there was some evidence in the
4 literature that suggested that it may be related to HPV
11:02AM 5 infection, so we basically studied the last 15 years of our
6 data. The data are basically being presented next month at an
7 oncology meeting.

8 We also studied --

9 THE COURT: Doctor, can you slow down just a little?

11:02AM 10 THE WITNESS: Sure.

11 THE COURT: Thank you.

12 THE WITNESS: We also studied breast cancer in
13 Hispanic women and presented two abstracts last year at the
14 San Antonio Breast Cancer Conference which kind of looked at
11:03AM 15 impact of access, impact of insurance, and outcomes. And,
16 obviously, that was of major interest because at County
17 Hospital, we have maybe 30 to 40 percent of women who have no
18 insurance, and we try to give them modern treatment while
19 keeping their financial needs in our sight.

11:03AM 20 And, of course, I was the part of the team that brought
21 a new molecule called p28. It's a molecule licensed by
22 University of Illinois, and one of the researchers who was
23 working with us. It's a molecule that's a novel molecule,
24 underwent Phase 1 trial, which means we did safety and
11:03AM 25 toxicity and dosing setup trials. The data was presented at

1 the American Society of Clinical Oncology meeting in Chicago
2 in 2011. And that molecule is now into its Phase II trials.

3 Q. Thank you.

4 And have you been involved in any clinical trials
11:04AM 5 for the -- involving endocrine therapy for treatment of breast
6 cancer?

7 A. So the major one was ATAC trial which compared
8 anastrozole to tamoxifen. And the trial was a national trial,
9 and I enrolled patients on it, and I was the principal
11:04AM 10 investigator for the site of University of Illinois in
11 Chicago. The trial looked at anastrozole versus tamoxifen
12 versus combination.

13 I also was the principal investigator for Chicago site
14 for a Tailor Rx trial, which basically asked the question if a
11:04AM 15 woman has a early ER cause to breast cancer, do all of them
16 require chemotherapy? And if all of them don't require
17 chemotherapy, some can be simply cured by surgery followed by
18 hormonal treatment alone, how would we detect that these are
19 the patients who can be spared chemotherapy?

11:05AM 20 And so the trial looked at the genomic makeup of the
21 tumor cell and distinguished who had a high lethal score and
22 would benefit from chemo, and who were slow-growing tumors
23 like turtles that were going to keep going for years and the
24 chemo would really not have any impact on it? So those trial
11:05AM 25 results are just coming out.

1 And then participated in a Phase III trial looking at
2 avastin versus chemotherapy, a Phase II trial of a new
3 molecule called Epithalone B. It was a negative trial, didn't
4 work in breast cancer.

11:05AM

5 And, of course, as I mentioned, the Phase I for p28.

6 Q. Have you been involved in any animal research studies
7 over the course of your career?

8 A. So, during my fellowship at UIC, my boss used to have a
9 lab where we worked. This was a lab that basically worked on
10 mice. And the idea was to look at impact of removing kidneys
11 and how they affected the blood of the -- the animal.

11:06AM

12 And subsequently during that time of my fellowship, I,
13 along with other trainees, would also look after the dogs who
14 were going through experimental bone-marrow transplants, and
15 we would come in over the weekend and week and basically
16 manage the dogs.

11:06AM

17 Over the time I was the chair for the oncology program
18 at the University of Illinois, Chicago, I was instrumental in
19 directing the Ph.D.s which were under my division. I would
20 approve their funding. I would approve -- look at the
21 research that is basically going up for further funding. I
22 would look at and mentor them about the animal research that
23 was going on to be published. And my team acted as a liaison
24 between the lab research and what the clinicians wanted the
25 question to be answered in the lab. This was during the

11:07AM

1 period I was in Chicago.

2 Q. And over the course of your career, have you presented or
3 published on topics of treatment of breast cancer?

4 A. Yes. So I have been a speaker all my life and a teacher
11:07AM 5 all my life, the last 15 years, I have addressed physician
6 audiences which sometimes included nurses and pharmacists on
7 breast cancer across United States and abroad, approximately
8 150 docs on treatment of breast cancer, management of breast
9 cancer, ER positive breast cancer as well as chemotherapy of
11:07AM 10 breast cancer.

11 Q. And Dr. Mehta, can you please take your binder that's
12 sitting in front of you and turn to the tab that's marked
13 DTX-276. It should be your first binder.

14 A. Absolutely.

11:07AM 15 MS. PENSABENE: Counsel, do you have a copy for us?

16 THE WITNESS: 276? Got it. 276?

17 THE COURT: It's about the fifth one, tab in.

18 MS. PETERSON: Is it not in your binder?

19 THE COURT: It's about the fifth tab in.

11:08AM 20 THE WITNESS: 276, right? Yeah. Got it.

21 BY MS. PETERSON:

22 Q. Sorry for that, Dr. Mehta. Can you identify DTX-276?

23 A. Yes.

24 Q. And what is this?

11:08AM 25 A. It's my copy of my CV.

1 MS. PETERSON: Your Honor, defendants move to enter
2 DTX-276 into evidence.

3 THE COURT: Any objection?

4 MS. PENSABENE: No objection.

11:09AM 5 THE COURT: In evidence.

6 (DEFENDANT EXHIBIT DTX-276 WAS RECEIVED IN EVIDENCE)

7 MS. PETERSON: At this point, defendants proffer
8 Dr. Mehta as an expert on the clinical treatment and research
9 of breast cancer.

11:09AM 10 THE COURT: Any objection, any voir dire?

11 MS. PENSABENE: No, Your Honor.

12 THE COURT: Okay. Subject to Rule 702, Dr. Mehta
13 will be permitted to testify in the areas identified by
14 counsel as an expert.

11:09AM 15 BY MS. PETERSON:

16 Q. Now, Dr. Mehta, are you here to testify today about the
17 opinions you have offered concerning invalidity of the patents
18 in suit?

19 A. Yes.

11:09AM 20 Q. And were all of the facts and data that you considered in
21 forming your opinions in this case disclosed in your expert
22 reports?

23 A. Yes.

11:09AM 24 Q. Dr. Mehta, can you just briefly explain for the Court
25 what the primary options are for treating hormonal-dependent

1 breast cancer?

2 A. So this is a tumor that is fed and nourished by
3 estrogens, and one of the main strategy was to withdraw
4 estrogen either surgically by removing ovaries or chemically
11:10AM 5 producing menopause. Then the same concept progressed to have
6 agents which would be blocking the estrogen receptors which
7 are like switches on the cells, turning the cells on and
8 egging the cell on for division and -- and of course, all
9 strategy that would reduce circulating estrogen around the
11:10AM 10 cancer cell.

11 Q. And what types of drugs would fall into the antiestrogen
12 category that you described?

13 A. So principally, there were three categories. First were
14 the drugs that were selected to be modified, the estrogen
11:10AM 15 receptors were concerned, tamoxifen being the principle
16 example. Other categories were aromatase inhibitors which
17 block the enzyme aromatase and made estrogen non-available to
18 the cell. And the third category where your antiestrogen or
19 estrogen down regulators, ERDs, and the example being
11:11AM 20 Faslodex.

21 Q. And as of the 1990s, how did clinicians determine what
22 treatment option to use for a patient?

23 A. Since most of the tumors, since most of the tumors were
24 estrogen receptor positive, the strategy largely had to decide
11:11AM 25 if the estrogen was -- the manipulation was the first

1 treatment to go to, and if not, if you actually wanted
2 chemotherapy, why.

3 So as the algorithm on these slides suggest, if you had
4 a life-threatening disease or the patient was extremely
11:12AM 5 symptomatic involving some important vital organ then
6 chemotherapy was fast, it would control the tumor and one
7 would go that route. But otherwise, almost everybody would
8 proceed to options that were listed on the left side of the
9 column where you begin your first line hormonal therapy.

11:12AM 10 Q. Dr. Mehta, were there different options for endocrine
11 therapy available in the 1990s?

12 A. So if you look at the slide again, talking about the
13 premenopausal versus postmenopausal. In the postmenopausal,
14 tamoxifen was still a major drug which was for the entire
11:12AM 15 decade, sort of dominated the breast cancer therapy. The
16 aromatase inhibitors that arrived and Anastrozole as an
17 example. Megestrol which used the mechanism to block the
18 progesterone receptor was a standard of care if there was
19 tamoxifen failure, and this was an old drug and sort of left
11:13AM 20 over from earlier part of the decade.

21 And there was also knowledge that if you could block
22 the androgens by just like hetero tested, breast cancer
23 sometimes responded and hetero testing was androgen blocking
24 was an option.

11:13AM 25 On the other end, in the premenopausal, bulk of the

1 strategies were around tamoxifen or making a woman menopausal.
2 To do -- to put a woman in menopause, the options included a
3 drug that would interrupt the pathway between pituitary and
4 ovary or actually physically taking the ovaries out, so called
11:13AM 5 oophorectomy.

6 And of course, down the line, the products that were
7 coming were looking at the fact that the post -- the
8 premenopausal woman couldn't be given the aromatase inhibitor
9 if she was made to resemble a postmenopausal woman by using
11:14AM 10 Anastrozole.

11 Megestrol and androgen, as I had mentioned in the
12 postmenopausal, they were leftovers from earlier part of the
13 decade were still options being used but less and less so.
14 Q. And just to be clear, looking at your demonstrative up on
11:14AM 15 the screen, DTX-1006, I think you were referring to the
16 treatments for postmenopausal which are on the left side --

17 A. Right.

18 Q. -- is that right?

19 A. Yes.

11:14AM 20 Q. And then the right-hand side of the screen?

21 A. Is the premenopausal.

22 Q. Were other candidate drugs and developments under
23 consideration at that time as well in the late 1990s?

24 A. So, on one hand, the aromatase inhibitors were already on
11:14AM 25 their way and they were successfully headed for clinical use,

1 and on the other hand, there were a very powerful group of
2 drugs known as antiestrogens.

3 Q. Other than the aromatase inhibitors and the pure
4 antiestrogen, were there any other categories of drugs that
11:15AM 5 were under development for hormone-dependent breast cancer?

6 A. There was more an attempt to also create better
7 tamoxifens. As tamoxifen was a drug that had basically
8 dominated breast cancer care, the question was, could you
9 create a better tamoxifen, higher efficacy or lower side
11:15AM 10 effects, and those were some of the products also being tried.

11 Q. So out of those three categories of drug candidates, did
12 any of the candidates within those categories appear to be
13 promising as a potential new therapy for hormone-dependent
14 breast cancer at the time?

11:15AM 15 A. So the prior art during that time identified fulvestrant
16 as a very promising candidate.

17 Q. Why do you say that?

18 A. Because there was strong preclinical data suggesting that
19 it was efficacious, it was a novel product, in terms of a new
11:16AM 20 mechanism of action, so it was likely to work when other drugs
21 had failed. The preclinical and clinical data was showing
22 that it did work when tamoxifen had failed. The data also
23 suggested that it being pure antiestrogen had no side effects
24 that would come if we were using tamoxifen, such as
11:16AM 25 endometrial and other changes.

1 So it had promise in terms of being novel, new
2 mechanism of action, efficacy and safety, and also the prior
3 art was suggesting that this was going to be delivered by a
4 mechanism or a method which would make sure that the patient
11:16AM 5 is compliant and the drug is in, based on the injections.

6 Q. Now, you mentioned one of the properties of fulvestrant
7 that it had been shown to work when tamoxifen had failed.
8 What's the significance of that?

9 A. So one of the important lessons of hormonal treatment has
11:17AM 10 been that if you go from one successful treatment to the
11 other, if the next one is effective and not basically negated
12 by prior treatment, you added life and survival to the
13 patient. So as you -- even though one drug fails, you go to
14 the next paradigm and next paradigm and next paradigm.

11:17AM 15 That's how -- I have had patients who have survived
16 five, ten, 15 years with Stage 4 disease and are doing well
17 because something works and then the cells start to become
18 resistant, something else works. That's what cross-resistant,
19 non-cross-resistant. So not being cross-resistant to
11:17AM 20 tamoxifen was a major attribute here.

21 Q. And I think you mentioned that fulvestrant was -- or the
22 category that fulvestrant belongs to, the pure antiestrogens,
23 there were no approved drugs within that category, is that
24 right?

11:17AM 25 A. That is correct.

1 Q. And what about the other two categories, were there
2 already approved drugs within those two categories?

3 A. So, the premenopausal group of course had tamoxifen and
4 all of the options of depriving ovarian outputs, such it LHRH
11:18AM 5 antagonists or removal --

6 THE COURT: Or what? Wait, slow down.

7 THE WITNESS: LHRH antagonist, the interpreter -- the
8 interrupter of pituitary to ovary access. On the other end,
9 in the postmenopausal group, there were -- one agent was
11:18AM 10 already there, which was a group in Europe and two more were
11 on their way, which was very, very promising.

12 Q. Now, within the category of the pure antiestrogens, was
13 there any one candidate or -- within that group, that
14 demonstrated more promise than the others?

11:18AM 15 A. I would say that would be fulvestrant.

16 Q. And why do you say that?

17 A. The prior art of fulvestrant and the excitement about
18 this being a new novel molecule can be illustrated by this
19 particular slide.

11:19AM 20 Your Honor, the San Antonio Breast Conference is a big
21 pow-wow of breast cancer focused physicians, researchers, even
22 patient care groups arrive and everybody has a way of
23 interacting and learning what's coming new.

24 So 1999, there were 440 studies presented of all kinds
11:19AM 25 of research on breast cancer of which the most prominent, most

1 promising 40 abstracts were chosen for a general session,
2 which meant that everybody who came to San Antonio would be
3 likely to attend the general sessions before the sessions
4 break out in smaller rooms. And of those, eight focused on
5 hormonal therapies -- studies. So there were a few of these
6 studies as abstracts presented to this general audience that
7 came from all over the world, including from United States,
8 and of all those studies presented, there was only one new
9 novel product at that time introduced and that was Faslodex.

11:20AM 10 Q. The other seven hormonal therapy studies that were
11 presented at that general session, did those not involve new
12 or novel products?

13 A. So some of them are comparing tamoxifen to some other
14 methods. Some of them had also talking about aromatase
15 inhibitors. Some had -- but none of them had any product that
16 was not yet in the approval process, and there was excitement
17 about it.

18 In fact, Dr. Robertson in his presentation on this
19 product was from Dr. Robertson, and he categorized the product
11:21AM 20 as the most advanced pure antiestrogen available in the
21 research community at that time.

22 Q. If I could actually ask you to turn to the tab marked
23 JTX-13 in your binder. I believe it should be towards the
24 end.

11:21AM 25 Can you identify JTX-13 for the record?

1 A. Yeah. It covers the abstracts from the general sessions,
2 Page 31.

3 Q. This is the Robertson abstract that you just referenced
4 in your prior demonstrative?

11:21AM 5 A. Yes.

6 Q. Marked DDX-10-07?

7 A. Yes.

8 Q. And how did Dr. Robertson describe Faslodex in his
9 abstract?

11:22AM 10 A. Simply the first line, he says that Faslodex is the most
11 advanced, of a new class of drugs, a non-agonist, which means
12 a pure steroidal antiestrogen currently in clinical trials in
13 postmenopausal women in the United States, I guess.

14 MS. PETERSON: Can you go back to JTX-13 first. I
11:22AM 15 think it was asking for the first few sentences.

16 THE WITNESS: Correct.

17 MS. PETERSON: Keep going. Yep. Blow that up.
18 Right where it starts, Faslodex.

19 THE WITNESS: It says, I was seeing the most advanced
11:22AM 20 of the new class of drugs, the non-agonist pure steroidal
21 antiestrogen currently in clinical trials in postmenopausal
22 women with advanced breast cancer.

23 He was reporting on a randomized, partially blind trial
24 of this particular product in three different dose categories,
11:23AM 25 50 milligrams, 125 and 250 milligrams in association with

1 tamoxifen or tamoxifen placebo to see if this drug added any
2 value to tamoxifen and several therapeutic efficacy biomarkers
3 were also measured in that trial.

4 BY MS. PETERSON:

11:23AM 5 Q. Now, Dr. Mehta, are you familiar with the term a person
6 of ordinary skill in the art?

7 A. Yes, I am.

8 Q. And have you provided an opinion as to the
9 characteristics of that -- of that person?

11:23AM 10 A. Yes, I have.

11 Q. Is it referenced here up on your demonstrative,
12 DDX-10-08? Can you explain?

13 A. So this person is a hypothetical person but highly
14 educated, having, for example, a Ph.D. or an MB, many years of
11:24AM 15 training and experience in the field of treating

16 hormone-dependent diseases of the breast. This is a person
17 who would understand that the drug development process is a
18 teamwork that requires input from various individuals with
19 various background. For example, a person of ordinary skill

11:24AM 20 in the art would have familiarity with the pharmaceutical
21 formulations or would call on a colleague or a team member for
22 such expertise to collaborate.

23 Q. And Dr. Mehta, would you consider yourself to have been a
24 person of ordinary skill in the art as of 2000?

11:24AM 25 A. Yes.

1 Q. Now, prior to 2000, would a person of ordinary skill in
2 the art have been interested in developing a new treatment
3 method with fulvestrant for treating hormone-dependent breast
4 cancer?

11:25AM 5 A. Yes.

6 Q. And I see you've prepared a demonstrative timeline here,
7 DDX-10-09.

8 Can you explain?

9 A. So this looks at a stage of -- stages of drug development
11:25AM 10 for fulvestrant, in terms of preclinical, clinical and some
11 corroborative evidence that came subsequently. For
12 preclinical, 2002, the evidence that then begins to look at
13 actual patient drugs.

14 Q. And when you said some corroborative evidence that came
11:25AM 15 subsequently, what was the date of those publications?

16 A. '97, '98, '99.

17 Q. So they followed the preclinical and clinical studies
18 that you referenced?

19 A. Yes.

11:25AM 20 Q. But they occurred before 2000, is that right?

21 A. They did.

22 Q. Now, who was authoring this literature in the 1990s?

23 A. So there was a group of physicians and researchers who
24 were very focused on estrogen receptor positive breast cancer.
11:26AM 25 Some of these people were originally being part of the team

1 that developed tamoxifen, and now we're on to a new product.
2 This is the team -- lot of -- each of these initial studies,
3 the preclinical and clinical had input or team members from
4 the Imperial Chemical Industry, ICI, the team members
11:26AM 5 subsequently Zeneca, AstraZeneca. It was a group that was
6 mentoring and testing a novel compound with a new mechanism of
7 action.
8 Q. And why is that significant, who these authors were?
9 A. It sort of -- if you, if you like that work and if these
11:26AM 10 are the people you follow, there is a linear progression of
11 research from their preclinical work which is handed on to
12 clinical work and the same group is now in the corroborative
13 phase talking about the same product.
14 Q. And where were these results being published?
11:27AM 15 A. In various, very prestigious journals.
16 Q. And what was the typical audience for these journals?
17 A. These were breast cancer clinicians, breast cancer
18 academicians, breast cancer experts, surgeons, pathologists,
19 entire group of doctors who would be interested in treatment
11:27AM 20 of breast cancer.
21 Q. And let's move on to your next demonstrative, DDX-10-10.
22 Can you -- can you describe this for us?
23 A. So in a broad overview, we see paper from Wakeling and
24 that basically looked at rational for this product of a pure
11:28AM 25 antiestrogen. The testing was in mice and this was a single

1 dose given every four weeks.

2 Moving on to Wakeling further, it was again looking at
3 rational testing in mice and the dose every four weeks. Dukes
4 data was in monkeys, long-acting castor oil formulation. IM
11:28AM 5 injections, 4 milligrams per kilogram every four weeks and
6 then Wakeling and Duke again revisiting the dose and frequency
7 of these treatments in hormone-dependent breast cancer, and
8 again, Dukes '93 going on with further research in the same
9 area.

11:28AM 10 Q. So does this demonstrative, DDX-10-10, does this describe
11 what you were referring to as the preclinical phase?

12 A. That is correct.

13 Q. Okay. Well, let's take a look at the first reference on
14 your list. This is Wakeling 1991.

11:28AM 15 Can you tell us actually a little bit about the
16 Wakeling study from 1991?

17 A. So this study basically looks at fulvestrant and
18 describes it as being a potent and specific inhibitor of
19 estrogen action, and it states that it demonstrated excellent
11:29AM 20 growth suppressive effects in both cells and animals in breast
21 cancer.

22 Q. And what journal was Wakeling 1991 published in?

23 A. This was published in Cancer Research.

24 Q. And who were the authors?

11:29AM 25 A. Dr. Wakeling, Dr. Dukes and Jean Bowler.

1 Q. And does the article indicate where they worked?

2 A. They were all part of ICI Pharmaceuticals.

3 Q. And what results does Wakeling 1991 report?

4 A. The most relevant part of the study was that this, in a
11:29AM 5 cell line, it compared the new product, fulvestrant, to
6 tamoxifen and on breast cancer cell lines, and it also tried
7 to see one of the criticisms of tamoxifen was that it was
8 stimulating the uterine lining and led to problems,
9 subsequently even endometrial cancer. So it was basically
11:30AM 10 showing an anti-uterotrophic action. So anti means against,
11 utero means uterus, trophic means stimulation of uterine
12 lining. It showed excellent anti-uterotrophic action, and
13 this was achieved without having other side effects of
14 tamoxifen; namely, body weight and impact on gonadotrophic
11:30AM 15 secretion. It was not really working in any other fashion
16 except as a pure antiestrogen.

17 Q. And these results that you were just referring to,
18 they're described on your demonstrative, DDX-10-12?

19 A. Yes.

11:30AM 20 Q. And why were these findings important?

21 A. This established the fact that you have a potent new
22 mechanism of action with a product that can -- in comparison
23 with tamoxifen, have an improved efficacy and without the
24 uncomfortable side effects that you worried about. So you saw
11:31AM 25 improved the efficacy, reduced toxicity. The therapy index

1 sort of goes up and so it points towards the possibility that
2 this product would have that kind of improved treatment
3 ability.

4 Q. And what animals were studied in Wakeling 1991?

11:31AM

5 A. So he used MCF-7 cell lines, these are the famous human
6 cell lines that have been nurtured, and are responsible for so
7 many advances in hormone treatment of breast cancer and these
8 were these cell lines on which he tested the first hypothesis,
9 which was the efficacy. He also used rats, and giving this

11:31AM

10 particular product, he also showed that the vaginal
11 cornification, which was one of the changes they described to
12 suggest that there was an estrogenic stimulation of uterus was
13 absent and he also showed in nude mice where he took these --
14 these MCF-7 cell lines, created a xenograft on the animal and
15 then see -- saw how the fulvestrant acted to see the efficacy.

11:32AM

16 So I think the -- all three models that he describes, I
17 believe he also worked on monkeys. So the Macaca monkeys,
18 they were basically looking at the same action. He basically
19 demonstrated that if you use fulvestrant, the weight increase
20 of the uterus did not happen, which means the uterus was
21 protected from the uterotrophic action.

11:32AM

22 THE COURT: Can you just spell what type of monkey
23 you said.

24 THE WITNESS: Macaca, M-A-C-A-C-A. It's a species
25 they used.

11:33AM

1 THE COURT: How do you spell it?

2 THE WITNESS: M-A-C-A-C-A.

3 BY MS. PETERSON:

11:33AM 4 Q. Were the animals that Dr. Wakeling studied -- were the
5 animals that were studied in Wakeling 1991, were they
6 ovariectomized?

7 A. Yes.

8 Q. What does that mean?

11:33AM 9 A. It basically means you created a physiological condition,
10 that is, simulating postmenopausal women.

11 THE COURT: What was the word you said?

12 MS. PETERSON: Ovariectomized.

13 THE COURT: Thank you.

14 BY MS. PETERSON

11:33AM 15 Q. Dr. Mehta, did Wakeling 1991 teach any information about
16 the preferred method of administration of fulvestrant?

17 A. So it looked at bioavailability of the drug in all the
18 works in its injectable form, and found this drug to have a
19 very poor bioavailability, and this study also then
11:34AM 20 demonstrated, had a potential efficacy of a depot oil
21 preparation in the nude mouse that were implanted with the
22 xenografts.

23 Q. And what is a depot formulation?

11:34AM 24 A. So it's usually a drug given as a -- it's part of an oil
25 depot and depot meaning it sort of stores the drug, releases

1 it slowly so you have blood levels in a sustained long-term
2 fashion, rather than immediately rising and dissipating
3 themselves.

4 Q. And why would a depot formulation be desirable?

11:34AM

5 A. In the typical route, it would reduce the frequency of
6 injection, it would also give a very sustained dependable
7 control of tumor. In real-life setting for patients, that
8 basically means that patient would have come less frequently,
9 be monitored with much more efficacy and the problems of

11:35AM

10 compliance that we see with pills would not exist, because we
11 would know the injection is given and it's in there. So if
12 it's working, it's working.

13 Q. And does Wakeling 1991 demonstrate the frequency of the
14 treatment with the oil depot formulation?

11:35AM

15 A. It was given once every four weeks.

16 Q. And what does Wakeling 1991 tell a person of skill in the
17 art about using fulvestrant to treat hormone-positive breast
18 cancer?

11:35AM

19 A. So if you look at the last line of what is put up there,
20 it says that data available for fulvestrant indicate that pure
21 antiestrogens may find a valuable place in treatment of breast
22 cancer. This product will be used to test this proposition.
23 So it kind of carries it forward and offers it for further
24 research to the colleagues as well as their own lab.

11:35AM

25 Q. And you're referring to DDX-10-14?

1 A. Yes, I am.

2 Q. Did Wakeling 1991 indicate whether further study with
3 fulvestrant would continue?

4 A. Yes, it did. The last line again states that this would
11:36AM 5 be used to test this proposition, which means further studies
6 would continue.

7 Q. Thank you. Let's move on to Wakeling's next publication
8 in 1992. And can you explain what was disclosed in Wakeling
9 1992?

11:36AM 10 A. Wakeling 1992 was a summary of what his findings were
11 from Wakeling 1991, being presented in sort of a review
12 fashion so that it was a -- his attempt to capsulize what they
13 found, his attempt to also disseminate information so other
14 researchers in the field would also move on with their
11:36AM 15 research with this product, and sort of set the standard of
16 care for what was available, known about this product at that
17 time.

18 Q. Okay. Let's go on to the next piece of literature, then,
19 Dukes 1992. And in what journal was Dukes 1992 published?

11:37AM 20 A. It was published in the Journal of Endocrinology.

21 Q. And who were the authors?

22 A. Authors again were Dr. Dukes, Dr. Miller, Dr. Wakeling
23 again and Waterton.

24 Q. And would the Journal of Endocrinology be reviewed by
11:37AM 25 breast cancer researchers?

11:37AM 1 A. Yes, it was a major journal to look at because bulk of
2 breast cancers were endocrine positive, ER positive and lot of
3 endocrine related research was appearing in the journals that
4 were dealing with endocrinology. So it was a major area where
5 these teams were being laid out.

6 Q. And what does Dukes 1992 indicate to a person of skill in
7 the art who would be interested in developing a treatment for
8 hormone-positive breast cancer?

11:38AM 9 A. So this study further explored the -- for potency and
10 efficacy of fulvestrant by studying the ovariectomized monkeys
11 and, in fact, on the uterus of these monkeys. They basically
12 used a novel technique which was an MRI scan. So they didn't
13 actually have to weigh the uterus, they would simply estimate
14 the growth of the lining of the uterus by doing sequential
11:38AM 15 MRIs, and this was important study in its own way because it
16 attained sustained blockade effect of estrogen on monkey
17 uterus in a dose-dependent manner for three to six weeks.

18 He also demonstrated that repeated injections of
19 4 milligrams per kilogram at four weekly intervals provided an
11:39AM 20 effective blockade for uterine proliferation.

21 This was an extension of what Dr. Wakeling had
22 suggested, but in a slightly more sophisticated technology.
23 This was confirming what had been seen earlier.

11:39AM 24 Q. And Dr. Mehta, just for the aid of the court reporters
25 here, if they have a question, if you can just --

1 A. Absolutely, I'm answering, I'm looking at them, I'm
2 answering. I speed up sometimes and I will slow down and
3 utter each word, no problem.

11:39AM 4 THE COURT: Was the objective of the Dukes 1992, was
5 it to study the uterine issue?

6 THE WITNESS: So it basically, yeah, it wanted to
7 study the uterine issue but it also wanted to study the
8 administration, the dose, the injectability. So it wasn't --
9 Macaca monkey is a larger animal and easier to study than
11:40AM 10 practices for mice, and I think the two things we established
11 here, one was that, yes, he proved again that the uterine
12 simulation was no longer happening with, because of this
13 product, and he showed that this was the way it could happen.

14 THE COURT: So it seems that it wasn't really related
11:40AM 15 to the treatment of breast cancer, but more so towards --

16 THE WITNESS: If the treatment was efficacious
17 towards the side effect, right.

18 THE COURT: Yes.

19 BY MS. PETERSON:

11:40AM 20 Q. And what was the significance of the monkeys in the study
21 having been treated with estrogen?

22 A. And so they were ovariectomized, which means there's a
23 physiological model resembling a postmenopausal woman, and
24 then being given estrogen means that they were challenged with
11:40AM 25 estrogen, but these powerful antiestrogen could block that and

1 not let the estrogens create increase in the size of the
2 lining of uterus. It would basically prove the hypothesis
3 that this was a product that protected the uterus.

11:41AM 4 Q. And was your testimony just now, that was a -- just for
5 the record, that was in relation to DDX-10-016?

6 A. Yes.

7 Q. And what other results did Dukes 1992 report?

11:41AM 8 A. So basically, the Dukes, again, from my vantage point,
9 brought the dose of 4 milligrams per kilogram and also showed
10 that there could be a sustained blockade for one month with
11 this dose, and this dosing interval is likely to be clinically
12 relevant in therapeutic studies of breast cancer. This is
13 from the abstract itself, largely because this would translate
14 into monthly visits and monthly injections.

11:41AM 15 Q. And you're referring to the language on DDX-10-17?

16 A. Yes, I am.

17 Q. Can you determine how the 4-milligram per kilogram
18 formulation tested in Dukes 1992 would compare to a dose for
19 breast cancer patients?

11:42AM 20 A. So, in '90s, when we calculated dose or ordered drugs,
21 the ruling paradigm was, we would say for a 60 to 70 kilogram
22 woman. And if you say 70 kilo, then you're coming to
23 280 milligrams of dose. If you do 60, then it's slightly less
24 than 250. So it sort of approximates the dose that was to
11:42AM 25 come in future.

1 Q. And does Dukes 1992 report on the duration of action of
2 fulvestrant?

3 A. Yes, it does, it says that the blockade continued for
4 four weeks.

11:43AM 5 Q. And how would that four week time period inform a person
6 of skill in the art about the use of fulvestrant for treating
7 breast cancer?

8 A. It would translate into a depot injection once every
9 month.

11:43AM 10 Q. Let's move on to the next preclinical study from your
11 overview, Wakeling 1993.

12 Did Wakeling 1993 report on another animal study?

13 A. He summarized the available state of art at San Antonio
14 Symposium of this new pure antiestrogen that got eventually
11:44AM 15 published in Breast Cancer Research and Treatment.

16 Q. And what does Wakeling 1993 report?

17 A. It again goes over these studies we have covered, it
18 looks at the -- can I have the available piece? Okay.

19 So Wakeling goes on to say that the oil base
11:44AM 20 formulation of fulvestrant in experimental studies in rats
21 showed that the antiestrogen activity could be sustained for
22 long periods with single injection.

23 Q. And what does Wakeling mention is described about the
24 administration of fulvestrant?

11:44AM 25 A. So it's basically describing an oil depot injection, a

1 single injection intramuscularly -- single injection at four
2 weekly intervals giving an effective blockade of the same
3 duration, four weeks.

11:45AM 4 Q. And does Wakeling 1993 provide any information to a
5 person of skill in the art as to what the dose and frequency
6 of administration should be for fulvestrant?

7 A. So again, as I indicated earlier, a 65, 60, 70 kilo
8 woman, the dose starts to approximate 250 milligrams, it's
9 given in a once a month oil depot injection and it allows you
11:45AM 10 to have a sustained blockade for about a month. So those are
11 the things that are starting to become somewhat clear in the
12 preclinical science.

13 Q. And this is in reference to your demonstrative DDX-10-19?

14 A. That is correct.

11:45AM 15 Q. What does Wakeling 1993 tell the person of skill in the
16 art about the mechanism of action of the fulvestrant?

17 A. Basically it talks about very powerful antiestrogen
18 reaction of this particular product, which can probably
19 sustain 100 percent blockade of the estrogen receptor. And
11:46AM 20 finally concludes by saying that there is a powerful rationale
21 which argues for the superiority of this particular
22 antiestrogen over other treatments.

23 THE COURT: Antagonist.

24 THE WITNESS: Antagonist.

11:46AM 25 BY MS. PETERSON:

1 Q. Did Wakeling 1993 provided any teaching as to the
2 sequence in which fulvestrant could be used as a potential
3 endocrine agent for the treatment of hormonal dependent breast
4 cancer?

11:46AM 5 A. It does, because these were oophorectomized patients and
6 the treatment of choice for patients who had relapsed after
7 tamoxifen was becoming an increasingly important subject. So
8 what Wakeling in his particular article surmises is that
9 there's a sound rationale for treating patients who have
11:47AM 10 relapsed on adjuvant tamoxifen therapy with the pure
11 antiestrogens.

12 Q. And you're referring to DDX-10-21 in connection with your
13 testimony here?

14 A. Yes, I am.

11:47AM 15 Q. What other conclusions did Wakeling 1993 provide?

16 A. So summarizing the fact that this was the results that he
17 found impressive for potentially this group of patients, he
18 goes on to say that an initial therapeutic trial has started
19 in patients with advance breast cancer who have failed on
11:47AM 20 tamoxifen.

21 Q. Let's go to the last of the preclinical publications from
22 your overview. Can you tell me what generally is reported in
23 Dukes 1993?

24 A. So again, looks at an antiuterotrophic effect of pure
11:48AM 25 antiestrogens on female monkeys with sequential MRI's.

1 Q. What would a person interested in developing a treatment
2 for hormonal dependent breast cancer take away from this
3 article?

11:48AM 4 A. So basically it's again validation of the earlier idea
5 that this was an important new mechanism of action. I think
6 the only difference about this particular group was that these
7 were not oophorectomize animals.

8 Q. And what does that mean?

11:49AM 9 A. That basically means that this particular physiological
10 system tried to resemble a premenopausal woman.

11 Q. And what were the results?

12 A. The results were described as being unpredictable and
13 variable, which means that they did not produce the kind of
14 results one saw in a postmenopausal mortal, these results were
11:49AM 15 not very, very predictable and reliable.

16 Q. Now, overall looking at all of these preclinical studies,
17 what do they tell a person of ordinary skill in the art
18 looking for new treatments for hormone positive breast cancer?

11:49AM 19 A. That there was a new agent, that it had a new mechanism
20 of action. That it did not have cross-resistance with the
21 drug in question, tamoxifen. That it was working very well in
22 postmenopausal women. That there was a way of administering
23 it at 4 milligrams per kilogram dose and in an oil based depot
24 injection that could be given for sustained blockade for four
11:50AM 25 weeks.

1 Q. So let's talk now about your clinical study slides.

2 What is depicted in this slide as it relates to the
3 clinical studies?

4 A. So DeFriend basically looked at tolerance,
5 pharmacokinetics, and short term biological effects in women
6 with primary breast cancer. This was a short-acting
7 formulation. They were able to reach plasma levels of 27
8 nanogram per mL. And was very well tolerated.

9 Howell, going on from there, established safety in
10 dosing in some oves. Howell went on to look at this in actual
11 patients who had relapsed on tamoxifen. So he looked at
12 pharmacokinetic, as well as therapeutic effects in advance
13 breast cancer. Again, having used a caster oil base injection
14 long-acting. Use 250 milligrams per month. And 13 out of 19
15 patients responded.

16 Q. Let's take a closer look at DeFriend 1994.

17 Can you identify who the authors were of DeFriend 1994?

18 A. We can see familiar names. Beside that of Dr. DeFriend,
19 we have Anthony Howell, we have Nicholson, we have Mitch
20 Dowsett, we have Dr. Robertson, we have Alan Wakeling, several
21 of the researchers from that time in the UK and several of the
22 team from AstraZeneca.

23 Q. And what does the fact that these authors were studying
24 fulvestrant, what does that mean to you?

25 A. These were all very leading authors in their field with

1 good track records, so they were focused on this product in
2 terms of bringing it to further in its research, the product
3 definitely meriting attention.

11:52AM

4 Q. Now, how many patients were included in the DeFriend
5 study?

11:52AM

6 A. So he had a control group of 19 patients and a treatment
7 group of 37 patients, they received daily intramuscular
8 injections of fulvestrant in two dose settings, 6 milligrams
9 and 18 milligrams for seven days and then they were taken for
10 surgery.

11 Q. And did the study include postmenopausal or premenopausal
12 women?

13 A. They were only considered for the study if the women were
14 postmenopausal.

11:53AM

15 Q. And what does DeFriend tell us about how the product was
16 administered?

17 A. He gave as an intramuscular injection in the buttocks of
18 a short-acting formulation.

11:53AM

19 Q. And what else does DeFriend tell us about the
20 short-acting formulation?

21 A. So he gave it for seven days and he used it in two doses,
22 so 6 milligrams versus 18 milligrams, and he was able to
23 measure impact in terms of estrogen receptors, clinical
24 biochemistries, and serum levels of certain hormones.

11:53AM

25 Q. And what was the dose that was administered?

1 A. Two kinds of dose, 6 and 18.

2 Q. I meant the concentration.

3 A. 20 milligrams per mL.

4 Q. And what were the results of this trial reported in

11:54AM 5 DeFriend 1994?

6 A. So one of the things reported were the blood levels he
7 got with the lower dose and the higher dose. And, as you can
8 see in the demonstrative, the higher dose, those levels go all
9 the way up to 25. So when we have 18 milligrams for seven

11:54AM 10 days, the end point seems to be ending at 25 and when we have
11 6 milligrams for seven days, the end point seems to be under
12 10.

13 Q. And is the DeFriend reference you're referring to
14 DDX-10-27?

11:54AM 15 A. I am.

16 Q. And does DeFriend report any information concerning the
17 biological activity of the drug?

18 A. He does. He found --

19 Q. Go ahead.

11:54AM 20 A. He found significant reductions in the estrogen receptor
21 levels in estrogen positive tumors in the group both at the 6
22 milligram level and 18 milligram level but very profound
23 reduction at the 18 milligram level. And the 18 milligram
24 level was statistically very significant, 0.01, and it brought
11:55AM 25 the level down from .73 to .01, which is an extremely low

1 estrogen level and impressive.

2 THE COURT: What dose levels, the 6 milligram and --

3 THE WITNESS: 18.

4 THE COURT: 18.

11:55AM 5 THE WITNESS: Only those levels, so we have the
6 lowest and highest possibly is there.

7 BY MS. PETERSON:

8 Q. Is reduction of receptor expression a measure of
9 efficacy?

11:55AM 10 A. It would translate into efficacy because if you have less
11 receptors, there's less switches to turn on this cancer and
12 its activity.

13 THE COURT: Can you explain that, please?

14 THE WITNESS: If you have less receptors -- each
11:56AM 15 receptor is like a switch on a tumor cell and it turns on the
16 electrical, the chemical messages start to go to the cell to
17 divide, multiple, spread, and having less number of estrogen
18 receptors would basically mean that it would be that much less
19 chance for the tumor to progress and grow.

11:56AM 20 BY MS. PETERSON:

21 Q. Did DeFriend report any information about side effects in
22 the patients?

23 A. Well, it was a seven day study and they saw no adverse
24 side effects, no patients were withdrawn from the study
11:56AM 25 because of drug toxicity.

1 Q. What does DeFriend 1994 teach a person of skill in the
2 art who would be interested in developing a treatment for
3 hormone positive breast cancer?

11:56AM 4 A. So this was a Phase II -- Phase I study in my mind, it
5 looked at the doses, it looked at safety, and it established
6 safety and established some guidelines for doses, and went on
7 to say that this was a new generation of potent pure
8 antiestrogens and is the first therapeutic agent to be
9 investigated in clinical trials with a potential so completely
11:57AM 10 to deprive breast cancer tumors of estrogenic stimulation.

11 And he goes on to say that Phase II trials with a long-acting
12 formulation of this agent are now in progress.

13 Q. Now, DeFriend 1994 used a short-acting formulation that
14 was administered once a day. Would that be feasible for
11:57AM 15 further clinical studies in humans?

16 A. In actual patient care that would be absolutely difficult
17 to administer because you cannot expect for months for a woman
18 to have daily injections, so this was impractical. For a
19 presurgical seven day trial it was okay.

11:58AM 20 Q. Okay. Let's move on to the next piece of literature from
21 your clinical study section.

22 This is the Howell 1996 article?

23 A. Yes.

24 Q. And what type of study was conducted in Howell 1996?

11:58AM 25 A. It was a pharmacokinetic, pharmacological in studying

1 antitumor effects of fulvestrant in women with advanced breast
2 cancer.

3 Q. And do you recognize the authors of Howell 1996?

4 A. They're all very well known. Dr. Howell, Dr. DeFriend,
11:58AM 5 Dr. Robertson, Sutcliffe, Walton, several from the labs of
6 Zeneca Pharmaceuticals.

7 Q. Would you refer to this as a Phase II clinical trial?

8 A. It was.

9 Q. And what journal is Howell 1996 published in?

11:59AM 10 A. It was published in the prestigious British Journal of
11 Cancer.

12 Q. Is that a journal read by breast cancer researchers?

13 A. Absolutely.

14 Q. What was the purpose of the study in 1996.

11:59AM 15 A. So this was the first investigation of an antiestrogen
16 fulvestrant in patients with breast cancer, and the
17 demonstrative that predicted levels of the drug from animal
18 experiments can be achieved and maintained for one month.

19 THE COURT: Are you saying predicted?

11:59AM 20 THE WITNESS: Predicted. Right.

21 Following intramuscular injections of the long-acting
22 formulation.

23 Can I have the next?

24 BY MS. PETERSON:

11:59AM 25 Q. Okay. How was the study designed?

1 MS. PETERSON: Next slide.

2 THE WITNESS: So these were again postmenopausal
3 women who had either become refractory to tamoxifen after
4 being given tamoxifen in an adjuvant setting or had disease

12:00PM 5 stabilization and then subsequently progressed and so now they
6 were not responding to tamoxifen.

7 THE COURT: Schooch the microphone away just a little
8 bit.

9 THE WITNESS: Yeah.

12:00PM 10 BY MS. PETERSON:

11 Q. How many patients were in the study?

12 A. The study, I believe, had -- I'm having a block for a
13 second.

14 19 patients.

12:00PM 15 Q. And what does Howell say about the dosage that was
16 administered?

17 A. So they gave a 5 mL depot intramuscular injection, which
18 was a castor oil base vehicle, and he started first five
19 patients at 100 milligrams to make sure there was no new

12:01PM 20 toxicity. And at the end of the month when they did not see
21 that, they upgraded all those patients to the 250 milligram
22 dose and started the new group of patients on 250 milligram
23 dose.

24 Q. And you're referring to DDX-10-32?

12:01PM 25 A. Yes, I am.

1 Q. What were the results reported in Howell 1996?

2 A. So all 19 patients were evaluated, six were unresponsive
3 and 13, 69 percent, responded. And they had a median
4 durational response of 25 months, which was pretty impressive
5 for a Phase II.

12:01PM

6 Q. Were some of the 13 patients that were designated as
7 responders, did they all show progression or did they all show
8 a partial response to the drug?

9 A. So I think six of them had stable disease and the rest
10 showed actual shrinkage of tumor.

12:02PM

11 Q. And would it be typical to categorize results, a new
12 change being an actual response to the drug?

13 A. So, number one, the group that published this, and we
14 even now basically consider no news is good news, there's no
15 progression in the disease, that means the patient is
16 responding. Because if the patient is not responding, there
17 would be progression and there would be proof of that, so
18 stable disease at this moment is considered a very effective
19 indicator of efficacy. One would obviously hope for shrinkage

12:02PM

20 of tumor evidence. Patients who actually responded were in
21 one category but people who were stable were sort of lumped
22 with people who responded.

12:03PM

23 Q. So I understand, you're saying the authors categorized
24 the patients who were stable or no change as also being
25 responders to the drug?

12:03PM

1 A. That is correct.

2 Q. The reference you're referring to is DDX-10-33, is that
3 right?

4 A. Yes.

12:03PM 5 Q. What does Howell say about the side effects of the dose
6 that was administered to the patients?

7 A. No side effects, serious side effects were seen in the 19
8 patients.

9 Q. And you are referring to DTX-10-34?

12:03PM 10 A. Yes, I am.

11 Q. Does Howell make any conclusions with respect to the
12 volume of the drug that was administered?

13 A. They were all either mLs in the buttock. And again,
14 talking about the side effects there were no local side
15 effects, no pain, no sciatica, no abscesses, things that we
16 worry about with large injections in that site.

17 Q. What do the authors ultimately conclude about the
18 clinical trial results reported in Howell?

19 A. So, this is a pure antiestrogen in long term treatment.
12:04PM 20 It seems to be active as an antitumor agent in patients with
21 advanced breast cancer who have relapsed previously on
22 tamoxifen.

23 Q. And for reference you are referring to DTX-10-35?

24 A. I am.

12:04PM 25 Q. Now, what is the significance of Howell 1996's conclusion

1 that fulvestrant is active as an antitumor agent in patients
2 who had previously relapsed on tamoxifen?

12:05PM 3 A. It tells you that there is no cross-resistance with
4 tamoxifen. People who failed tamoxifen will still respond to
5 this drug. That basically mean it's active in that particular
6 group and something worth exploring.

7 Q. Let's take a look now, shift to what you had referred to
8 earlier as the corroborative studies, I believe. Turning to
9 the first one in the group, Robinson 1997. What is that?

12:05PM 10 A. So, Robinson 1997 was a study where he took the data from
11 Howell, the patients -- 19 patients and he took his patients,
12 who were on metrozole acetate.

13 Let me digress and give a little idea of metrozole
14 acetate. So until that point before these other drugs were to
15 arrive on the horizon when people failed on tamoxifen,
16 megestrol acetate was considered to be standard of care second
17 line drug. And so we said okay, if this is the standard
18 second line drug, let's compared it to this new product, is it
19 the same or better or what. But this was not the same trial,

12:06PM 20 these people were not in the same trial, he took Howell's
21 trial, which he was part of, and he took another trial where
22 his be patients failed on megestrol and he compared efficacy.

23 And he came up with the findings that in case of
24 those who were treating with fulvestrant, the duration of
12:06PM 25 remission, whether they have partial remission or stable

12:06PM 1 disease, was 26 months. And if you went to the standard of
2 care at that time for failure, which was megestrol, it was
3 14 months. So it was an almost doubling of the duration. And
4 this -- basically they concluded, this particular study in the
5 paper by saying that these finding support further clinical
6 comparisons between established estrogen therapies and
7 fulvestrant.

8 Q. What journal was Robinson 1997 published in?

9 A. The Breast.

12:07PM 10 Q. And would breast cancer researches in the nineteen
11 nineties have been following that journal?

12 A. Absolutely.

13 Q. For reference, you've been referring to DTX-10-37 as part
14 of your testimony just now?

12:07PM 15 A. Yes, I am.

16 Q. Now, did Robinson 1997 describe the Howell 1996 in any
17 other way?

18 A. He goes on to say that a -- number one, he calls it Phase
19 II study, so he's basically looking at efficacy. And he goes
12:07PM 20 onto say rather surprisingly for a second antiestrogen not
21 only did most patients respond, but the median duration was
22 longer than suspected. So they were basically taken by
23 surprise that this drug suddenly was far better than what they
24 were using in clinical practice to treat women who had failed
12:08PM 25 on tamoxifen. Rather surprisingly, it's just their major

1 comment.

2 Q. And you are referring to your demonstrative DDX- 10-3?

3 A. Yes, I am.

4 Q. In what your opinion, what does Robinson 1997 teach the

12:08PM 5 person of ordinary skill in the art about the use of

6 fulvestrant to treat hormone positive breast cancer?

7 A. It basically again confirms that there is an antitumor
8 efficacy. It confirms that there is -- there are no signs of
9 agonist activity that one sees with tamoxifen. It sort of

12:08PM 10 sets up the stage for him being able to say that this was a
11 exciting new product and seems to be working in patients who
12 have progressed on tamoxifen.

13 Q. And I think you had explained earlier that this wasn't
14 actually a real study between two -- between the two drugs,
15 right?

12:09PM 16 A. So, the classic Phase III study would be randomized where
17 half would be on one and half would be on the other. The one
18 would be the standard of care and the other arm would be the
19 new drug. And then this would then be tested to see if one
20 was better than the other.

12:09PM 21 He did do a comparison to standard of care, but not
22 within the umbrella of single trial. He used Howell's
23 patients and looked at their response and then looked at other
24 patients that were in his trial on megestrol and compared it.
25 That's called cross-trial comparison and it's used basically

1 to see if the hypothesis seems to be working.

2 Q. Now, earlier this week Dr. Robinson testified that there
3 were several questions remaining about the use of fulvestrant
4 to treat hormone positive breast cancer after the results of
12:10PM 5 Howell 1996 were reported. Do you recall his testimony?

6 A. Yes, I do.

7 Q. Chris, could you bring up slide number 45 from Dr.
8 Robinson's direct testimony?

9 THE COURT: Were you here when he testified?

12:10PM 10 THE WITNESS: Yes.

11 MS. PENSABENE: I'm going to object to this as not
12 having any notice from the defendants that they were going to
13 use this slide with this witness.

14 MS. PETERSON: Well, it's not one of our
15 demonstratives, it's one your demonstratives.

16 MS. PENSABENE: Your Honor, the pretrial order is
17 really clear, the demonstratives that are going to be used on
18 direct examination have to be identified prior to the witness.
19 This is a demonstrative, it's being used on direct examination
12:10PM 20 with their witness.

21 MS. PETERSON: We can do the examination without the
22 demonstrative.

23 THE COURT: Okay.

24 BY MS. PETERSON:

12:10PM 25 Q. So, Dr. Mehta, you were here when Dr. Robinson testified

1 on Monday, right?

2 A. Yes, I was.

3 Q. Do you recall Dr. Robinson testifying that there were
4 several questions remaining about the use of fulvestrant to
12:11PM 5 treat a hormone-positive breast cancer, right?

6 A. Yes.

7 Q. Did Dr. Robinson reference Howell 1996 containing a group
8 of favorably selected patients? Do you recall that?

9 A. Yes, he did.

12:11PM 10 Q. Do you agree with Dr. Robinson that that was a concern
11 with the Howell results?

12 A. I don't.

13 THE COURT: Was it the patients the 19, were favored?

14 THE WITNESS: Highly selected group. Highly, that's
12:11PM 15 what he said.

16 THE COURT: What was the word he used, biased or --

17 THE WITNESS: Highly selected or, you know, the ones
18 they were probably likely to respond and so subsequently they
19 felt that maybe in a more generic group the similarly
12:11PM 20 responses might not have come. So his words were "highly
21 selected group."

22 THE COURT: Yes. Do you disagree with him?

23 THE WITNESS: I do.

24 THE COURT: Why?

12:11PM 25 THE WITNESS: So, the drug paradigm we were looking

1 for in this time frame would be postmenopause women that had
2 taken tamoxifen, and that's all these women were. They were
3 highly selected in a way, but yes, they were not triple
4 negative. They are highly selected in the way --

12:12PM

5 THE COURT: They were not what?

12:12PM

6 THE WITNESS: Triple negative. They were also not
7 ones that had failed other compounds. Like, if this was a
8 second line trial of this drug, it is likely to be quite
9 successful, but not third for people who had not yet been
10 exposed to aromatase inhibitors which were in trial. So,
11 subsequently criticism was that, okay, this is a selected
12 group because you pick patients who had just failed tamoxifen
13 and they were not down the line in terms of lines of therapy.
14 That's what I understand. Nobody has actually in the
15 literature explained what they meant by highly selected.

12:12PM

16 But the group was basically, by Howell's own
17 admission, postmenopausal women who had progressed on
18 tamoxifen. And these were women who were -- either failed on
19 tamoxifen and progressed or they stopped tamoxifen and then
20 the disease had come back and now they had progressed. So,
21 it's sort of the classic patient where such a drug would be
22 looked for but certainly not a patient who has been failing
23 several lines of treatment where this drug would have been
24 introduced. That's what I think he meant and I think I don't
25 agree.

12:13PM

1 BY MS. PETERSON:

2 Q. And do you also recall Dr. Robinson's testimony about
3 Howell 1996's categorization of patients with no change as
4 responders?

12:13PM 5 A. Yes, I do.

6 Q. Would you have found that to be a clinically relevant
7 finding?

8 A. I think no change is response. Because in oncology in
9 stage four disease no news is good news. So if a patient does
10 not show progressive tumor and the tumor is stable, achieving
11 stability means you are controlling the growth. So

12 controlling growth is what we are trying to do. And stable
13 patients without symptoms and without anything is good news.

14 Q. What about tamoxifen withdrawal? What does that refer
15 to?

16 THE COURT: Can we put up that chart?

17 MS. PETERSON: Sure.

18 THE COURT: From Howell?

19 MS. PETERSON: Oh.

12:14PM 20 THE COURT: Isn't that the chart he's referring to?
21 The responders?

22 MS. PETERSON: Yeah, sure. That would --

23 MR. PRUGO: You are referring to Table 2?

24 THE COURT: Yes. Could I just see it?

12:14PM 25 So, you disagree with how Dr. Robinson broke down the

1 responders and nonresponders, is that's what you are saying?

2 THE WITNESS: That's correct. He took away the six
3 with no change saying that should not be counted as
4 responders. But in classic oncology teaching, stable disease
12:15PM 5 in metastatic breast cancer is control. You don't always see
6 shrinkage of tumor, but not growing tumor, not having
7 increasing symptoms basically means that the tumor is under
8 control and you would accept that.

9 THE COURT: And you would put it under a response
12:15PM 10 category?

11 THE WITNESS: I would.

12 THE COURT: Thank you.

13 BY MS. PETERSON:

14 Q. Just for clarity as well, the authors of Howell, what
12:15PM 15 category did they put the no change patients in?

16 A. They put it as part of the 69 percent that responded. So
17 they had bunched it with the responses.

18 Q. And was Dr. Robinson one of authors on that study?

19 A. Yes, he was.

12:15PM 20 Q. Okay. I think we were going to talk next about tamoxifen
21 withdrawal.

22 A. Yes.

23 Q. Are you familiar with that term?

24 A. Yes, I am.

12:15PM 25 Q. What does that refer to?

1 A. So, patients who are failing on tamoxifen, there is one
2 small group that is -- actually, tamoxifen is fueling the
3 growth of the tumor because it also has the estrogen
4 stimulating faculties. And it does that. And in that case,
12:16PM 5 if you withdraw tamoxifen, that small group, you will see a
6 short response as the stimulators disappear and then the tumor
7 would start to grow again.

8 Q. Now, do you agree with Dr. Robinson's conclusions about
9 Howell 1996 and the effect of tamoxifen withdrawal?

12:16PM 10 A. So, I don't think one can quantify it because, again,
11 when you have tamoxifen withdrawal, this is a short-lived
12 phenomenon, can't really use it for therapeutic action. I
13 mean, yes, you can stop tamoxifen, there may be some time
14 during which the tumor may stop progressing, but soon tumor
12:17PM 15 will start to grow again. So I'm not exactly sure how it
16 impacted the numbers. The overall numbers are small, so,
17 again, I'm not sure how much impact it would have had. It's
18 sort of conceptual.

19 Q. And are you familiar with the term "estrogen
12:17PM 20 sensitivity?"

21 A. Yes, I am.

22 Q. Can you explain that?

23 A. So, to prolong life a woman in stage four breast cancer,
24 as you proceed down the treatment line, first line, second
12:17PM 25 line, third line, it's important that the tumor cells retain

1 endocrine sensitivity. If the endocrine sensitivity goes way,
2 then the tumor becomes unresponsive.

3 Q. And do you recall what Dr. Robinson's testimony was
4 regarding the endocrine sensitivity that was reported?

12:17PM 5 A. He was worried that in 10 patients, patients stopped
6 responding to megestrol after the antiestrogen fulvestrant was
7 used and he wondered at that time that -- whether that would
8 mean that if you used fulvestrant would the woman be deprived
9 of any further treatment options.

12:18PM 10 Q. So, was Dr. Robinson -- is the suggestion -- strike that.
11 Is the suggestion that if you take someone off of
12 fulvestrant that they would become sensitive to all other
13 endocrine therapies?

14 A. No. The suggestion was that would fulvestrant cause a
12:18PM 15 situation where subsequent treatments would fail. That was
16 his main concern that he voiced.

17 Q. And the subsequent treatment at issue in Robinson 1997,
18 what drug was that?

19 A. That was megestrol.

12:18PM 20 Q. And so do you agree necessarily with the hypothesis that
21 the patients who later became insensitive to the megestrol
22 acetate, that would mean that they have demonstrated an
23 endocrine sensitivity profile overall?

24 A. Again, I don't agree.

12:19PM 25 Q. Why not?

1 A. So, you already have proven by also prior art that the
2 fulvestrant is a far more powerful agent. And what we are
3 finding on quality is if you use a powerful targeting agent to
4 block a target such as an endocrine receptor, the agents which
12:19PM 5 were of an earlier era, which were much weaker, would now not
6 work. You could only use the most powerful weapon. And if
7 the disease progresses, you cannot go back to drugs which were
8 inferior to that.

9 THE COURT: Hold on a second.

12:19PM 10 MS. PENSABENE: Your Honor, we've been really patient
11 with this outside the scope, but this is way outside of the
12 scope of the expert reports here.

13 MS. PETERSON: I think I'm almost done with this. We
14 can move on.

12:19PM 15 MS. PENSABENE: I move to have this testimony
16 stricken, your Honor.

17 THE COURT: I don't know what's outside the scope.
18 The last answer?

19 MS. PENSABENE: His whole last answer, this last two
12:19PM 20 answers.

21 MS. PETERSON: The ones on the endocrine
22 insensitivity.

23 MS. PENSABENE: This witness never testify about
24 that, never expressed such an opinion in his expert reports.

12:20PM 25 THE COURT: Okay.

1 Do you agree with that? I mean, unless there is an
2 objection I'm assuming that it's all relevant and within the
3 scope of the expert report. It's much harder for the court to
4 go back and strike testimony because much of it becomes
12:20PM 5 intertwined. So, do you agree that his opinions relating
6 to -- I guess it's the endocrine sensitivity issue, those are
7 all outside the scope?

8 MS. PETERSON: Well, Dr. Mehta did include the
9 Robinson and discussed the Robinson '97 publication in his
12:20PM 10 expert reports, and in particular the subsequent treatments
11 with megestrol acetate. I don't know if he specifically
12 mentioned the words "endocrine sensitivity" in his report, but
13 he certainly did discuss the Robinson 1997 article and the
14 impact of it.

12:21PM 15 THE COURT: So, the objection goes to the
16 insensitivity to the megestrol acetate? Is that the issue?

17 MS. PENSABENE: That is correct, your Honor, that was
18 never discussed in --

19 THE COURT: Okay.

12:21PM 20 MS. PENSABENE: -- Dr. Mehta's report.

21 THE COURT: So that testimony will not be considered.

22 MS. PETERSON: And just to confirm, you are talking
23 about the endocrine sensitivity testimony?

24 THE COURT: Apparently, yes.

12:21PM 25 BY MS. PETERSON:

1 Q. Okay. Moving on. Are you familiar with the term of an
2 off target effect?

3 A. Yes, I am.

4 Q. And do you recall criticism by Dr. Robinson about
5 fulvestrant relative to impacts on other off target tissues?

6 A. Yes.

7 Q. What does that mean, this off target effect?

8 A. If the target is the estrogen receptor positive breast
9 cancer, then all other organs outside that domain would be off

10 target. And what he was referring to was the effect of this
11 particular agent on other organ systems, bones, heart,
12 etcetera.

13 Q. And had that already been reported in the prior art?

14 A. There is reference in the prior art where there is a
15 suggestion that there is no impact on bone health.

16 THE COURT: On what?

17 THE WITNESS: On bone health.

18 Q. And when you have potential downsides like that, how does
19 a clinician weigh those in view of the other benefits of the

20 drug?

21 A. So, all new therapies have obviously some drawbacks. One
22 has to see what you are trying to achieve. If you are trying
23 to achieve efficacy for long life and provide one more mode of
24 bringing the disease in control, and if there were some side
25 effects that did not seem to be as important as controlling

1 the disease, that would be a tradeoff that one would be able
2 to accept as the therapy index. You have this much of
3 efficacy and you accept this much of toxicity.

12:23PM

4 Q. In your opinion, would the fact that fulvestrant had been
5 administered as an intramuscular injection in the Howell
6 study, would that have dissuaded a person of skill in the art
7 from continuing work with fulvestrant?

8 A. No.

9 Q. Why not?

12:23PM

10 A. Because I think intramuscular is the route that ensures
11 compliance, close physician visits and takes away the chance
12 of patients missing their oral pills. So it's actually a very
13 good way of dealing with a very difficult stage of disease.

12:24PM

14 Q. And another aspect of Howell was the five mL injections
15 volume. Do you recall that?

16 A. Yes.

17 Q. In your opinion, would a 5 mL injection volume, would
18 that have been too large to have been considered as a possible
19 route of administration?

12:24PM

20 A. No. And there were no side effects reported of that.

21 Q. Are you familiar with the concept of maximum tolerated
22 dose?

23 A. Yes, I am.

24 Q. Can you describe what that is?

12:24PM

25 A. So, when you are doing Phase I studies, one of the

1 objectives is to say what's the maximum tolerated dose, and
2 what kind of toxicities it will produce. And based on the
3 toxicities, a dose is set which is then moved on to Phase II
4 trials to see efficacy. In oncology, sometimes maximum
12:25PM 5 tolerated doses is what you want to use because underdosing
6 can lead to tumor resistance and progression. Underdosing can
7 lead to a tumor line to evolve and get out of control, and
8 then subsequently not respond to even higher doses. So
9 maximum tolerated dose basically insures that you have
12:25PM 10 no emergence of resistance or late emergence of resistance and
11 that's what you want to administer to get maximum benefit for
12 what you are doing.

13 Q. Is that concept applicable to treatments for breast
14 cancer?

12:25PM 15 A. Yes, it is.

16 Q. And is it also applicable to treatments -- hormonal
17 therapy treatments?

18 A. Yes, it is.

19 Q. Why is that?

12:25PM 20 A. Because for every drug there is a optimum dose. And when
21 you are trying to set a dose, if the evidence suggests, like
22 in Howell it was 250 mg and it was tolerated without major
23 side effects and showed efficacy, I would stay with that dose
24 because in subsequent studies I would not like to tinker with
12:26PM 25 the possibility that the efficacy would drop.

1 THE COURT: But do you agree that he taught a lower
2 dose?

3 THE WITNESS: The Howell does say that one should try
4 lower doses, yes.

12:26PM 5 BY MS. PETERSON:

6 Q. But despite that, did researches, including Howell and
7 Dr. Robinson, continue testing the 250 mg dose?

8 A. They did. And that went into the Phase III trials.

9 Q. And the suggestion in Howell that you should be lower
12:26PM 10 than 250 mg, would that have motivated researches to not even
11 look at the 250 mg dose anymore?

12 A. The most impressive prior art was Howell's one study at
13 125 and 250, and so why would anybody try to change that?
14 Because you would base your further clinical studies on most
12:27PM 15 effective dose at a Phase II trial.

16 Q. Does it negate the results that were reported in Howell
17 with that 250 does?

18 A. It doesn't negate the results.

19 Q. Was the 250 mg dose in Howell 1996 the maximum tolerated
12:27PM 20 dose for fulvestrant?

21 MS. PENSABENE: Objection. That's outside the scope
22 of this witness' expert reports.

23 MS. PETERSON: We disagree. This opinion was
24 disclosed in his reply report.

12:27PM 25 THE COURT: Do I have it?

1 MS. PETERSON: Paragraph 16.

2 THE COURT: Do you recall rendering that opinion?

3 THE WITNESS: Yes, I do.

4 MS. PETERSON: Would you like a copy?

12:28PM 5 THE COURT: Yes. I don't think I have it up here.

6 Is it in his binder?

7 MS. PETERSON: It's not in his binder, your Honor.

8 THE COURT: Okay, thank you.

9 What was the question that was asked? Was the 250 mg

12:28PM 10 dose in Howell the most tolerated dose for fulvestrant? Is

11 that the question?

12 MS. MORAN: Maximum tolerated dose.

13 THE COURT: Excuse me, maximum.

14 MS. PETERSON: Yes, that was the question.

12:29PM 15 Okay. I'm sorry, your Honor, actually it's paragraph

16 17 of his report. Would you like a copy? May I approach?

17 THE COURT: Yes, please.

18 MS. PENSABENE: Now that counsel submits that, your

19 Honor, I'll withdraw the objection.

12:29PM 20 THE COURT: It seems it was. I'll keep it up here if

21 there is another objection. Thank you.

22 I think we're going to break it there. Why don't you

23 answer the question and we'll break for lunch.

24 THE WITNESS: I'm sorry?

12:29PM 25 THE COURT: Continue to answer the question.

1 THE WITNESS: If I remember the question correctly,
2 was that the maximum tolerated dose or not?

3 THE COURT: Was the dose that is disclosed in Howell,
4 which what was the 250 mg, was that the maximum tolerated dose
12:29PM 5 of fulvestrant?

6 THE WITNESS: No. I believe if you consider the
7 DeFriend trials, they had gone with 6 mg versus 18 mg dose.
8 That was given once a day for 7 days. If that was given once
9 a day for 7 days and if you take a 4-week interval where it
12:30PM 10 could be repeated and extrapolate to a 28-day cycle and
11 multiplication of 28 by 18 leads to a dose that is closer to
12 500 mg. So the dose disclosed in the Phase I trial seems to
13 have no side effects in that particular trial of DeFriend.
14 So, the dose disclosed seems to be around 500 milligrams of
12:30PM 15 fulvestrant.

16 THE COURT: Okay. We'll leave it at that.
17 We'll break for lunch. And if counsel many recall, I
18 will see you back at 2 o'clock. Okay? Thank you.

19 THE DEPUTY CLERK: All rise.

12:30PM 20 (Luncheon Recess 12:30 p.m.)

21 THE DEPUTY CLERK: All rise.

22 THE COURT: Okay. Great. Thank you. You may be
23 seated.

24 So, my criminal matter has been adjourned, and I
01:52PM 25 thought we would make use of the time. So we'll go about an

1 hour-ish or so, and then we will take our afternoon break.

2 Okay? So we can continue on.

3 MS. PETERSON: Actually, your Honor, before we
4 continue, upon further review, we did go back and look at
01:52PM 5 Dr. Mehta's expert reports with respect to the objection about
6 whether he had disclosed testimony concerning the endocrine
7 resistance, and we do think that it was properly disclosed in
8 his reply report, which you do have a copy of in front of you,
9 at Paragraph 15.

01:52PM 10 THE COURT: Did you share it with Ms. Pensabene?

11 MS. PETERSON: We have not yet.

12 THE COURT: You didn't talk to her about this?

13 MS. PETERSON: No.

14 But in Paragraph 15, he does -- Dr. Mehta does refer
01:52PM 15 to this portion of Robertson 1997 and the possibility of
16 fulvestrant resistance precluding further endocrine treatments
17 as a cause for concern. And then throughout the paragraph, he
18 discusses the benefits and down sides in the analysis that
19 would apply there. So we would ask for a reconsideration of
01:53PM 20 your ruling.

21 MS. PENSABENE: Your Honor, that is not about this
22 further endocrine insensitivity that's discussed in Robertson
23 1997. Robertson 1997 is not cited here; nor are the opinions
24 that were provided by Dr. Mehta on further endocrine
01:53PM 25 insensitivity. So I would stand by my objection that this is

1 not disclosed in his expert report.

2 THE COURT: So it doesn't seem to be within the scope
3 of what he was testifying to, but I would prefer to have the
4 benefit of the transcript. So were you through with the
5 questioning?

01:53PM

6 MS. PETERSON: I was through with the questioning,
7 and the witness was through with his answer, as well.

8 THE COURT: Okay. So there is a motion to
9 reconsider, and I'll reserve.

01:53PM

10 MS. PETERSON: Okay. Thank you, Your Honor.

11 Defendants will recall and resume the testimony of
12 Dr. Mehta.

13 BY MS. PETERSON:

14 Q. Dr. Mehta, if we could move on to the next publication
15 discussed in your overview timeline. This would be McLeskey
16 1998. Can you tell us what journal McLeskey 1998 was
17 published in?

01:54PM

18 A. *Clinical Cancer Research*.

19 Q. And tell me about the *Clinical Cancer Research* journal.

01:54PM

20 Is that something that breast cancer researchers would be
21 interested in?

22 A. Yes. It is the official journal of the American
23 Association of Cancer Research, and something that sort of is
24 offered just to clinicians, researchers, and people who are
25 doing bench and animal research. So it's kind of a place

01:54PM

1 where all research streams come together.

2 Q. And what was -- and, for the record, Dr. Mehta's
3 testimony here, he is referring to DDX-10-040.

4 Dr. Mehta, what was the purpose of McLeskey 1998?

01:55PM

5 A. So, McLeskey had a very unique idea. She basically was
6 looking at the MCF-7 cell line, which was until then the most
7 estrogen-sensitive cell LINE for experimentation. She changed
8 it in an -- she changed it in her laboratory, in her lab, and
9 created a cell line.

01:55PM

10 THE COURT: In her laboratory.

11 THE WITNESS: In her laboratory, and went on to
12 create a cell line that was totally independent, she thought,
13 of endocrine manipulation.

01:55PM

14 Now, to test her hypothesis, what she needed to do
15 was to try and bring two to three most powerful antiestrogenic
16 agents of that time, and what she chose were three agents that
17 she would test on the cell line and see if it retains its
18 independence, because her further research depended on showing
19 it, because this cell line was not manipulatable by changing
20 anything about the estrogen receptivity.

01:56PM

21 Q. So, if I could just make sure that we all understand,
22 Dr. McLeskey had taken a -- a cell line that was typically
23 hormone --

24 A. Sensitive.

01:56PM

25 Q. -- sensitive, and what did she do to it?

1 A. She changed it in her lab to make it a hormone
2 independent cell line. It's called transfection. And it was
3 basically a application of a growth factor, which then created
4 a cell line that would not respond to hormonal manipulation.

01:56PM 5 Q. And then what was the purpose for which she used the
6 fulvestrant on that cell line?

7 A. To prove that -- her hypothesis that this was not a
8 hormone manipulative cell line.

9 Q. And what other compounds did Dr. McLeskey use?

01:56PM 10 A. So she used a -- two aromatase inhibitor and one pure
11 antiestrogen. So she used letrozole, which was then
12 considered to be one of the powerful aromatase inhibitors; she
13 used formestane which, until mid-90s, was proved in Europe and
14 a major aromatase inhibitor; and for the antiestrogen, she
01:57PM 15 chose Faslodex® which was, in her mind, a very powerful new
16 antiestrogen agent.

17 Q. And, for the record, in your testimony, were you
18 referring to DDX-10-41 and -42?

19 A. Yes.

01:57PM 20 Q. Does Dr. -- or does McLeskey 1998 describe the
21 formulations of the fulvestrant that were used in this study?

22 A. She does. She uses two kinds of formulation. One is
23 a -- is a injectable in warm peanut oil, and she uses a second
24 formulation which is a injectable in castor oil. And these
01:58PM 25 are the two things that she basically is using as a source

1 material for fulvestrant.

2 Q. And does McLeskey 1998 provide any further description of
3 the composition of the castor oil formulation?

4 A. Yes, it does. It basically says it was a 50 milligram
01:58PM 5 per mL preformulated drug, in a vehicle of 10 percent ethanol,
6 15 percent benzyl benzoate, 10 percent benzyl alcohol, and
7 brought to volume with castor oil.

8 Q. And who supplied the formulation, the castor oil
9 formulation, to Dr. McLeskey?

01:58PM 10 A. This was supplied by Mr. B.M. Vose of AstraZeneca.

11 Q. And, for the record, Dr. Mehta's testimony -- was your
12 testimony related to DDX-10-043?

13 A. Yes.

14 Q. Now, why would McLeskey 1998 be relevant, in your
01:59PM 15 opinion, to a person of skill in the art who would be
16 interested in treating hormone-positive breast cancer?

17 A. So if you are looking for options in women who had
18 basically progressed on tamoxifen, and the prior art has
19 suggested that there was a powerful new antiestrogen, and you
01:59PM 20 were looking for validation that that was considered to be a
21 new agent with fairly reproducible efficacy, this particular
22 this particular article in this particular experiment goes on
23 to prove that Dr. McLeskey and her group also considered among
24 the three major agents to use to try and prove a hypothesis
01:59PM 25 that they had cell line that were resistant to hormone

1 manipulation. So, of the three agents she chose, she chose
2 fulvestrant, and this kind of, for me, would, again, reinforce
3 my interest in this product as being something I would be
4 interested in treating ER-positive breast cancer.

02:00PM

5 THE COURT: Could you try that again?

02:00PM

6 THE WITNESS: So, I think this particular piece of
7 art identifies and sort of says, okay, if you were to choose
8 the most interesting and powerful agents of that time to test
9 the hypothesis that we have a cell line that if we try to

10 manipulate with a hormonal treatment, it will still remain
11 independent, because there is a theory that you must
12 eventually develop a cell line that is completely hormone
13 independent. Eventually ER-positive cancer requires

02:00PM

14 chemotherapy because the hormonal manipulations eventually
15 fail to do anything. And even then, they are basically moving
16 on to chemo when tamoxifen and subsequent drugs fail. So
17 this -- basically, she -- her hypothesis was that these cells
18 are independent because there is another pathway in progress.

02:01PM

19 And so, if the estrogen manipulation blocks one
20 pathway, the cancer cells find a way and keep growing because
21 they are being driven by a different pathway. So when they
22 start to grow, the tumor grows, and now, manipulating estrogen
23 receptor by any kind of pharmacological agent would not lead
24 to any kind of efficacy.

02:01PM

25 And, to prove that point, she selected three major

1 agents of that time. One was letrozole, which was a very
2 powerful aromatase inhibitor. Another was formestane. And
3 what antiestrogen did she choose? Fulvestrant. And all three
4 failed to affect her independent cell line, proving her point
02:01PM 5 that she had an independent cell line. But point for me of
6 interest is that she picked fulvestrant as one of the three.

7 MS. PETERSON: Maybe I could ask a few follow-up
8 questions to maybe clarify.

9 THE COURT: Okay.

02:01PM 10 BY MS. PETERSON:

11 Q. So would you expect an antiestrogen like fulvestrant to
12 block the tumor activity in an estrogen-dependent cell line?

13 A. Yes.

14 Q. Now, would you expect an antiestrogen like fulvestrant to
02:02PM 15 block the tumor activity in an estrogen-independent cell line?

16 A. No.

17 Q. Now, had Dr. McLeskey created an estrogen-independent
18 cell line?

19 A. That is correct.

02:02PM 20 Q. What was she trying to prove?

21 A. That it was estrogen independent.

22 Q. And so was she trying to prove a hypothesis that -- or
23 strike that.

24 So what was she using the fulvestrant for as part of
02:02PM 25 that hypothesis?

1 A. So she was basically saying a fulvestrant, which is a
2 powerful antiestrogen, cannot stop the growth of this
3 particular cell line, and so it's not affected by it, proving
4 its independence from that agent.

02:03PM

5 THE COURT: But it was a hormone-independent cell
6 line.

7 THE WITNESS: Right. She had to prove that point
8 before she went on with the cell line.

02:03PM

9 THE COURT: So if you were interested in treating a
10 hormone-dependent breast cancer, what would McLeskey say to
11 you?

02:03PM

12 THE WITNESS: Basically, again, all it would say to
13 you is that among the three agents she chose, of her time,
14 which was considered very powerful to test this hypothesis,
15 Faslodex® had made the grade, and so it must have been
16 impressive enough for ICI, AstraZeneca to supply, from the
17 other side, but not to supply the letrozole, and, of course,
18 fulvestrant -- the formestane is the third aromatase inhibitor
19 already in the market in Europe, so they are using that as a
20 third agent to see. Because these are all again -- the
21 hypothesis is that if this cell line indeed is independent,
22 these three powerful agents, none of them will show that the
23 growth of the cell line will slow down. And that's what she
24 was wanting to show, and that's what she ended up showing.

02:03PM

02:04PM

25 Q. So would a person of skill in the art reading McLeskey

1 understand that ICI 182,780 was chosen because it was
2 recognized to be an effective antiestrogen?

3 A. Chosen because it was novel and a powerful antiestrogen,
4 yes.

02:04PM 5 Q. And did she prove her hypothesis?

6 A. She did.

7 Q. So does that mean that McLeskey's study was actually a
8 success?

9 A. From the viewpoint of what she was trying to prove, yes.

02:04PM 10 Q. And so do you consider McLeskey 1998 to represent a
11 treatment failure, in your opinion?

12 A. No.

13 THE COURT: Were you here for Dr. Kern's testimony?

14 THE WITNESS: Yes. No. I was here for

02:05PM 15 Dr. Robertson.

16 THE COURT: Were you here this morning for

17 Dr. Kern's?

18 THE WITNESS: No.

19 BY MS. PETERSON:

02:05PM 20 Q. So would a person -- a person of skill in the art
21 interested in using fulvestrant to treat hormone-positive
22 breast cancer, what would such a person learn from McLeskey?

23 A. That if you are looking for a new powerful agent in the
24 antiestrogen category, you had an interesting agent that
02:05PM 25 deserved attention and further studies.

1 Q. And what would a person of skill in the art understand
2 from McLeskey with respect to the castor oil-based
3 formulation?

02:05PM 4 A. So, McLeskey follows Howell, and Howell talks about a
5 castor oil formulation. And McLeskey gives that formulation
6 with the other fill-in-the-blanks agents. And it's around the
7 same time that Howell's results are published, subsequently
8 comes McLeskey, and to me, it would suggest that if I see ICI
9 or AstraZeneca supplied Dr. Howell his product, then the same
02:06PM 10 product was in McLeskey's article, and so that's the formula
11 of fulvestrant at that time in use.

12 Q. And did McLeskey 1998 cite to and reference the Howell
13 1996 study?

02:06PM 14 A. She does. One of the references she cites is exactly
15 that article, Reference 19.

16 Q. And you are referring to your demonstrative, DDX-10-044?

17 A. Yes.

02:06PM 18 Q. Is there anything in McLeskey 1998 that would have
19 dissuaded a person of skill in the art from pursuing a
20 long-acting, 50 milligram per milliliter, castor oil-based
21 fulvestrant formulation to treat hormone-dependent breast
22 cancer?

23 A. No.

02:07PM 24 Q. Let's move on to the last publication from your overview.
25 This would be the Robertson 1999 abstract.

1 And can you just briefly tell us again what does the
2 Robertson '99 abstract teach?

02:07PM

3 A. So these are the postmenopausal women. These were being
4 scheduled for surgery, and before surgery, a treatment
5 protocol was given. The women were given fulvestrant dose of
6 50 or 125 or 250 intramuscularly, with tamoxifen in one group,
7 and in the comparator group tamoxifen placebo. And his idea
8 was to -- that group's idea was to test this -- and he calls
9 it the most advanced of the new class of drugs. In this
10 particular two category, you see what happens.

02:08PM

11 Q. And is this the same abstract you identified earlier in
12 your testimony?

02:08PM

13 A. This is the same abstract that was presented to the
14 preliminary session of the San Antonio Breast Conference in
15 1999, selected out of 440 abstracts presented at that
16 particular conference.

17 Q. And what does Robertson 1999 say about fulvestrant
18 relative to other pure antiestrogens under development at the
19 time?

02:08PM

20 A. He goes on to call it the most advanced of the new class
21 of drugs, a non-agonist, and to quote, "pure," steroidal
22 antiestrogen.

23 Q. Before we move off this topic of all the prior art, I do
24 want to go back and follow up on one point.

02:09PM

25 A lot of -- do you recall a lot of the papers you had

1 discussed involved research discussing anti-uterotropic effects
2 of fulvestrant?

3 A. Yes.

02:09PM

4 Q. Why would that be relevant to a breast cancer researcher
5 looking for a new treatment?

02:09PM

6 A. So, think of what was prevalent at that time. The most
7 important drug at that time was tamoxifen. And while it was
8 very useful in most of the women, where it created problems
9 was that it was not a pure estrogen blocker. In some
10 instances it stimulated like a estrogen.

11 And the one other it stimulated was uterus. It would
12 increase the uterine lining. There are problems with
13 menorrhagia and excessive blood loss.

02:09PM

14 And the worst of it was that in a small number of
15 women, the incidence of the lining of the uterus cancer going
16 up was noted.

02:10PM

17 So one of the ways you start looking at a drug is to
18 say is it efficacious, and the prior art shows in the earlier
19 preclinical phase that on the cell line, in the xenograft,
20 there was efficacy.

02:10PM

21 But, simultaneously, the second question that was
22 equally important was: Does it have any advantage in terms of
23 side effects? And it came up with this not have it being a
24 very strong anti-uterotropic agent, which basically meant that
25 it did not have the attribute to stimulate the lining of

1 uterus, and thereby, it was possible that the side effect of
2 uterine cancer could be prevented.

3 So you have a drug that has a promise of efficacy and a
4 promise of not having the side effects of the prevailing main
02:10PM 5 agent you are trying to find an alternative. And that's
6 probably the way this science then progressed.

7 MS. PETERSON: Your Honor, before we move into the
8 next area of Dr. Mehta's testimony, I would like to move into
9 evidence the exhibits that he has discussed thus far. The
02:11PM 10 defendants move to enter PTX-392, DTX-285, JTX-13, DTX-39,
11 DTX-48, JTX-16, DTX-49, JTX-17, JTX-15, JTX-11, JTX-14, and
12 JTX-10.

13 THE COURT: Okay. Any objections?

14 MS. PENSABENE: No objection, your Honor.

02:11PM 15 THE COURT: Okay. In evidence.

16 (DEFENDANT EXHIBITS' PTX-392, DTX-285, JTX-13, DTX-39, DTX-48,
17 JTX-16, DTX-49, JTX-17, JTX-15, JTX-11, JTX-14, and JTX-10
18 WERE RECEIVED IN EVIDENCE.)

19 BY MS. PETERSON:

02:11PM 20 Q. Dr. Mehta, in your opinion, would a person of ordinary
21 skill in the art have been motivated to select fulvestrant to
22 treat hormonal dependent breast cancer?

23 A. Yes.

24 Q. Why?

02:11PM 25 A. Because the prior art had a sort of seamless transition

1 from preclinical studies showing efficacy, safety,
2 tolerability, a definite method of administering it, which
3 would create a sustained drug level and require less frequent
4 administration, and the Phase I trial showed that it was safe,
02:12PM 5 and the Phase II trial again confirmed in human beings that it
6 was really efficacious. And so all that would basically bring
7 us to the corroborative pieces again, with Dr. Robertson and
8 other articles, that basically at that time heralded this drug
9 as the most advanced of the antiestrogen, and that would
02:12PM 10 certainly make it a very interesting subject to pursue.

11 Q. And, in your opinion, would a person of ordinary skill in
12 the art have been motivated to select fulvestrant to treat
13 hormonal dependent breast cancer over candidates in other
14 categories of antiestrogens?

02:13PM 15 A. So the candidates in other category were already moving
16 on. If you had a postmenopausal woman and the development was
17 for aromatase inhibitors, three agents are already on their
18 way to approval.

02:13PM 19 In case of the SERMs, the category where tamoxifen was
20 the principal agent, there were attempts to develop better
21 tamoxifen or safer tamoxifen, except really no agent came to
22 surpass or better the level of tamoxifen.

02:13PM 23 In some of them, which were similar to tamoxifen, but
24 not really efficacious, but they were found to have better
25 side-effect profile, and moved on to get approved for

1 something like preventing osteoporosis like Raloxifene.

2 But in the third category of pure antiestrogen, which
3 was a novel mechanism category, the most promising compound
4 was fulvestrant. And somebody who is interested in developing
02:14PM 5 something at that stage would say, okay, I realize they are on
6 their way to approval and are already doing very well.

7 Tamoxifen is the centerpiece of this particular mechanism.

8 This is interesting because a different mechanism, not likely
9 to be cross-resistant, and I'm interested. And the prior art

02:14PM 10 would lead you then to develop that further.

11 Q. In your opinion, would a person of ordinary skill in the
12 art have been motivated to develop a long-acting
13 fulvestrant-based breast cancer therapy before 2000?

14 A. Yes.

02:14PM 15 MS. PETERSON: Chris, if you could pull back up again
16 Dr. Mehta's demonstrative DDX-10-09.

17 BY MS. PETERSON:

18 Q. So, if you could just explain your opinion.

19 A. So, basically, that is a seamless transition in terms of
02:14PM 20 time and evidence. The Wakeling and Dukes data tells us that
21 on cell lines of MCF-7, this product was efficacious.

22 It tells us that on rats and monkeys, the side effect
23 of stimulating uterine lining was not present.

24 It takes us to a Phase I study in DeFriend where before
02:15PM 25 surgery, given every day for seven days, the product was seen

1 to be safe and had efficacy in terms of reducing estrogen
2 receptors.

3 In Howell, in Phase II, it proved that it was
4 efficacious in actual patients who have resistance to
02:15PM 5 tamoxifen, were postmenopausal, and produced 69 percent
6 improvement in a fairly impressive duration of response.

7 And, to go on, if that evidence is not enough, there
8 were evidence and praise coming in from some of the principal
9 authors of the preceding papers who were now saying this is
02:15PM 10 the most advanced of the antiestrogens. And they were already
11 trying it in their own patients for further trials with
12 standard of care, megestrol, or further trials where they were
13 saying preoperatively, let's look at the product, plus
14 tamoxifen which is a product, plus placebo, and see where we
02:16PM 15 go.

16 So not only did it impress these investigators, but
17 they are proceeding with further studies and clinical studies
18 which were on their way to Phase III trials.

19 Q. And, in your opinion, would a person of ordinary skill in
02:16PM 20 the art have had a reasonable expectation of success that a
21 fulvestrant formulation would work to treat hormonal dependent
22 breast cancer?

23 A. Yes.

24 Again, same argument. The preclinical, clinical
02:16PM 25 studies progressed in a logical lockstep, and come to Howell,

1 where you see the efficacy of 69 percent in this population,
2 which was resistant to tamoxifen, and you have other evidence
3 that suggests that it will basically be a product of promise.

02:17PM

4 Q. And would your opinion be the same for a person of
5 ordinary skill in the art having a reasonable expectation of
6 success that a castor oil-based formulation would work to
7 treat hormonal dependent breast cancer?

02:17PM

8 A. So Howell used a castor oil-based formulation once every
9 month and showed his results, and, yes, I would expect that to
10 be the principal formulation of interest.

11 Q. And what does the teaching of McLeskey 1998 add to your
12 opinion?

02:17PM

13 A. It basically tells me that that group also considered
14 Faslodex® as a principal representative of the antiestrogens
15 to test their hypothesis that the estrogen therapies do not
16 work in that independent cell line.

17 THE COURT: Which would be more valuable to someone
18 who was looking for a treatment for hormonal independent
19 breast cancer, correct?

02:18PM

20 THE WITNESS: That, and if somebody was saying, okay,
21 I have enough evidence about fulvestrant that it seems
22 interesting from Howell, here was another proof that another
23 group of investigators chose that drug to test their
24 hypothesis that such a powerful drug would not modulate this
25 cell line. So it sort of identifies and stamps the product

02:18PM

1 with approval from another set of investigators.

2 And McLeskey was not part of the AstraZeneca ICI
3 complex. She was an independent investigator. So her group,
4 having brought this product for their experiment, sort of
5 created one more impression which, in my mind, is
6 corroborative, saying okay, it's a front runner with letrozole
7 and with the formestane, that this is the product she chose.
8 So even though the cell lines didn't respond to them, they
9 were not supposed to. The fact that she chose that, it

02:18PM

02:18PM

10 basically tells you that she also evaluated the prior art that
11 was assisting them and said, okay, of the antiestrogens, I'm
12 going to use this to prove my hypothesis.

13 THE COURT: When you said earlier that it was not a
14 treatment failure, is that what you meant?

02:19PM

15 THE WITNESS: I meant that it is not a treatment
16 failure because she was not looking for treating
17 estrogen-positive breast cancer.

02:19PM

18 Her study had a hypothesis that these are independent
19 cell lines, and she was successful in proving it. And so it's
20 a positive study. She would report as a positive study. And
21 you can't go and say it's a treatment failure because she
22 wasn't treating estrogen-positive hormone cancer.

02:19PM

23 THE COURT: So let me see if I can summarize what
24 you're saying. It was a success, her study was a success
25 because it proved her hypothesis that the line that she was

1 developing was hormonally independent.

2 THE WITNESS: Right.

3 THE COURT: And she proved that hypothesis by
4 treating it with Faslodex® and powerful, to use your word,
02:19PM 5 antiestrogen.

6 THE WITNESS: Yes.

7 THE COURT: But it did not deal with treating the
8 disease itself.

9 THE WITNESS: No.

02:20PM 10 THE COURT: Okay. Thank you.

11 BY MS. PETERSON:

12 Q. Dr. Mehta, just to make the record clear, the hypothesis
13 that Dr. McLeskey was teaching, did that relate to a method of
14 treatment or was it just -- or was it related to establishing
02:20PM 15 whether a cell line was independent?

16 A. So I think what it basically established is that this
17 powerful product would not have any effect on her independent
18 cell line, but the fact that she used that particular
19 formulation means that she thought that if she had to test
02:20PM 20 with the best working formulation of that time, that the
21 AstraZeneca supplied, then she would use the formulation that
22 had shown success in Howell which came before her. So why
23 would she use something else?

02:21PM 24 Q. Was it unexpected that an antiestrogen like fulvestrant
25 would not work on her estrogen-independent cell line?

1 A. So, if it was truly independent, then it should not work.

2 Q. And that's why she successfully proved her hypothesis?

3 A. She did.

4 Q. Do you recall Dr. Robertson's testimony about several

02:21PM 5 hormonal therapies from the 1990s that failed to receive

6 approval?

7 A. Yes, I do.

8 Q. In your opinion, does the fact that a drug fails to

9 receive FDA approval indicate that it was not efficacious?

02:21PM 10 A. No.

11 Q. Why not?

12 A. Because so many drugs don't reach FDA approval. Some are

13 effective but may not complete all the trials. Some, the

14 pharmaceutical industry that's sponsoring it may lose

02:21PM 15 interest. There are a lot of products that don't complete the

16 entire journey, but they may be otherwise quite relevant.

17 Q. Now, Dr. Mehta, you're familiar with the patents-in-suit,

18 right?

19 A. Yes.

02:22PM 20 Q. Can we put up demonstrative DDX-10-46.

21 Do you recognize this claim from the '122 patent,

22 generally representative of the claims asserted in this case?

23 A. Yes, I do.

24 MS. PENSABENE: Your Honor, this claim is not at

02:22PM 25 issue in this case.

1 THE COURT: Okay.

2 MS. PETERSON: I'm only trying to establish --

3 THE COURT: Background?

4 MS. PETERSON: Yes, just background. I'm only trying
02:22PM 5 to establish what elements of the claim, in general,
6 Dr. Mehta's testifying to.

7 MS. PENSABENE: Your Honor, it's not representative.
8 The assertion that's being made is that this claim is
9 representative of the claims at issue in this case and that's
02:23PM 10 just not true.

11 MS. PETERSON: And, your Honor, we provided notice of
12 this demonstrative to AstraZeneca I think two days ago, and
13 they did not indicate that they had any objection to us using
14 it. We could have prepared a different demonstrative using
02:23PM 15 one of the asserted claims. But --

16 THE COURT: What is the question? Let me hear the
17 question.

18 BY MS. PETERSON:

19 Q. Within these claim elements, which portion are you
02:23PM 20 opining on?

21 A. Method of treatment.

22 THE COURT: "Method of treatment" he said. Okay.

23 MS. PETERSON: And that's it.

24 THE COURT: Okay. Are you going to show him the
02:23PM 25 relevant claim?

1 MS. PETERSON: I can, sure.

2 THE COURT: Okay.

3 BY MS. PETERSON:

4 Q. Can you pull up JTX-1? Actually, pull up JTX-4, please.

02:24PM

5 Go to the claims. If you could go in on -- go to Claim 1,
6 which is the original independent claim on which one of the
7 asserted claims-in-suit depends from.

8 Dr. Mehta, looking at Claim 1, can you tell me what
9 element of the claim you're primarily opining on?

02:25PM

10 A. The one where it says the method for treating hormonal
11 dependent benign or malignant disease of the breast or
12 reproductive tract comprising administering intramuscularly to
13 a human in need of such a treatment a formulation comprising
14 of 50 milligrams of fulvestrant, and then the description of
15 ethanol benzyl alcohol, benzyl benzoate, and sufficient amount
16 of castor oil vehicle.

02:25PM

17 Q. Okay. And you just read the entire claim.

18 A. Right.

19 Q. I was just asking you which portion of the claim are you
20 opining on?

02:25PM

21 A. The method.

22 Q. And then if we could go down to Claim 10 now.

23 THE COURT: Ms. Peterson, if you want to use your
24 prior chart, that's fine. I just didn't know if you were
25 going to get to it but -- what was the number?

02:25PM

1 MS. PETERSON: The demonstrative?

2 THE COURT: Yes.

3 MS. PETERSON: It was Number 46.

4 THE COURT: Yes, I don't see any harm in using it.

02:26PM 5 BY MS. PETERSON:

6 Q. Dr. Mehta, you're not -- oh, excuse me.

7 THE COURT: Yes, okay. Go ahead.

8 BY MS. PETERSON:

02:26PM 9 Q. So you're primarily responding -- you're primarily
10 opining on the method-of-treatment aspects of the claims,
11 right?

12 A. Yes.

13 Q. Are you offering opinions as to the formulation or
14 pharmacokinetic aspects of the claims?

02:26PM 15 A. No, I am not.

16 Q. Okay. You could take that down.

17 If you could pull back up Demonstrative Number 47.

02:26PM 18 Dr. Mehta, can you summarize for us the patient
19 populations and animal models that were used in the studies of
20 fulvestrant that you described earlier today?

21 A. So, all the studies except one basically looked at either
22 ovariectomized animal systems or postmenopausal women.

23 Q. And, again, what are the ovariectomized animals?

02:27PM 24 A. So they are the physiological model for a postmenopausal
25 woman.

1 Q. And is there a study in this group of studies that is a
2 different patient population?

3 A. So Dukes 93 had intact ovaries and similar testing to
4 other hypothesis was done.

02:27PM 5 Q. And what does that patient population represent?

6 A. So, that patient population refers to the premenopausal
7 women.

8 Q. Now, do the postmenopausal women and ovariectomized
9 animal populations in your demonstrative reflect the
10 indication for which Faslodex® was originally approved to
11 treat?

12 A. Yes.

13 Q. Now, switching back to the patents in the case, you have
14 reviewed the specification of the patents?

02:28PM 15 A. Yes.

16 Q. And, in your opinion, does the specification of the
17 patents-in-suit inform a person of ordinary skill in the art
18 that the inventors were in possession of a method for treating
19 hormonal dependent breast cancer in premenopausal women?

02:28PM 20 A. No.

21 Q. Why not?

22 A. Because there's no data. The data that you have on the
23 chart there, the only particular group that even simulates the
24 premenopausal women were Dukes 93, and there the outcome was
02:28PM 25 that the -- when the drug was used, the results were variable

1 and unpredictable, so really you can't translate that into
2 clinical efficacy in any way.

3 Q. Limiting your analysis just to the patent, does the
4 specification of the patent inform a person of skill in the
02:29PM 5 art that the inventors were in possession of a method for
6 treating hormonal dependent breast cancer in premenopausal
7 women?

8 A. No.

9 Q. Why not?

02:29PM 10 A. There is no -- no evidence or data supporting that
11 contention.

12 Q. There is no evidence or data supporting that contention
13 where?

14 A. In these patients.

02:29PM 15 Q. Do you agree or disagree that once a scientific rationale
16 for a drug has been demonstrated in postmenopausal women, that
17 could be applied to premenopausal women? Do you agree with
18 that?

19 A. No, I don't.

02:29PM 20 Q. Why not?

21 A. These are two different models in terms of what's
22 happening in their systems.

23 The premenopausal hormonal system is a tsunami of
24 estrogen hormone. So throughout the menstrual periods, the
02:30PM 25 estrogens rise and fall; throughout lactation, they rise and

1 fall; throughout pregnancies, there is a very sustained surge,
2 and the ovaries produce a very large number of -- amount of
3 estrogen.

02:30PM 4 Compared to that, in a postmenopausal woman, the
5 ovaries are gone. In terms of functionality, estrogen levels
6 have dropped. Slowly, the ovarian function is starting to
7 diminish to the point where all of the menopausal symptoms and
8 signs are taking over.

02:30PM 9 And these two -- these two models are -- when breast
10 cancer happens have totally different applicability.

11 So, for example, a postmenopausal woman will respond
12 even to a tiny amount of estrogen, that is converted from
13 androgen by enzyme aromatase.

02:30PM 14 But in the case of premenopausal woman, these surges of
15 estrogen are high, and hence, the same system, same idea of
16 control, does not usually work.

17 So these are -- for all the times we have treated them,
18 the premenopausal milieu, M-I-L-I-E-U, is a totally different
19 entity, and has different efficacy for different drugs.

02:31PM 20 Q. Now, in your opinion, could a person of ordinary skill in
21 the art use fulvestrant to treat hormonal dependent breast
22 cancer in premenopausal women without undue experimentation?

23 A. No.

24 Q. Why not?

02:31PM 25 A. Because, again, there is no data to suggest how it is to

1 be used or whether it will be useful, and so it would require
2 a new experimentation to prove that point.

3 Q. Does the patent provide any examples of how to treat
4 premenopausal women?

02:31PM 5 A. No, it does not.

6 Q. And what does the prior art say about treating
7 premenopausal women with hormone dependent breast cancer?

8 A. Until that time, nothing. And the only report that we
9 have is from Dukes 93, which sort of suggests that it probably
02:32PM 10 is not a good idea because the results are variable and
11 unpredictable.

12 Q. In your opinion, does the specification, the patent
13 specification, inform a person of ordinary skill in the art
14 that the inventors were in possession of a method for treating
02:32PM 15 hormone dependent breast cancer in men?

16 A. No.

17 Q. Why not?

18 A. So, male breast cancer arises in a totally different
19 environment. While it is a cancer in the breast as a
02:32PM 20 location, the male's predominate hormone is estrogen -- is
21 androgen, the ogesterone, and these tumors have arise in a
22 testosterone resistant manner. While they are ER/PR positive,
23 they also express androgens. Just because there are no trials
24 in men, you can't automatically presume that everything that
02:33PM 25 has been proven for postmenopausal women would automatically

1 apply to men. These are different characteristics, they have
2 different prognoses, different sensitivity, even the hormones,
3 even the estrogen receptors in the male breast are taught not
4 to be functional. They express proteins in a different way.

02:33PM

5 The presence of estrogen receptor makes them a different kind
6 of a hormonal model and I would say that there is nothing to
7 suggest that male breast cancer has similar treatment outcomes
8 as female breast cancers.

02:33PM

9 Q. And does the patent provide any guidance on using
10 fulvestrant to treat breast cancer in men?

11 A. No, it doesn't.

12 Q. And does the prior art say anything about using
13 fulvestrant to treat hormone-dependent breast cancer in men?

14 A. No.

02:34PM

15 Q. Dr. Mehta, before we move on, if we could go back to
16 demonstrative 48. So, I just wanted to ask you again, I think
17 you had already explained about the teachings of Dukes with
18 respect to premenopausal women, were there any other teachings
19 that you are aware of in the art with respect to the use of

02:35PM

20 fulvestrant in premenopausal women?

21 A. So, one of the important voices of that time was Mitch
22 Dowsett and he says in 1995 that all the same -- it will be of
23 value to determined the effect of fulvestrant on ER/PR of
24 premenopausal breast cancer. And if you go on to Dr.

02:36PM

25 Robinson's opinion in 2007, he goes on to say that fulvestrant

1 250 mg has no effect, zero, on hormone sensitivity and
2 proliferation in premenopausal women with primary breast
3 cancer measured at 14 to 21 days. So, the prevailing wisdom
4 from the mid nineties and beyond, and even today, is that it's
5 a different animal requiring different kinds of treatment
6 programs.

02:36PM

7 Q. In support of your opinion, are you relying on Dowsett
8 DTX-433 and Robinson DTX-881?

9 A. Yes, I am.

02:36PM

10 Q. Are you also relying on the DTX-309 Potter reference, the
11 DTX-320 Clark reference and the DTX-311 Wittliff reference?

12 A. Yes, I am.

13 MS. PETERSON: Your Honor, we would move to enter
14 those exhibits into evidence.

02:37PM

15 MS. PENSABENE: No objection, your Honor.

16 THE COURT: Okay. In evidence.

17 (DEFENDANT EXHIBITS DTX-433, 881, 309, 320 AND 311 WERE
18 RECEIVED IN EVIDENCE)

19 BY MS. PETERSON:

02:37PM

20 Q. If we could move forward to DTX-49. Dr. Mehta, can you
21 confirm you were relying on DTX-317 and DTX-318 in support of
22 your opinions concerning treatment of breast cancer in men?

23 A. Yes, I was.

24 MS. PETERSON: Defendants move into evidence DTX-317
25 and DTX-318.

02:37PM

1 MS. PENSABENE: No objection.

2 THE COURT: In evidence.

3 (DEFENDANT EXHIBITS DTX-317 AND DTX-318 WERE RECEIVED IN
4 EVIDENCE)

02:38PM 5 BY MS. PETERSON:

6 Q. Now, Dr. Mehta, you also provided opinions in this case
7 responding to Dr. Robinson's testimony concerning certain
8 secondary considerations. Do you recall that?

9 A. Yes.

02:38PM 10 Q. And one of those secondary considerations that Dr.

11 Robinson has relied on is that Faslodex® has received acclaim
12 and praise from the industry based on certain industry
13 articles. Do you agree with Dr. Robinson's opinion?

14 A. I don't.

02:39PM 15 Q. Why not?

16 A. Around the launch of products, as well as when there is a
17 label change and the company needs to bring it again to the
18 attention the oncologists, a lot of pharma newsletters,

19 announcement at meetings, press releases start to talk about
02:39PM 20 the drug. Also review articles start to appear. I see that
21 more as part of marketing than actually sort of industry

22 praise. And a lot of things that are appearing in pharma

23 newsletters about the new product or a new indication are put

24 there to basically bring it to the attention of the treating

02:39PM 25 community that such a change is happening and in case they

1 have missed it.

2 Q. So, in your opinion are reports from practitioners better
3 indicators of industry recognition?

4 A. They are.

02:39PM 5 Q. Now, earlier we talked a lot about Dr. Howell and his
6 clinical study in the nineteen nineties. Right?

7 A. Yes.

8 Q. Has Dr. Howell commented on the performance of
9 fulvestrant compared to other hormonal therapies since it was
02:40PM 10 launched in the two thousands?

11 A. Howell's opinion was compared with other hormonal
12 therapies, the performance of Faslodex® was equivalent,
13 nothing better.

14 Q. Now, Dr. Robinson also testified that Faslodex® has
02:40PM 15 received acclaim and praise from those in the industry based
16 on the inclusion of Faslodex® in clinical guidelines. Do you
17 agree with that?

18 A. No, I don't.

19 Q. Why do you not agree with that?

02:40PM 20 A. So, let's take the most formidable American guidelines of
21 NCCN. NCCN is staffed by oncologists from all major NCI
22 designated cancer centers, and these are the leading experts
23 in their area of interest, and they look at all the evidence
24 and add new indications or new drugs as they see fit. But
02:41PM 25 they are obligated to add an agent to the list of agents

1 approved for that indication if FDA gives an approval.

2 Because FDA approval is one of the stamps saying okay, for
3 this particular paradigm you can use this particular drug.

4 So, it's almost automatic that guidelines will adopt
02:41PM 5 a drug into their algorithm of treatment when it receives FDA
6 approval, because when a physician opens up those guidelines,
7 he needs to know the drugs listed there have been approved by
8 FDA for the disease.

9 Q. Are you aware of any instances where a guideline has
02:42PM 10 failed to recommend Faslodex®?

11 A. There is a British guideline which is very well respected
12 in the industry which ruled otherwise.

13 Q. And which guideline was that?

14 A. The NICE one. I think it's the next one. That's
02:42PM 15 correct.

16 Q. And what is NICE?

17 A. So, this is the National Institute of Health and Care
18 Excellence, it's based in the UK. And drugs, as they enter
19 the treatment formulation in the National Health Service and
02:42PM 20 otherwise, the NICE takes a position on whether a new drug
21 with all its claims of improvement, etcetera, is something
22 they recommend for their patients. And as late as 2011 NICE
23 basically said that fulvestrant is not recommended within its
24 licensed indication as an alternative to aromatase inhibitors
02:43PM 25 for treatment of estrogen in a separate positive, locally

1 advanced or metastatic diseases in postmenopausal women.

2 Q. One other opinion that Dr. Robinson offered was that
3 Faslodex® has received acclaim and praise from the industry
4 based on its use as a control arm of a clinical trial. Do you
5 agree with that opinion?

02:43PM

6 A. No, I don't.

7 Q. Why not?

8 A. So, I think one has to understand why a drug gets into
9 the control arm. A drug company wants to bring in a new
10 product and they basically are looking at saying okay, this is
11 a product and we're going to compare it against something
12 else. And they would choose a drug -- sometimes if they can
13 help it they will choose a drug where the company that is
14 marketing the competitor arm, a drug that is used as control,
15 joins into the research, joins into the expenditure, because
16 these are very expensive trials. And the fact that Faslodex®
17 was used as a control arm is largely recognition of the fact
18 that AstraZeneca was pretty forward in making sure that it
19 used their control arm in this trial. And that's a -- my take
20 on that is that that basically is largely because these then
21 become trials where the drugs are supplied free to the
22 patients, and these are expensive drugs, still under patent,
23 and the drug companies try to find partners where the
24 competitor drug is supplied.

02:43PM

02:44PM

02:44PM

02:44PM

25 Q. Is your testimony based on DTX-10-53?

1 A. The NCCN, yes.

2 Q. I'm sorry. Did we have the wrong slide up? Okay, go
3 back. So the DTX-10-53.

4 A. 10-53.

02:45PM

5 Q. And if we could go back to DTX-10-52. Your testimony
6 about whether Faslodex® was included in the NICE guideline,
7 was that reference to DTX-10-52?

8 A. Yes.

02:45PM

9 Q. And the opinions that you've just offered with respect to
10 whether Faslodex® has received industry praise, were your
11 opinions from a perspective of a person of skill in the art
12 prior to 2000?

13 A. Yes.

02:46PM

14 Q. Just so I didn't -- I don't want to make anything
15 confusing, I wasn't meaning just your opinions relating to
16 secondary considerations were from the perspective of one of
17 skill in the art of 2000, and that applies to all of your
18 opinions, correct?

19 A. Yes.

02:46PM

20 Q. Now, Dr. Robinson has also offered opinions regarding
21 unexpected results as well, right?

22 A. Yes.

23 Q. Do you agree with Dr. Robinson's opinion that Faslodex®
24 has unexpectedly improved side effects profiles?

02:47PM

25 A. No.

1 Q. Why not?

2 A. So, if you are looking at the prior art before
3 January 2000, the prevailing works, the major research are
4 summarized on this slide. Howell is again saying that the
5 long-acting administration of 4 mL was tolerated locally
6 without any problems.

02:47PM

7 THE COURT: Was tolerated locally?

8 THE WITNESS: Without any problems.

9 A. Howell again said that the greater exposure was not
10 associated with any increased side effects or efficacy.

02:47PM

11 Howell again stated that the product was associated with high
12 response rate and long experienced duration in patients
13 previously treated with tamoxifen. But even down to -- and
14 then I quote Wakeling, who basically went on to say that
15 analysis of bone density in rats on Faslodex® did not reveal
16 any deleterious effects.

02:47PM

17 So, all of the prior art we have looked at that comes
18 to Howell and beyond, one of the remarkable things everybody
19 notes is that its side effect profile is very good and that
20 then should not come as a surprise now.

02:48PM

21 Q. And, for the record, is your testimony in relation to
22 DTX-10-054?

23 A. Yes.

24 Q. And is it based on JTX-11 and DTX-49?

02:48PM

25 A. Yes.

1 Q. Dr. Mehta, just going back to a topic one more time that
2 we covered before. Would there have been a motivation to use
3 a long-acting castor oil-based formulation of fulvestrant to
4 treat hormone dependent breast cancer before 2000?

02:49PM 5 A. Yes.

6 Q. And can you explain why?

7 A. So, the linear progression of preclinical to clinical
8 studies which showed that there was efficacy, there was
9 safety, there was a method of delivery. The method of
02:49PM 10 delivery was a once a month type of injectability possible.
11 The Phase I studies showing safety and efficacy in terms of
12 estrogen receptors, Phase II showing efficacy and again
13 safety, all the 19 women had hardly any side effects, all
14 these things lead you to the point where you say okay, the
02:49PM 15 drug has promise and a person of skill in ordinary art would
16 basically consider it as something that would be interesting
17 enough to explore further.

18 Q. And likewise, would there have been motivation to use a
19 long-acting castor oil-based formulation of fulvestrant to
02:50PM 20 treat hormone-dependent breast cancer before 2000 as
21 administered intramuscular by 5 mL injections?

22 A. Yes.

23 Q. And why is that?

24 A. So, again, Howell uses that formulation and brings his
02:50PM 25 results. And that's a formulation that is --

1 THE COURT: He uses that formulation and brings his
2 what?

3 THE WITNESS: Brings his efficacy that we have
4 described. And he basically brings up the possibility of
02:50PM 5 having a therapeutic agent that can be administered monthly by
6 intramuscular depot progressions and reducing the need for
7 more frequent injections.

8 MS. PETERSON: Defendants also move to enter the
9 following exhibits into evidence: JTX-1, JTX-3, JTX-4,
02:51PM 10 PTX-432, DTX-282, DTX-287, DTX-306 and DTX-307.

11 THE COURT: Any objection?

12 MS. PENSABENE: Let me just ask, are these the
13 exhibits that were discussed here?

14 MS. PETERSON: They were discussed in the last
02:51PM 15 section on secondary considerations plus the patents.

16 MS. PENSABENE: No objection, your Honor.

17 THE COURT: Okay, in evidence.

18 (DEFENDANT EXHIBITS JTX-1, JTX-3, JTX-4, PTX-432, DTX-282,
19 DTX-287, DTX-306 and DTX-307 WERE RECEIVED IN EVIDENCE)

02:51PM 20 MS. PETERSON: Pass the witness.

21 THE COURT: Okay. So this is a good time to take our
22 break. So I was in the middle of a sentencing. I don't think
23 it will go maybe 20 minutes. So if I can ask you to just --
24 we'll take about a 20-minute break, okay? You can sort of pop
02:52PM 25 in and see in we're done. So, don't get too comfortable.

1 Okay. We'll pick right back up. All right?

2 THE DEPUTY CLERK: All rise.

3 (Brief Recess at 2:52 p.m.)

4 THE COURT: Whenever you're all ready. Sorry for the
03:37PM 5 delay.

6 Ms. Peterson, can I give you back the reply report?

7 MS. PENSABENE: Thank you, your Honor.

8 THE COURT: As I indicated, counsel, we'll go to
9 about 5:00.

03:40PM 10 MS. PENSABENE: Thank you, your Honor.

11 THE COURT: Okay?

12 MS. PENSABENE: Thank you, your Honor.

13 (CROSS-EXAMINATION OF DR. MEHTA BY MS. PENSABENE:)

14 Q. Good afternoon, Dr. Mehta.

03:40PM 15 A. Good afternoon, counselor.

16 Q. It's nice to see you again.

17 A. Same here.

18 Q. Dr. Mehta, you said that McLeskey had a very unique idea,
19 right? You remember that?

03:40PM 20 A. Yes.

21 Q. And you said she had success from the viewpoint she was
22 trying to prove. And that's hormonal independence, right?

23 A. That's correct.

24 Q. Now, you used the term "powerful antiestrogen agent"
03:41PM 25 several times during the discussion of McLeskey. She never

1 used those words, right?

2 A. No, subsequent and proceeding prior art had used
3 terminology saying the most advanced. And the evidence also
4 had suggested that this was powerful enough to be used in
03:41PM 5 tamoxifen resistant breast cancer patients, it was a powerful
6 new agent.

7 Q. That's your interpretation?

8 A. Yes, it is.

9 Q. That's not the interpretation of Dr. McLeskey's paper, is
03:41PM 10 that right?

11 A. No.

12 Q. Now, you talked about Dr. McLeskey's paper using a
13 particular formulation. So to be clear, there were two
14 formulations of fulvestrant in that paper, isn't that right,
03:41PM 15 and she used both of them?

16 A. Yes, she did.

17 Q. And she doesn't distinguish between them, does she?

18 A. No.

19 Q. And so your point is -- I want to make sure I'm getting
03:42PM 20 this right.

21 Your point is that she selected the compound for study
22 not the formulation, right?

23 A. I think she selected the formulation.

24 Q. You agree that she used two formulations interchangeably,
03:42PM 25 don't you?

1 A. She has mentioned both formulations, yes.

2 Q. And you agree she used them interchangeably, right?

3 A. I'm not sure what you mean by "interchangeably."

4 Q. She doesn't distinguish between one from another?

03:42PM 5 A. She used both phrases, yes.

6 Q. And you'd agree with me there's nothing in the paper --

7 no data in the paper that compares the two formulations, no

8 data in the paper that says that one -- or statement in the

9 paper that says one formulation is better than the other

03:43PM 10 that's right?

11 A. That is correct.

12 Q. And you would also agree with me that all of the

13 formulations in that McLeskey paper are animal formulations,

14 right? You'd agree with me on that?

03:43PM 15 A. Yes.

16 MS. PENSABENE: Okay. And let's put --

17 BY MS. PENSABENE:

18 Q. So you'd agree with me --

19 MS. PENSABENE: Let's put up that McLeskey methods

03:43PM 20 section.

21 Thank you, Mr. Hoy.

22 BY MS. PENSABENE:

23 Q. So you'd agree with me that McLeskey's is four different

24 antiestrogen compounds. And for the letrozole formulation,

03:43PM 25 that's not a commercial formulation, right?

1 A. No.

2 Q. That's a research formulation for use in animals, right?

3 A. That's correct.

4 Q. And for her experiments with tamoxifen, McLeskey used a
03:43PM 5 preformulated pellet that's only sold for animal research and
6 that's not the formulation for humans either, right?

7 A. That's correct.

8 Q. Okay. That's an animal formulation, right?

9 A. Yes.

03:44PM 10 Q. Okay. And you would agree with me that the peanut oil
11 formulation that McLeskey uses similarly is the animal
12 research formulation that's used in the early preclinical
13 research that you discussed during your direct testimony,
14 right?

03:44PM 15 A. Yes.

16 Q. And I think you already agreed with me, let me just be
17 sure, McLeskey is about hormone independent pathway?

18 A. That is correct.

19 MS. PENSABENE: You know what, I just want to keep
03:44PM 20 track of stuff, so do you mind if I write some things down on
21 the board?

22 Your Honor, may I approach and use that chart?

23 THE COURT: You may.

24 BY MS. PENSABENE:

03:44PM 25 Q. I hope you will indulge my handwriting. I apologize.

1 It's -- I'll try to be neat.

2 So I've written here McLeskey and under it hormone
3 independent. You'd agree with that?

4 A. Yes, I would.

03:45PM 5 Q. Okay. Now, if you could take a look, please, at the
6 method section for the formulations that were used of
7 fulvestrant, you would agree with me that both of those
8 formulations were administered subcutaneously, is that
9 correct?

03:45PM 10 A. That is correct.

11 Q. Okay. I'm just going to write that down here on this
12 chart then.

13 And you'd also agree with me, right, Dr. Mehta, that
14 the fulvestrant formulations, the two fulvestrant formulations
03:45PM 15 were both administered once weekly?

16 A. That is correct.

17 Q. So if I write "weekly" on the chart, that expresses what
18 we just agreed upon?

19 A. Agreed.

03:46PM 20 Q. You would also agree with me that in the McLeskey system,
21 the fulvestrant formulations were cross-resistant with
22 tamoxifen, is that right?

23 A. Say that again?

24 Q. In the McLeskey system --

03:46PM 25 MS. PENSABENE: We can pull up the title, perhaps,

1 Mr. Hoy?

2 THE WITNESS: That's okay. Go ahead.

3 Can you repeat the question?

4 BY MS. PENSABENE:

03:46PM 5 Q. In the McLeskey system the fulvestrant formulations were
6 cross-resistant with tamoxifen, is that right?

7 I'll just read the title for you, Dr. Mehta, and maybe
8 that will help.

03:46PM 9 THE COURT: Were the formulations that she used
10 cross-resistant with tamoxifen?

11 THE WITNESS: I think basically says the cell line is
12 cross-resistant. Where does it say it is cross-resistant to
13 tamoxifen?

14 BY MS. PENSABENE:

03:47PM 15 Q. Let's read the title together. Okay?

16 A. So I read for you.

17 Tamoxifen resistant FGF-transfected MCF-7 cells are
18 cross-resistant *in vivo* to the -- Faslodex is the other
19 approach. So that means they don't respond to these products
03:47PM 20 not tamoxifen. It's a fancy way of saying this is a hormone
21 independent cell line, that's how I interpret this particular
22 title.

23 Q. Okay. So you don't interpret this title to mean that the
24 cells are resistant to both ICI 182,780 and tamoxifen?

03:48PM 25 A. Basically she's talking about cell lines being

1 cross-resistant in terms of these three products she used,
2 which is another way of saying these are independent of these
3 three hormonal manipulator drugs.

03:48PM

4 Q. So I can write here on my chart cross-resistant? I just
5 want to be accurate in what your opinion is.

6 A. Yes.

7 Q. Okay. I'll go back over here so I'm not leaning over
8 your shoulder, Dr. Mehta. Sorry about that.

03:48PM

9 Okay. Now, you would agree with me that the McLeskey
10 paper doesn't give any data on the extent of estrogen pathway
11 suppression for any of the compounds that were used in any of
12 the formulations, correct?

13 A. Correct. Yes.

03:49PM

14 Q. And you would agree with me, too, that the McLeskey paper
15 doesn't gave any pharmacokinetic data for any of the
16 treatments that were used, right?

17 A. That is correct.

18 Q. Also the McLeskey paper doesn't give any data on
19 antiestrogen effect for any compound used, right?

03:49PM

20 A. Yes.

21 Q. Now, the only results that are given for the formulations
22 with ICI 182,780 for fulvestrant is that it is a treatment
23 failure, right?

24 A. No.

03:49PM

25 Q. Do you disagree with me that McLeskey describes the

1 results with ICI 182,780 as a treatment failure?

2 A. Basically it's one way of saying that these are
3 independent cells that are not possible to be manipulated by
4 three powerful antiestrogens. And if that's what you mean by
03:50PM 5 the question, I agree.

6 Q. And those are the words that were used by Dr. McLeskey in
7 her paper is "treatment failure," you'd agree with that,
8 right?

9 A. Yes.

03:50PM 10 Q. And you'd also agree that Dr. McLeskey in her paper says
11 that treatment with fulvestrant does not inhibit tumor growth,
12 right?

13 A. That is correct.

14 Q. And you'd also agree that Dr. McLeskey says in her paper
03:50PM 15 these treatments did not slow estrogen independent growth or
16 prevent metastasis of tumors, right?

17 A. That is correct.

18 Q. And your goal in treating a patient with hormonal
19 dependent breast cancer is indeed to slow growth and prevent
03:51PM 20 metastasis, is that right?

21 A. By and large, yes.

22 Q. And I think you used the term "successful." But McLeskey
23 doesn't use the word "successful" about the use of any of the
24 fulvestrant formulations within her paper, does she?

03:51PM 25 A. What it basically means is she was testing that these are

1 hormone independent cell lines, which normally are hormone
2 sensitive because of MCF-7, and she has created a cell line
3 which are totally independent than using these drugs and
4 showing that they are hormone independent is a successful
03:51PM 5 experiment because that's what she was trying to show. So
6 success is basically proving the hypothesis.
7 Q. And you agree there's no data about an estrogenic effect
8 of these compounds, right?
9 We'll move on. I'll withdraw.
03:52PM 10 Okay. I think you cited a connection with the Howell
11 paper from McLeskey, right?
12 A. Yes.
13 Q. Okay. And you included a footnote that cites to Howell
14 but you didn't include what that citation was for. So can we
03:52PM 15 look together as to what that citation was for?
16 A. Yes.
17 Q. What I did, I took your slide and put that together, and
18 you should check it and make sure it's right.
19 MS. PENSABENE: Can you pop that up, Mr. Hoy? I
03:52PM 20 think it's -- we put it together with Dr. Mehta's slide.
21 BY MS. PENSABENE:
22 Q. Just so we're on the same page. Okay?
23 A. Right.
24 Q. Here we go. Sorry about that.
03:53PM 25 Okay. So you had cited to Footnote 19, and that's a

1 Howell paper. So let's look first at what McLeskey says in
2 the abstract. She says that only 30 to 40 percent of patients
3 have a positive response to second hormonal therapies, and
4 then she calls that a lack of response. Do you see that?

03:53PM 5 A. Yes.

6 Q. Okay. And then she goes on to explain within the body of
7 the paper, and there she says that, early results for small
8 numbers of tamoxifen resistant patients have shown that only
9 about 30 to 40 percent of such patients have a positive

03:53PM 10 response to subsequent ICI 182,780 or aromatase inhibitor
11 therapy. Do you see that?

12 A. Yes.

13 Q. And that's where she cites Howell, isn't that right?

14 A. Yes.

03:54PM 15 Q. She cites it as one of a series of papers about endocrine
16 therapy, right?

17 A. Right.

18 Q. And her point being endocrine therapy doesn't work all
19 that well so we're looking for another pathway to work on,

03:54PM 20 isn't that what she's saying?

21 A. Yes.

22 Q. She's distinguishing what she's doing from endocrine
23 therapy, right?

24 A. Right.

03:54PM 25 Q. Okay. And I think that's been some of your point, right,

1 Dr. Mehta?

2 A. Yes.

3 Q. That this is different, totally different from endocrine
4 therapy.

03:54PM 5 A. That's correct.

6 Q. I'm sorry, let me make sure I'm clear.

7 This is totally different from hormonal dependent
8 pathways, right?

9 A. That is correct.

03:54PM 10 Q. Okay. All right. And now in thinking about the McLeskey
11 paper and sort of where it fits into this time line, you had
12 noted several times I think today the names of some well-known
13 researchers, and you noted Dr. Robertson and Dr. Howell, and
14 some people also from AstraZeneca.

03:55PM 15 A. Yes.

16 Q. Dr. Wakeling and Dr. Dukes. So let's take a look at the
17 McLeskey paper.

18 MS. PENSABENE: Can you pull up the front of the
19 paper, please, Mr. Hoy? And that's JTX-10. Great. There we
03:55PM 20 go.

21 BY MS. PENSABENE:

22 Q. Okay. You would agree with me, right, Dr. Mehta that
23 none of these folks that are authors on this paper or any of
24 those researchers that you've been naming and none of them are
03:55PM 25 from AstraZeneca, right?

1 A. That is true. This is the Lombardi Cancer Center, which
2 was independent of the research going on in the UK.

3 Q. Okay. And you would agree with me, right, that there
4 were other researchers who had used fulvestrant as a research
03:56PM 5 tool in their work with animals, right?

6 A. Yes.

7 Q. Okay. So you would agree with me, like, for example, the
8 Al-Matsubi reference, I think you and I talked about that at
9 your deposition.

03:56PM 10 A. Yes.

11 Q. You would agree with me that that reference was looking
12 at the estrogenic cycle in sheep also used fulvestrant and
13 that used it for basic animal research and injected it
14 intramuscularly, right?

03:56PM 15 A. I would have a look at it.

16 Q. I can show that to you and see if you agree.

17 A. Please.

18 Q. I want to make sure we're right on the same page.

19 MS. PENSABENE: May I approach, your Honor?

03:57PM 20 THE COURT: Yes.

21 MS. PENSABENE: May I hand you one?

22 THE COURT: Yes. Thank you.

23 BY MS. PENSABENE:

24 Q. And, Dr. Mehta, this work is just also basic animal --

03:57PM 25 Let me just clarify. This is PTX-693. So the record

1 will be clear, it's the Al-Matsubi paper.

2 BY MS. PENSABENE:

3 Q. And this is just talking about the compound fulvestrant,
4 its using it in animal research. This time it's injecting the
03:57PM 5 compound intramuscularly into sheep and it's the same kind of
6 situation, some basic animal research, right?

7 A. Yes.

8 Q. Okay. And here also they, to the last page, the
9 researchers thanked ICI Pharmaceuticals for their gift of the
03:58PM 10 compound, right?

11 MS. PETERSON: Your Honor, we object to this line of
12 testimony on the Al-Matsubi reference. Dr. Mehta did not
13 provide any opinion about this on direct testimony and I think
14 it's not in the scope of his expert reports as well.

03:58PM 15 MS. PENSABENE: Actually, it's in the scope of his
16 report.

17 That was the last question, anyway. The point being
18 the compound was used for basic animal research and in a
19 number of different --

03:58PM 20 THE COURT: That's for the general proposition?

21 MS. PENSABENE: I'm sorry?

22 THE COURT: For the general proposition?

23 MS. PENSABENE: Yes, exactly, your Honor. No
24 specifics about that.

03:58PM 25 THE COURT: Okay. For that purpose I'll permit it.

1 BY MS. PENSABENE:

2 Q. Now, just to finish off talking a little bit about
3 McLeskey here. I want to just get an idea where McLeskey
4 falls on this picture we've got here to understand where it is
5 in the pathways if you don't mind.

03:59PM

6 So you'd agree with me, Dr. Mehta, that McLeskey is
7 looking at FGF, one of these growth factors, right?

8 A. Right.

9 Q. As a possible pathway for hormone independent breast
10 cancer, is that correct?

03:59PM

11 A. Yes.

12 Q. Okay. So if I put this up here, that's correct that
13 McLeskey is FGF hormone independent. And I've circled the FGF
14 receptor in these growth factor pathways.

03:59PM

15 A. Yes.

16 Q. And that's different from the estrogen receptor and the
17 hormonal dependent pathways, is that right?

18 A. That's correct.

19 Q. And I think that was your point, right?

04:00PM

20 A. Yes.

21 Q. Okay. Let's go back a little bit and talk about options
22 for active ingredients for treatment for hormonal dependent
23 breast cancer. Okay?

24 You would agree with me, right, that by 2000 treatment
25 that had been used for hormonal dependent breast cancer

04:00PM

1 included tamoxifen, other SERMs, third generation aromatase
2 inhibitors and other aromatase inhibitors, progestin,
3 androgen, hydro estrogen. Do I have it right?

4 A. Yes.

04:00PM 5 Q. Okay. And so the SERMs, those were a proven mechanism,
6 right?

7 A. That's correct.

8 Q. And aromatase inhibitors also proven mechanism, right?

9 A. Yes.

04:01PM 10 Q. And the progestin, also proven mechanism?

11 I think you have to answer audibly so we get it on the
12 record.

13 A. Yes. Yes.

14 Q. Thank you.

04:01PM 15 And the androgen, those are also a proven mechanism?

16 A. Yes.

17 Q. And the hydro estrogens, also a proven mechanism?

18 A. Old fashion but, yes.

04:01PM 19 Q. All right. And all those categories are still being
20 investigated for improvements?

21 A. I would disagree. The hydro estrogens, the megestrol
22 type of categories, the agents that target the progestins,
23 they're becoming less of an interest because the direct drugs
24 that were evolving for estrogen related pathways were far more
04:02PM 25 interesting and powerful. So you're right, in general these

1 were the options available at that time.

2 Q. And in fact antiprogestins were being researched at this
3 time as promising options, is that correct?

4 A. Yes.

04:02PM 5 Q. And I think you'd agree lots of ideas about approaching
6 the estrogen receptor positive breast cancer, right?

7 A. Correct.

8 Q. And probably every group considered their idea the best
9 and touted it in their papers, right?

04:02PM 10 A. I would suppose so, yes.

11 MS. PENSABENE: And, Neil, can you put up our chart,
12 of some of these promising compounds, please?

13 BY MS. PENSABENE:

04:02PM 14 Q. And so you would agree with me that there was research
15 and promising compounds being -- being researched in all of
16 these categories, the aromatase inhibitors, the SERMs, the
17 androgens, the antiprogestins, the pure antiestrogen, the
18 progestins?

19 A. Yes.

04:03PM 20 Q. And in your direct, you didn't talk about any of these
21 specific compounds, right? Like, you didn't talk about
22 Vorozole, for example, right?

23 A. No, I didn't.

04:03PM 24 Q. And you didn't compare what was known about any of these
25 compounds --

1 A. No.

2 Q. -- to fulvestrant, right?

3 A. That's correct.

4 Q. Okay. Now, let's just look at those pure antiestrogens
04:03PM 5 if we could for a second.

6 There were -- this was a small -- a small class, right?

7 A. That's correct.

8 Q. At the time in 2000, right? There's only -- there's only
9 five of them and two of them are related, the EM compounds,
04:03PM 10 right?

11 A. Yes.

12 Q. In your direct, you didn't address EM 800 which is a pure
13 antiestrogen that had some promising Phase II results that had
14 been published and were currently in Phase III, right?

04:04PM 15 A. No, I didn't, no.

16 Q. So you didn't consider that in your thoughts about
17 fulvestrant. Now --

18 A. I would take exception to that statement. The issue here
19 is that, yes, these products at that time were also being

04:04PM 20 worked on. But if you look at the team from ICI and

21 subsequently AstraZeneca that had been currently developed
22 tamoxifen, and then subsequently anastrozole, a very reputable
23 group of doctors who were focused on, mid-1980s, '90s, or even
24 earlier on one product, because national interest in meetings,

04:04PM 25 they pronounced as the most advanced antiestrogen and had a

1 clear track record in the research proceeding seamlessly from
2 preclinical data of efficacy and toxicity to clinical efficacy
3 and safety clinical data and corroborative presentations all
4 the way up to Dr. Robertson in 1999 in San Antonio.

04:05PM

5 So while these other products were certainly around, it
6 is not unreasonable that based on that kind of testimony, I
7 would pick fulvestrant as a drug development.

04:05PM

8 Q. You would agree with me, wouldn't you, Dr. Mehta, that
9 Dr. Howell and Dr. Robertson and Dr. Dowsett all worked on
10 aromatase inhibitors, on SERMs, on antiprogestins. You would
11 agree with that, right?

12 A. I would agree with that, yes.

13 Q. Okay. So those groups have worked on all these different
14 options?

04:05PM

15 A. I have a clarification.

16 THE COURT: You had a clarification, but let her
17 finish the question first and then you can clarify.

18 What was your question?

19 BY MS. PENSABENE:

04:06PM

20 Q. Okay. So let me rephrase -- because now, I have totally
21 forgotten my question, I'm sorry.

22 THE COURT: That's okay.

23 BY MS. PENSABENE:

04:06PM

24 Q. So you would agree with me, right, that you started with
25 fulvestrant because that's what the patent is about, right,

1 Dr. Mehta?

2 A. No. I -- a hypothetical POSA would find this product of
3 interest is what we're talking about here.

4 THE COURT: Okay. I think I might be confused now.

04:06PM 5 What is it that you wanted to clarify earlier? I don't want
6 the record to not be complete. What is it?

7 THE WITNESS: So while the team that was mentioned as
8 the team working on other products, the same team basically
9 was not only mentoring this product into clinical studies, but
04:06PM 10 at every national forum and international forum was talking
11 about it, so if one was -- there were already great products
12 coming in, aromatase inhibitors, such as anastrozole,
13 letrozole, exemestane, and that if somebody is interested in
14 developing a new product with a new mechanism of action, there
04:07PM 15 was no sense going there.

16 All the competitors of the SERMs, were again not
17 proving to be either better than tamoxifen or safer than
18 tamoxifen. And so one category that stood out to be novel,
19 with a new mechanism of action, with lack of cross-resistance
04:07PM 20 with tamoxifen, that was again by this team that had been
21 heralding all these important drugs, had been touting it as
22 the new major advance, that is probably the reason why it
23 would be reasonable to expect that a POSA would find that
24 product ahead of others and develop it.

04:07PM 25 BY MS. PENSABENE:

1 Q. Okay. So, Dr. Mehta, your opinion doesn't address the
2 data or literature from any of those other compounds. It's
3 looking at the -- you're just looking at the team that had
4 worked on fulvestrant, right?

04:08PM

5 A. Looking at the team and the massive amount of prior art
6 that is accumulating basically in support of this particular
7 product.

8 Q. Okay.

9 THE COURT: But it sounds -- I'm sorry.

04:08PM

10 MS. PENSABENE: Oh, I'm sorry, Your Honor.

11 THE COURT: But it sounds like your opinion includes
12 an assessment that given the prior success that the team at
13 AstraZeneca had, that you would expect fulvestrant to be
14 further developed. Does that sound --

04:08PM

15 THE WITNESS: Absolutely.

16 THE COURT: That's what you're saying.

17 THE WITNESS: I am.

18 THE COURT: Okay.

19 BY MS. PENSABENE:

04:09PM

20 Q. Dr. Mehta, you would agree with me, wouldn't you, that
21 there is another AstraZeneca pure antiestrogen on this list,
22 too, right?

23 A. Yes.

24 Q. Okay. And that one was ultimately not successful, right?

04:09PM

25 A. That is correct.

1 Q. And you would agree with me that the Howell and Robertson
2 and Dowsett team have worked on many of these compounds and,
3 in fact, many of them were -- all -- in fact, all of them,
4 except for fulvestrant, were unsuccessful, isn't that right?

04:09PM 5 A. That is correct.

6 Q. Okay. Now during your direct today, you discussed the
7 1999 San Antonio Breast Cancer Symposium. Do you remember
8 that?

9 A. Yes.

04:09PM 10 Q. Okay. And you would agree that the '99 San Antonio
11 abstract book contained over 440 abstracts, right?

12 A. Yes, that's correct.

13 Q. Now, you used a methodology to sort of narrow that down,
14 and in that methodology, you excluded the growth factor
04:10PM 15 treatments, right, because you considered them to be not
16 relevant to the question here, right?

17 A. So I just considered the hormone-related treatments of
18 breast cancer.

19 Q. And I think you said, and correct me if I'm wrong --

04:10PM 20 THE COURT: Excuse me, treatments of breast cancer.

21 BY MS. PENSABENE:

22 Q. I think you said what was recommending the Robertson '99
23 abstract to you, was that it was the only one that was about a
24 novel agent, is that right?

04:10PM 25 A. By and large, yes.

1 Q. I'm sorry?

2 A. By and large, yes.

3 Q. Oh, okay. I just want to take a look at the page that
4 the Robertson abstract is on.

04:10PM 5 That's at -- it's not JTX-13.

6 MS. PENSABENE: And I'll ask Mr. Hoy, would you mind
7 popping that up on the screen.

8 BY MS. PENSABENE:

9 Q. And this is in your book, too --

04:11PM 10 A. Yes.

11 Q. -- Dr. Mehta, that's over there on the side from your
12 direct. So what I'd like to do, this is -- this is the --
13 this is the abstract that you were talking about, about

04:11PM 14 Dr. Robertson, but I'd like to look up on the same page, if I
15 could, up at an abstract in the -- catty-corner to this. It's
16 Abstract No. 25.

17 So you would agree with me, Dr. Mehta, that this is
18 talking also about a hormone-dependent endocrine -- also about
19 an endocrine therapy, right?

04:11PM 20 A. Yes.

21 Q. It's about a SERM, right?

22 A. Yes.

23 Q. And this is also about a novel compound, right?

24 A. Yes, it is.

04:12PM 25 Q. It's about a novel SERM. This one is about LY 353381.

1 A. Yes.

2 Q. That's correct, right?

3 Okay. So there were a lot of novel compounds -- there
4 were other novel compounds. Let me be more accurate. There
04:12PM 5 are other novel compounds, weren't there, other novel
6 endocrine therapies that were being discussed in the general
7 session at San Antonio, right?

8 A. So this particular paper was discussed in the general
9 session? Can we confirm that?

04:12PM 10 Q. Mm-hmm. Yes, yes, it's part of that --

11 A. Okay.

12 Q. It's part of those general session discussions.

13 A. So I stand corrected. There might have been more than
14 one.

04:12PM 15 Q. Okay. And then looking on this same page, this page also
16 talks about Raloxifene and discusses Arimidex, right? And
17 those are also endocrine therapies, right?

18 A. Arimidex has already been approved by that time and so
19 it's not an oral therapy. It's already on its way to becoming

04:13PM 20 a standard of care for postmenopausal women. Raloxifene, the
21 data is basically moving it towards a treatment for

22 osteoporosis and prevention of breast cancer. The data for
23 treating breast cancer itself in hormone-dependent category
24 for Raloxifene is five, three years at the most, it doesn't

04:13PM 25 really stand out -- it's being moved towards treatment of

1 osteoporosis, because it improves the bone health, but in
2 terms of comparing it to the anticancer properties of
3 tamoxifen, it was proven to be not equivalent.

04:13PM 4 Q. Okay. Then you would agree with me, right here on the
5 same page as the Robertson 1999 abstract, there are at --
6 there's an abstract for a novel SERM, another SERM, and a
7 aromatase inhibitor, is that correct?

8 A. True.

9 Q. In the general session --

04:14PM 10 A. Yes.

11 Q. -- of San Antonio. And that's just a snapshot, right?

12 So -- and you would agree with me that EM 800, which
13 was another pure antiestrogen was -- had reported high
14 response rates in Phase II trials by 2000 and was currently in
04:14PM 15 Phase III trials, right?

16 MS. PETERSON: Your Honor, I object to this line of
17 questioning. I don't think this has anything to do with the
18 abstract from the San Antonio Breast Cancer Conference.
19 That's outside the scope of his direct testimony.

04:14PM 20 MS. PENSABENE: Your Honor, this goes directly to
21 credibility, because this witness has testified -- is
22 testifying that one would choose fulvestrant as the most
23 advanced of all the anti -- pure antiestrogens, EM 800, as an
24 antiestrogen. This was published before 2000.

04:15PM 25 It is phase -- it's in Phase III trials and it has

1 promising Phase II data. It directly goes to the -- to the
2 witness's opinion about fulvestrant.

3 THE COURT: To his opinion that fulvestrant is the --
4 what --

04:15PM

5 MS. PENSABENE: His opinion was that fulvestrant was
6 the most advanced of all of -- if you could put the chart back
7 up, just so I can -- I know there's a lot of names, sir,
8 floating about.

9 THE COURT: Why would you quarrel with that?

04:15PM

10 MS. PENSABENE: I'm sorry?

11 THE COURT: Why would you quarrel with that?

12 MS. PENSABENE: That fulvestrant was the most
13 advanced at this time in 2000?

14 THE COURT: Yes.

04:15PM

15 MS. PENSABENE: I would quarrel with it because I
16 don't -- I disagree that fulvestrant was the most advanced and
17 the clear choice here.

18 MS. PETERSON: And we would also disagree with her
19 characterization of Dr. Mehta's testimony. I don't believe

04:15PM

20 that he's offered an opinion that it was the most advanced.
21 He was simply reporting what others in the literature reported
22 and described it as including Dr. Robertson and other people.

23 I believe Dr. Mehta's testimony was limited to
24 expressing reasons why people would be interested in pursuing
04:16PM 25 tamox -- in pursuing fulvestrant, but not necessarily that it

1 was the most advanced.

2 THE COURT: So the dispute is the words "most
3 advanced."

4 MS. PETERSON: Well, and also the line of questioning
04:16PM 5 asking Dr. Mehta about other compounds that he did not discuss
6 within his direct testimony.

7 THE COURT: Well, do you agree with what
8 Ms. Pensabene said that at the time that fulvestrant was the
9 most advanced of these pure antiestrogens?

04:16PM 10 THE WITNESS: So if you're looking at --

11 THE COURT: Can you just answer that with a yes or
12 no? And if you don't understand the question, then you have
13 to tell me.

14 THE WITNESS: Yeah, please repeat the question.

04:16PM 15 THE COURT: Yeah. Do you agree that at the time, in
16 2000 -- 2000, is that the question?

17 THE WITNESS: Right, 1999, 2000, yeah.

18 THE COURT: That fulvestrant was the most advanced?

19 THE WITNESS: That is correct. That was --

04:17PM 20 THE COURT: In terms -- of the purest antiestrogens,
21 you agree with that.

22 THE WITNESS: Yes.

23 THE COURT: So then if Ms. Pensabene wants to impeach
24 that statement, she may, despite the fact that he did or did
04:17PM 25 not -- well, I don't recall that he testified about EM 800,

1 but it's subject to impeachment, go ahead.

2 BY MS. PENSABENE:

3 Q. So Dr. Mehta, you would agree with me, right, that there
4 had been promising Phase II data published on EM 800?

04:17PM 5 A. Yes.

6 Q. And EM 800 was also by 2000 in Phase III clinical trials?

7 A. That is true.

8 THE COURT: It almost sounds as if you are saying,
9 and correct me if I'm wrong, that Dr. Robertson shouldn't have
04:17PM 10 been surprised by the results --

11 THE WITNESS: Yes.

12 THE COURT: -- that he achieved. So his testimony
13 that he was, you --

14 THE WITNESS: I don't agree, yeah, right.

04:18PM 15 THE COURT: You don't agree that he was surprised?

16 THE WITNESS: So I think, basically, in the
17 preclinical phase and the clinical phase and before '99, there
18 was already -- they, themselves, were saying that this was the
19 most advanced product. They were mentoring it into clinical
04:18PM 20 trials which happened right around this time, and it went on
21 to receive approvals, an FDA approval.

22 So to subsequently say that this was not a -- you know,
23 there was no surprise about it or people were surprised the
24 drug was doing very well, is exactly contrary to what they
04:18PM 25 presented at San Antonio, that this is the most advanced and

1 they want -- the further studies will continue. So I think
2 there's a dichotomy there.

3 The same group that was developing this compound was
4 very positive at that time and they would not have been
04:18PM 5 shepherding it into further trials and presenting it to
6 international audiences such as San Antonio, if they didn't
7 believe that it was a compound with major potential and
8 interest for them, and that's all I'm saying is that in
9 looking at those options in that frame of time, if I'm looking

04:19PM 10 for antiestrogen as one of the agents I want to use, it is
11 reasonable that I would put this product for development.

12 THE COURT: Okay.

13 BY MS. PENSABENE:

14 Q. Dr. Mehta, you would agree with me, right, that there
04:19PM 15 were prominent researchers who were looking at Vorozole for
16 example, and touting its promise, is that correct?

17 A. Yes.

18 Q. And there were prominent researchers who -- at -- in
19 2000, were looking at ORG 33201 and touting its promise,

04:19PM 20 right?

21 A. I have not seen any touting of promise by any of those,
22 so I really have to generically agree, saying yes, everybody
23 must be proud of what drugs they were working on. But as

24 Dr. Robertson also indicated, some of these drugs were killed
04:20PM 25 because they didn't seem to work. And so just because you

1 were working on it, doesn't mean they were touting it.

2 Here was a team very consistently saying they're a new
3 product with promise, and they were calling it most advanced
4 and advancing it in their clinical trials and using it on
04:20PM 5 their patients in clinical trials. So I think that's
6 basically the direction in which my mind would go when I'm
7 looking at a possible product for development.

8 Q. Okay. Let me just see if I'm understanding you.

9 So your point is that because of this -- because this
04:20PM 10 team was behind this product, it really didn't matter what the
11 other choices were, or what the data on the other
12 possibilities is, that you would pick whatever compound they
13 were working on and saying was promising?

14 A. Again, that is a mischaracterization of what I'm trying
04:20PM 15 to say.

16 THE COURT: Let me -- let me see if I understand what
17 your testimony is.

18 Were you here when Dr. Robertson testified about the RU
19 compound?

04:21PM 20 THE WITNESS: Yes.

21 THE COURT: Which, at the time was -- appeared to be
22 promising. Do you agree with that?

23 THE WITNESS: Yes.

24 THE COURT: So are you saying that at the time that
04:21PM 25 the ICI 182 appeared to be promising, the RU 58668 compound

1 appeared to be promising, but you have Team A and Team B and
2 Team A sort of -- they hold the gold --

3 THE WITNESS: Mm-hmm.

4 THE COURT: -- medal?

04:21PM 5 THE WITNESS: Yes.

6 THE COURT: And the RU team sort of holds the bronze
7 medal. So are you saying, then, that all bets were on the ICI
8 team? Is that what you're saying?

9 THE WITNESS: Something similar to that, but I would
04:21PM 10 basically say it's not all based on one product. It's simply
11 that you can look at the clinical evidence, the clinical
12 evidence. The mounting body of evidence that suggest there's
13 going to be a successful product and you look at the people
14 who are developing it, their track record.

04:22PM 15 THE COURT: The gold -- the gold medalist.

16 THE WITNESS: Right. So you basically both give the
17 weight to the product and say, okay, this is the team, this is
18 the body of data, why would I not go develop it.

19 BY MS. PENSABENE:

04:22PM 20 Q. Dr. Mehta, you included in that team Michael Dukes, is
21 that right?

22 A. He was one of the presenters, yes.

23 Q. And you looked at -- when you were talking about
24 preclinical research, the two Dukes' papers?

04:22PM 25 A. Right.

1 Q. Right? And you would agree, I think from what you're
2 saying that Michael Dukes is a well-respected researcher in
3 this field?

4 A. Yes.

04:22PM 5 Q. Okay. And you would agree that Dukes has a very
6 respectable track of work that led to the paper that you
7 quoted?

8 A. Yes.

04:23PM 9 Q. Now, the Dukes works that you were -- the Dukes work that
10 you were talking about earlier today was a valuation of
11 fulvestrant in primates, right?

12 A. Yes.

13 Q. There were two papers, right?

14 A. Yes.

04:23PM 15 Q. Now, in your timeline here, you don't include the Dukes
16 '814 patent, do you?

17 A. No, I don't.

18 MS. PENSABENE: May I approach, Your Honor?

19 THE COURT: Yes.

04:24PM 20 BY MS. PENSABENE:

21 Q. Now, the inventor of this patent, this is the Dukes '814
22 patent, right? It's JTX-18 for the record.

23 This patent is assigned to AstraZeneca, is that
24 correct?

04:24PM 25 A. Yes.

1 Q. And the inventor is the same Michael Dukes who we had
2 been talking about and you had been looking at his work during
3 your direct testimony, right?

4 A. That is correct.

04:24PM 5 Q. Okay.

6 MS. PENSABENE: And can you pull up Example 3 of this
7 patent, please?

8 BY MS. PENSABENE:

9 Q. And you would agree with me that this patent to Dr. Dukes
04:24PM 10 is -- includes examples of formulations of fulvestrant, right?

11 A. Yes.

12 Q. And here, in Example 3, the patent describes a castor
13 oil-based intramuscular injection that is 50-milligrams per
14 milliliter and it has -- the composition is given, right?

04:25PM 15 It's 40 percent benzyl alcohol, right?

16 A. Right.

17 Q. Okay. Now, that's not the same composition as in the
18 formulation you were talking about earlier in the McLeskey --

19 A. It's not.

04:25PM 20 Q. -- paper.

21 And the Dukes patent --

22 MS. PENSABENE: If we can go down a little further to
23 the table.

24 BY MS. PENSABENE:

04:25PM 25 Q. This patent -- the patent includes some data, too, on

1 antiestrogen activity, right?

2 A. Yes.

3 Q. So if we look at our timeline of AstraZeneca work and we
4 can actually look at our timeline, that's back -- that's back
04:26PM 5 behind us. You could see that Dukes patent is on there,
6 right?

7 A. Yes, it is.

8 Q. Okay. Because that's part of the AstraZeneca work that
9 was on fulvestrant, right?

04:26PM 10 A. That is correct.

11 Q. Okay. But you didn't consider the dukes patent, right?

12 MS. PETERSON: Your Honor, we object to this line of
13 questioning as well, and Dr. Mehta did not opine on the '814
14 patent or offer any opinions during his direct testimony.

04:26PM 15 MS. PENSABENE: And, Your Honor, that's the point.

16 THE COURT: No, but it goes to the weight of his
17 opinions.

18 THE WITNESS: So is this a yes or no answer, or is
19 there any chance or elaborating what I mean by yes or no?

04:26PM 20 THE COURT: What you mean by what --

21 THE WITNESS: I mean, almost all of the questions are
22 yes or no, but I do need to -- and I would love to agree with
23 everything, you know, but I can't.

24 THE COURT: So in cross-examination, that is quite
04:27PM 25 typical.

1 THE WITNESS: I know that.

2 THE COURT: So Ms. Peterson will get up on redirect,
3 if there's anything you need to explain, she will ask if
4 there's --

04:27PM 5 THE WITNESS: I get that, all right.

6 THE COURT: Okay. However, if a truthful answer to
7 the question can't be answered with yes or no, then you have
8 to tell Ms. Pensabene that you can't answer it with a yes or
9 no. Okay?

04:27PM 10 THE WITNESS: So I can't answer it with yes or no,
11 the last question.

12 THE COURT: What, that you didn't consider the Dukes
13 '814 patent?

04:27PM 14 THE WITNESS: No, that -- the answer to that is yes,
15 but I can't do the last part. All right. Proceed.

16 BY MS. PENSABENE:

17 Q. Okay. And you -- in forming your opinions, you didn't
18 consider whether the Howell paper that you talked about might
19 have used the Dukes patent formulation, right?

04:28PM 20 A. Look at the timeline. If Howell is being published in
21 '95, '96, and McLeskey around that time is being supplied by
22 AstraZeneca, Mr. Vose, with a castor oil-based intramuscular
23 preparation or injectable preparation, why would AstraZeneca
24 that is trying to test this product in clinical lines, as well
04:28PM 25 as other investigators who requested, why would they supply a

1 product that was available from '80s and obviously was
2 undergoing further development, because what McLeskey got
3 supplied was a different formula.

04:28PM 4 So I basically would think that in terms of the
5 timeline, what Howell got in his reserve were attributable to,
6 must be the same product or similar one supplied by
7 AstraZeneca in that timeline, because they were testing that
8 product. Why would they pull out the product from the prior
9 decade?

04:29PM 10 Q. You have no idea, right, you whether -- what formulations
11 Howell used, right?

12 A. I don't have that idea, no. I'm just making logical
13 conclusions.

14 Q. Okay.

04:29PM 15 THE COURT: Excuse me. Are you speculating?

16 THE WITNESS: I am. There is nothing in the
17 literature to confirm my speculation.

18 BY MS. PENSABENE:

04:29PM 19 Q. If we could stay with your preclinical work. Looking at
20 your slide DTX- 019, you would agree with me -- this is the
21 Wakeling '91 paper. You would agree with me, wouldn't you,
22 that what Wakeling is saying here is he wants to use
23 fulvestrant to explore the possibilities of this unproven
24 mechanism, right?

04:30PM 25 A. That is correct.

1 Q. Okay. Because it's an unproven mechanism. You don't
2 even know how it's going to work, what's going to be the
3 mechanism of action. So there is a lot of research to be
4 done, right?

04:30PM 5 A. That is correct.

6 Q. Let's take a look at your slide DTX-1-030. That's also
7 in your preclinical work.

8 A. Yes.

9 Q. This is Wakeling 93. And I think here with this slide
04:31PM 10 you did a dose conversion, right, from monkeys to humans from
11 this paper. Do you remember that during your direct?

12 A. Yes.

13 Q. And your dose conversion from this paper was that the
14 monkey dose used in discussing Wakeling 1993 was equivalent to
04:31PM 15 a 250 mg dose for a woman, right?

16 A. Yes.

17 Q. And your opinion was that that dose, that 250 mg dose
18 sustained 100 percent estrogen receptor blockade, right?

19 A. I was quoting the article, yes.

04:32PM 20 Q. So, there is nowhere to go. You can't go up from there,
21 right?

22 A. No.

23 Q. Now, let's turn our attention to the early clinical work,
24 okay, in your timeline. All right?

04:32PM 25 A. Yes.

1 Q. And let's talk about DeFriend. That's at JTX-15. Maybe
2 we can pull up your Slide 38. Now, I just want to make sure
3 we're on the same page here because I see that you have some
4 highlighting in the authors and highlighting in the
5 institutions that they are with. Dr. DeFriend and Dr. Howell
6 and Dr. Robinson, they are not with Zeneca, right?

04:33PM

7 A. No.

8 Q. So you are just highlighting Zeneca to --

9 A. There is a separate highlight in the names that are
10 recognized and seem consistent through research papers, I
11 highlighted simply to point out the commonality.

04:33PM

12 Q. In your view someone of skill in the art could not start
13 with the DeFriend formulation as being one that had been used
14 with success, right?

04:33PM

15 A. That is correct.

16 Q. And one wouldn't take from the DeFriend study a teaching
17 of once-daily dose, right?

18 A. DeFriend was basically looking for side effects. It's --
19 but one would not take that dose as a dose one wants to double
20 up in a once a month depot injection, it's that's just the
21 data, that's how they used it over their 7-day period.

04:34PM

22 Q. So, DeFriend is -- in your view DeFriend is looking at
23 side effects not at --

24 A. And efficacy.

04:34PM

25 Q. Okay. But not on the issue of daily dose, right?

1 A. That's what he uses so that's the -- that's one of the
2 features of that particular trial, is that 7 days before
3 surgery they give them a -- non daily doses.

04:34PM 4 Q. Dr. Mehta, you are familiar with the experience with
5 endocrine therapies that greater doses even without toxicity
6 did not lead to increased efficacy, right?

7 A. I'm familiar with that.

8 Q. And, for example, anastrozole was tolerated at 10 mg and
9 1 mg, but there is no additional clinical benefit for the
04:35PM 10 higher dose, right?

11 A. That is correct.

12 Q. And that was known in 2000?

13 MS. PETERSON: This is outside the scope of his
14 testimony as well.

04:35PM 15 THE COURT: Sustained.

16 MS. PENSABENE: Your Honor, he testified about dosing
17 and he testified and he did multiplication from DeFriend and
18 said you could come to a different -- and he talked about
19 maximum tolerated dose. This is directly relevant to that
04:35PM 20 testimony.

21 THE COURT: But I don't think he talked about
22 efficacy.

23 MS. PENSABENE: That's exactly what he was talking
24 about, your Honor. He was talking about maximum tolerated
04:35PM 25 dose, that there would be a reason to increase dose. And he

1 said you would go to a maximum tolerated dose, that would be
2 the theory that would apply. Not so. And now testing that
3 theory because the endocrine agents do not fit in that theory,
4 that is not how dosing is done -- was done with the endocrine
04:35PM 5 agent at this time.

6 MS. PETERSON: We would disagree. Dr. Mehta was not
7 drawing an opinion based on -- drawing an opinion of efficacy
8 based on the dosing.

9 THE COURT: Did you render an opinion about the
04:36PM 10 dosage and the correlation between dosing and efficacy?

11 THE WITNESS: No, ma'am.

12 THE COURT: What were you talking about when you
13 talked about the maximum dose?

14 THE WITNESS: It sort of points out that if you look
04:36PM 15 at this dose, it gives you some idea of how -- if you were to
16 take this on a daily basis for 28 days, how it might actually
17 calculate to a different dose level than 250. So, it's
18 possible that that dose could enter the calculations in
19 future. But beyond that, you can't make any other
04:36PM 20 assumptions.

21 THE COURT: Yes. I don't think he was correlating it
22 with efficacy.

23 THE WITNESS: Not at all.

24 THE COURT: I think he was saying that -- looking at
04:36PM 25 DeFriend was during a short period of time, but if you did the

1 math or some -- I don't remember --

2 THE WITNESS: So it's 28 times 18.

3 THE COURT: Did the math, you would come out at
4 approximately 250 monthly. I thought that's what he was
04:37PM 5 discussing.

6 MS. PENSABENE: That you would come out with 250?

7 THE WITNESS: 500.

8 THE COURT: 500.

9 MS. PENSABENE: And as long as Dr. Mehta is not
04:37PM 10 talking about efficacy related to that dose or is not talking
11 about a reason to go to an increased dose from 250, if
12 that's -- as long as he's not testifying about that, then
13 we'll move on. But our point being we should have the
14 opportunity to question that opinion if he is testifying that
04:37PM 15 that was a reason to go to a higher dose.

16 THE COURT: I understood, correct me if I'm wrong,
17 the import of your testimony was with respect to that
18 publication that you can't necessarily discount the value of
19 that publication because of the lower doses because that was a
04:38PM 20 7-day dosage.

21 THE WITNESS: Right.

22 THE COURT: But if you did the math you would come
23 close on a monthly basis to 500.

24 THE WITNESS: Yes.

04:38PM 25 THE COURT: And you did that simply -- did you do it

1 because you correlated it to efficacy?

2 THE WITNESS: Not at all.

3 THE COURT: Okay. Does that resolve the issue?

4 MS. PENSABENE: As long as DeFriend is not going to
04:38PM 5 be used as an argument for going to a higher dose.

6 THE COURT: Well --

7 MS. PETERSON: Well, I think that -- you know, if
8 DeFriend, if the data can be extrapolated to convert it to a
9 once monthly dose of 500 mg, that's what it is.

04:38PM 10 MS. PENSABENE: In that case, your Honor, I think we
11 should have the opportunity to test that hypoposias.

12 THE COURT: I think that you can. Go ahead.

13 MS. PENSABENE: Okay.

14 BY MS. PENSABENE:

04:38PM 15 Q. And, Dr. Mehta, you would agree that in fact anastrozole,
16 aminoglutethimide and fadrozole studies all showed that higher
17 tolerated doses did not provide greater efficacy?

18 A. That is correct.

19 Q. And all of that was known prior to 2000, correct?

04:39PM 20 A. That is correct.

21 THE COURT: So, would it be somewhat of a leap to use
22 DeFriend for the proposition that you are positing?

23 THE WITNESS: Somewhat of a leap, yes. And I think,
24 on the other hand, the 250 dose as Howell successfully uses
04:39PM 25 it, if I were a developer at that time you finally found a

1 dose that has brought 69 percent response rate with good
2 duration of response, you found a safety profile that is
3 completely acceptable. Going forward into Phase III trial, I
4 would not monkey with the dose bringing it down because I
04:39PM 5 don't know if I would be hurting those women saying -- that's
6 the whole idea of Phase II trials, you are setting efficacy
7 and it's set on the doses which are set by the Phase I trial.
8 So, I think that at the end of the Phase II as you
9 are beginning randomized trial where you tell women this is
04:40PM 10 the standard of care, but half of you are not going to get it,
11 you are going to get this new drug, why would you lower the
12 dose of something that just worked? And what would be the
13 justification to say I'm going to try 25 or 50 mg and see what
14 happens why those women don't get controlled. You should have
04:40PM 15 known that's probably not a very scientific way of doing
16 research clinically.
17 So there is an awesome amount of responsibility to
18 getting a dose that has actually given you safety and efficacy
19 into the next set, and that's exactly what happened. 250
04:40PM 20 was -- went through their Phase III trials, it's just that
21 subsequently it was realized that that was not as efficacious
22 as they would have hoped and then 500 was cleared. So, yeah,
23 the 500 is simply a leap of faith in terms of it's interesting
24 that this 7-day dose actually translated to 500. But Howell,
04:41PM 25 did they know that? I don't know. I wasn't part of that

1 discussion. But to take Howell 250 mg, which is efficacy and
2 safety data, the only Phase II then, which everybody's now
3 saying, so now we test it further, how would I assure a women
4 saying I'm going to try a little lower on you because that
04:41PM 5 might work? It's not a good idea. It's a new compound and
6 laws about SERMs and AIs may not work there.

7 Q. Dr. Mehta, you would agree with me that the gold metal
8 team that you talked about --

9 A. Yes.

04:41PM 10 Q. -- went down in dose after Howell following the Howell
11 teachings, right?

12 A. Yes.

13 Q. Okay, let's take a look at Howell, if we could. That's
14 at JTX-11. You'd agree with me that you selected Howell to
04:42PM 15 consider because it related to hormone-dependent breast
16 cancer?

17 A. Yes.

18 MS. PENSABENE: Your Honor, if I could, I'd like to
19 just fill in the rest of our chart over here --

04:42PM 20 THE COURT: Okay.

21 MS. PENSABENE: I'm going to fill in the rest of our
22 chart over here that's nearest Dr. Mehta.

23 BY MS. PENSABENE:

24 Q. So, let's fill in for Howell. I'm accurate if I put here
04:42PM 25 under Howell "hormone-dependent," right?

1 A. Postmenopausal hormone-dependent, yes.

2 Q. And the Howell formulation was given intramuscularly?

3 A. That is correct.

4 Q. So I can fill that with intramuscularly, correct?

04:43PM 5 A. Yes.

6 Q. And the Howell formulation is given every 4 weeks, once
7 monthly, right?

8 A. That is correct.

9 Q. Okay. And in Howell the fulvestrant was not
10 cross-resistant?

11 A. That's correct.

12 Q. So, you would agree with me that this chart, that
13 McLeskey and Howell don't match in four areas that we've
14 discussed, right?

04:44PM 15 A. Yes.

16 Q. Okay. So they don't, McLeskey and Howell don't match on
17 hormone dependence. McLeskey is hormone-independent, Howell
18 is hormone-dependent, right?

19 A. Which is not a surprise, right.

04:44PM 20 Q. And McLeskey, the formulations of fulvestrant were
21 subcutaneous and in Howell the formulations were
22 intramuscular?

23 A. Yes.

04:44PM 24 Q. So, they do not match on that either, the route of
25 administration, right?

1 A. True.

2 Q. And in McLeskey the formulations were administered once
3 weekly and in Howell the fulvestrant formulations were
4 administered once monthly, so they do not much on dosage
5 frequency, right?

04:44PM

6 A. Yes.

7 Q. And McLeskey found that the fulvestrant formulation to be
8 cross-resistant and Howell not cross-resistant, so they do not
9 match on cross-resistance, right?

04:45PM

10 A. Yes.

11 Q. Let's talk a bit more about Howell, if we could. Now,
12 reading the Howell paper, Howell says in the paper that the
13 patients were highly selected. Is that right?

14 A. Yes.

04:45PM

15 Q. And Howell also says in the paper that tamoxifen
16 withdrawal may have accounted for the response seen in up to
17 one third of the patients. Do you remember that?

18 A. He does say that, yes.

19 Q. Now, you just disagree with both of those things; is that
20 right?

04:46PM

21 A. So, I have my own interpretation of that data, yes.

22 Q. But your interpretation is different from the
23 interpretation of the paper?

24 A. Yes.

04:46PM

25 Q. And you are familiar with the fact that researchers at

1 the time cautioned that the Howell response rate should be
2 interpreted with care.

3 A. That's always true for Phase II studies, so yes, that was
4 said.

04:46PM 5 Q. And you are familiar, aren't you, with the paper that Dr.
6 Dowsett published in the Lancet about the Howell study?

7 A. I'm familiar with that.

8 Q. And let's just talk for a moment. The Lancet, that's one
9 of the premier medical journals, right?

04:46PM 10 A. Yes.

11 Q. It's like sort of the gold standard medical journal,
12 right?

13 A. Yes.

04:47PM 14 Q. And Dr. Dowsett, he was one of the people that you
15 mentioned as being on this gold metal team, right?

16 A. Yes.

04:47PM 17 Q. And what Dr. Dowsett said was, he criticized -- he said
18 it should be -- Howell should be viewed with caution for two
19 reasons, and one of those reasons was that Howell had included
20 the no change patients in the response rate, and the second
21 reason was that the patients were highly selected. Did I get
22 that description of Dowsett's criticisms correct?

23 A. That description is correct.

04:47PM 24 Q. But you disagree with both of those criticisms by Dr.
25 Dowsett that he made in the Lancet in 1995 at the time of the

1 Howell research?

2 A. I do.

3 Q. Dr. Mehta, you'd agree with me that the Howell study in
4 the papers published, that Howell published in 1995 and 1996,
04:48PM 5 he indicated that further research was needed to confirm the
6 response rate?

7 A. That is true.

8 Q. And the Howell papers also indicated that further
9 research was required to see long-term effects on bone because
04:48PM 10 that was a concern, right?

11 A. That is true, yes.

12 Q. And Howell also indicated that further research was
13 required on amount on dose, right?

14 A. Yes.

04:48PM 15 Q. So, those were all open questions according to the Howell
16 paper, right --

17 A. Yes.

18 Q. -- in 1996, right?

19 A. Yes.

04:48PM 20 THE COURT: Excuse me. Remind me again why it's
21 significant to you that Howell viewed no change -- why you
22 view that to be a response?

23 THE WITNESS: So, there is a body of thought that --
24 and they were being honest, so basically said okay, we are
04:49PM 25 bunching the no responses with the responses, but that may or

1 not be true. But the prevailing wisdom then and prevailing
2 wisdom now is that if you have rapidly progressive disease or
3 metabolic disease and a patient stabilizes and you have stable
4 disease, that is counted as response. Today, drugs are
04:49PM 5 approved based on a result that says patient stabilized. So
6 it's become -- so my basic take is that while they were being
7 very cautious in interpreting their data, I interpreted it
8 differently. I interpreted that only progression was
9 progression, deaths were deaths, either a woman stabilized and
04:49PM 10 there was stable disease and a woman responded, they were all
11 in the same basket.

12 THE COURT: And so, my question is would a person
13 skilled in the art -- was that how a person skilled in the art
14 would interpret those results? And, if so, then why did
04:50PM 15 Howell break it down?

16 THE WITNESS: He's the one who reports the 69 percent
17 response rate. By being an honest investigator, he's also
18 listing caveats. And listing caveats in terms of this may be
19 the reason why these results are this good is a good way of
04:50PM 20 doing it because subsequent studies will basically look at
21 that option. And if that's the reason why this happened, then
22 that drug would probably start to lose its support. So, all
23 Phase II studies that are at times these thoughts expressed
24 which basically -- may look at the results and look at the --
04:50PM 25 look at the population and come up with what they may honestly

1 feel might have resulted in the results that were described,
2 but in my opinion the stable disease was counted and should be
3 counted as part of those who responded.

4 Q. Dr. Mehta, your interpretation is today, is that correct?

04:51PM 5 A. That was my interpretation then.

6 MS. PENSABENE: Can you put up the Howell paper for
7 me, please? If you could just enlarge that a little so we can
8 see it.

9 BY MS. PENSABENE:

04:51PM 10 Q. And what Dr. Dowsett is saying here is that the approach
11 of including no change patients is uncommon. And that was in
12 1995?

13 A. Right.

14 Q. That's his statement here in 1995, right?

04:51PM 15 A. Yes. It's uncommon but it's not unheard of. And it
16 became over the next 15 years a dictum that everybody accepts
17 that stable disease is good news. We tell our patients no
18 news is good news and that's exactly what this is.

19 Q. Dr. Mehta, in your timeline in your pre --

04:52PM 20 THE COURT: Excuse me. What is the exhibit number
21 that was just up on the screen?

22 MS. PENSABENE: I'm sorry. That is Dowsett, it's
23 been admitted into evidence, it's PTX-421, your Honor.

24 THE COURT: Thank you.

04:52PM 25 BY MS. PENSABENE:

1 Q. Dr. Mehta, there's a couple other things I just want to
2 talk about that aren't included in your timeline.

3 So right after Howell, you understand that four oral
4 clinical trials with fulvestrant were conducted from 1994 to
04:53PM 5 1997?

6 A. Yes.

7 Q. Okay. But you didn't include that in your analysis --

8 A. No.

9 Q. -- right?

04:53PM 10 Another thing that's not in your timeline is the early
11 clinical work for Thomas.

12 A. Yes.

13 Q. Now, that publication by Thomas came to the conclusion
14 that fulvestrant showed activity in premenopausal women, isn't
04:53PM 15 that right?

16 A. Can I see the publication?

17 Q. Oh, certainly.

18 A. Because there was a mixed conclusion from Thomas.

19 MR. O'BOYLE: Your Honor, may I approach?

04:54PM 20 MS. PENSABENE: May my colleague approach?

21 THE COURT: Yes.

22 BY MS. PENSABENE:

23 Q. This is PTX-249. And, Dr. Mehta, you'd agree with me
24 that PTX-249, the Thomas study, that's not on your timeline.

04:54PM 25 It's another seven day study, like DeFriend, that looked at

1 fulvestrant in premenopausal patients?

2 A. Yes.

3 Q. And Thomas concludes that the compound may be able to be
4 used in premenopausal women based on biological activity,
04:54PM 5 right?

6 A. Yes. If I read his conclusion, in going to the last
7 page, the last paragraph, he basically says that fulvestrant
8 was well tolerated during short-term use. It did not cause an
9 increase in LH or FSH secretion and may suppress LH surge.

04:55PM 10 There was no evidence of ovarian hyperstimulation although
11 follicular growth continued.

12 And so he basically confirmed that in premenopausal
13 woman using of this product would not stimulate the lining of
14 the uterus, which we already know from other prior art. I

04:55PM 15 don't interpret this article to say that there was a
16 therapeutic response that he was basically talking about in
17 terms of not having uterus vehicle side effects is what he's
18 talking about. If response in terms of how hormones were
19 affected in a premenopausal woman was something he was talking
04:56PM 20 about, but there's no mention of treating premenopausal women
21 without looks that improved because of this particular study.

22 Q. Dr. Mehta, do you remember having your deposition taken
23 in this action?

24 A. Yes.

04:56PM 25 MS. PENSABENE: And if you could put up Mehta

1 transcript 163, Lines 10, I think, to 17.

2 BY MS. PENSABENE:

3 Q. Do you remember that we talked about the Thomas paper at
4 your deposition Dr. Mehta?

04:57PM 5 A. Yes, I do.

6 Q. And I asked you the following question and you gave the
7 following answer:

8 QUESTION: And Thomas concludes, right, that the
9 absence of adverse events or of evidence of ovarian

04:57PM 10 hyperstimulation suggests that this compound may be able to be
11 used for the treatment of estrogen dependent diseases in
12 premenopausal women, right?

13 And there was an objection.

14 And your answer was:

04:57PM 15 ANSWER: That's what he concludes.

16 Correct?

17 A. Right.

18 Q. Okay. So in terms of treatment of premenopausal women,
19 if you could just look at your slide DDX-1-10 -- I'm sorry.

04:57PM 20 No, 1-11. I apologize.

21 A. Yes.

22 Q. On the right-hand side of this slide you would agree with
23 me this shows how to treat premenopausal women with endocrine
24 therapy?

04:58PM 25 A. It shows options available at that time.

1 Q. So one could treat premenopausal women with fulvestrant
2 after using an LHRH agonist and that was known? The use of
3 LHRH agonists were known?

04:58PM 4 A. So the understanding was that because it does not work in
5 premenopausal women you had to convert the premenopausal woman
6 into a menopausal female by some means so that now you will
7 have physiology which is similar to postmenopausal and then
8 this product would be used. So the option of using
9 fulvestrant was always possible if the woman agreed to go into
04:59PM 10 menopause.

11 THE COURT: Ms. Pensabene, do you have much more?

12 MS. PENSABENE: I don't -- of course it depends on
13 the witness.

14 THE COURT: Let me ask this, were you planning on
04:59PM 15 coming back in the second phase of the trial?

16 THE WITNESS: No. I could.

17 MS. PENSABENE: I can hurry up and maybe we can
18 finish redirect.

19 THE WITNESS: I could come back if that's what it
04:59PM 20 takes.

21 MS. PETERSON: He does have plans to return home and
22 was not planning on coming back for the second week of trial.
23 So if we could accommodate the witness, we would like to try
24 to finish today if that's okay.

04:59PM 25 MS. PENSABENE: That's fine.

1 MS. PETERSON: I appreciate you volunteering but we
2 would like to finish.

3 THE WITNESS: I'll speed up my answers.

4 THE COURT: Well, don't talk any faster.

04:59PM

5 So let's see if we can finish him up as a curtesy to
6 the witness.

7 MS. PENSABENE: Absolutely, your Honor. We'll cross
8 a bunch of things out, Dr. Mehta.

9 BY MS. PENSABENE:

04:59PM

10 Q. Dr. Mehta, you'd agree with me that in 2000, as well as
11 today, treatment of male breast cancer follows the same
12 principles as treatment of female breast cancer, right?

13 A. That's the treatment we offer, yes.

14 Q. And in your practice you offer hormone therapy for male
15 breast cancer?

05:00PM

16 A. Yes, I do.

17 Q. And the paradigm for treatment of women's breast cancer
18 just transfers to men's breast cancer, right?

19 A. Yes.

05:00PM

20 Q. You know, just going back to your thoughts about this
21 gold medal team, Dukes was on the gold medal team, right?

22 A. Yes.

23 Q. And McLeskey was not on the gold medal team, right?

24 A. Yes, McLeskey was an independent investigator in the

05:00PM

25 United States, she was not part of AstraZeneca's stable of

1 investigators.

2 Q. Dr. Mehta, your focus has been on treating patients, I
3 understand from when we've talked before, and not on
4 researching new treatments, right?

05:01PM 5 A. I have been involved in human research. And there is no
6 oncology practice or person in this country that in some way
7 or other would not participate in research because so many
8 questions need answering.

9 Q. And you're not an expert on pharmacokinetics, right?

05:01PM 10 A. No, I'm not.

11 Q. And you've never been involved in preclinical research,
12 right?

13 A. So the American Society of Oncology 2011 presentation in
14 Chicago was a big clinical research on a Phase I molecule
05:02PM 15 called B28, so that's the molecule that was shepherded and
16 subsequently it was now in Phase II trial. So in my time in
17 the academic world I have participated in clinical studies.

18 Q. Let me be more precise then. Prior to 2000 you were
19 never involved in preclinical research?

05:02PM 20 A. During my fellowship, I was. But once I left for India,
21 no.

22 Q. And you've never formulated any compounds, right?

23 A. No.

24 Q. And you don't have any experience using breast cancer
05:02PM 25 animal models, right?

1 A. No.

2 Q. And you've never advised a pharmaceutical company on
3 whether to select a drug for development, continue
4 development, or abandoned development, right?

05:03PM 5 A. No.

6 Q. And you've never served on a scientific advisory board on
7 drug development, right?

8 A. No.

9 Q. And you did not publish any scientific papers prior to
05:03PM 10 2005, right?

11 A. That's correct.

12 Q. And you've never been involved in the selection of
13 clinical end points for a breast cancer trial, right?

14 A. Yes, that is correct.

05:03PM 15 Q. Okay. You would agree with me that breast cancer is a
16 very complicated disease?

17 A. It is.

18 Q. And the ability to extend endocrine therapy was important
19 because that means patients have a better chance of survival,
05:04PM 20 right?

21 A. That is correct.

22 Q. And if you had a patient with expected life survival of
23 six months and adding one month to survival becomes very
24 relevant, right?

05:04PM 25 A. True.

1 Q. And if you have a choice between two treatments, all else
2 being equal, in your view that additional time to progression
3 would be a factor in choosing between those treatments?

4 A. Yes.

05:04PM 5 Q. Now, I think you and I both agree that the development of
6 treatment for breast cancer is very difficult, right?

7 A. Yes.

8 Q. And tamoxifen, as an example, almost didn't get to the
9 market, right?

05:04PM 10 A. Yes.

11 Q. And tamoxifen took decades actually to develop into a
12 breast cancer treatment, right?

13 A. That is correct.

14 Q. But tamoxifen saved millions of lives, right?

05:05PM 15 A. Yes. It did, yes.

16 Q. So suffice it to say it was important to patients to
17 spend that time and effort on development, right?

18 A. Yes.

19 MS. PENSABENE: I have nothing further, your Honor.

05:05PM 20 I'll pass the witness.

21 THE COURT: Redirect.

22 MS. PETERSON: Yes, Your Honor.

23 (REDIRECT EXAMINATION OF DR. MEHTA BY MS. PETERSON:)

24 MS. PENSABENE: I'm sorry, so sorry.

05:05PM 25 BY MS. PETERSON:

1 Q. Dr. Mehta, looking at the board over there that
2 Ms. Pensabene wrote on describing Howell and McLeskey, the
3 studies in Howell and McLeskey, were they for a different
4 purpose?

05:06PM 5 A. They were for different purpose, yes.

6 Q. And the purpose in Howell, was that to treat humans?

7 A. Purpose in Howell was to treat postmenopausal women with
8 metastatic disease.

9 Q. And was the purpose in McLeskey to test a hypothesis
05:06PM 10 about estrogen independent cell lines?

11 A. That is correct.

12 Q. Are there any similarities between McLeskey and Howell,
13 in terms of the formulation that was administered?

14 A. The only similarities that involved castor oil base and
05:06PM 15 they are drawn from the same source around the same time.

16 Q. What do you mean, drawn from the same source at the same
17 time?

18 A. Most were supplied by AstraZeneca in -- around the same
19 time, so one would feel that AstraZeneca at that time was
05:06PM 20 testing same iteration of the product.

21 Q. And are there any similarities in the concentration of
22 the drug that was delivered?

23 A. Similarities with what?

24 Q. Or the concentration of the drug that was administered.

05:07PM 25 A. In Howell?

1 Q. Yes, and McLeskey.

2 THE COURT: Are there any similarities in the
3 concentrations between the two?

4 THE WITNESS: 15-milligrams per mL was the reigning
05:07PM 5 principle, so...

6 BY MS. PETERSON:

7 Q. Now, Ms. Pensabene asked you if the formulation in
8 McLeskey was an animal formulation.

9 Do you recall that?

05:07PM 10 A. Yes.

11 Q. And, of course, the formulation in McLeskey, was that
12 administered to animals in her study?

13 A. Yes.

14 Q. Now, would that fact dissuade a person of skill in the
05:07PM 15 art from using that formulation in humans if it contained the
16 same components?

17 MS. PENSABENE: Objection. Leading.

18 THE WITNESS: It would not.

19 THE COURT: Wait, wait, wait. No, I'll allow it.

05:08PM 20 THE WITNESS: It -- it would not detract from using
21 it.

22 BY MS. PETERSON:

23 Q. Now, Ms. Pensabene also referenced the Robertson 19 --
24 I'm sorry, strike that. I'll start again.

05:08PM 25 Ms. Pensabene mentioned that Howell had instructed or

1 told people to go down in dose.

2 Do you recall that?

3 A. Yes.

4 MS. PETERSON: If we could pull up JTX-13, please,

05:08PM 5 and go to Abstract No. 28 on the bottom right?

6 BY MS. PETERSON:

7 Q. And do you recognize this?

8 A. Yes.

9 Q. What is this?

05:08PM 10 A. This is the Robertson abstract on Faslodex versus

11 tamoxifen.

12 Q. And this came after in time after -- did this come after

13 in time after Howell?

14 A. Yes.

05:08PM 15 Q. At what point in time?

16 A. This was '99, so many years later.

17 Q. And what doses were being tested in Robertson?

18 A. 50, 125 and 250 milligrams of fulvestrant.

19 Q. So even after Howell, the researchers were continuing to

05:09PM 20 test the 250-milligram dose, correct?

21 A. They were.

22 Q. And I wasn't sure, when Ms. Pensabene was asking about

23 the Dukes patents, I didn't know if there was something that

24 you wanted to clarify about your answer or if you understood.

05:09PM 25 Was there something you wanted to clarify?

1 A. So I think again, it's my common sense that tells me that
2 if Duke patent, the product was available from '80s, got
3 patients in early '90s, but subsequently if McLeskey is
4 supplying a product in the time frame of '95, '96 by
05:09PM 5 AstraZeneca's executives for testing it, then that's the
6 product they actually been giving others who are trying to
7 test it in humans.

8 And so it makes sense that that's exactly the product
9 that brought the results that Howell describes. Why would
05:10PM 10 something else be tried at two times because the results would
11 then not make any sense.

12 So while it is possible that you couldn't have any
13 product because we don't have information, common sense
14 suggests that what formulation McLeskey lists in that time
05:10PM 15 frame supplied by AstraZeneca, was the product AstraZeneca
16 supplied its team of researchers that did the most important
17 phase through trial for a very important product the company
18 was in the process of developing.

19 So I think I would basically, as a POSA, feel that
05:10PM 20 that's the leap of faith I was willing to take.

21 THE COURT: I was just going to ask that -- it sounds
22 as if you have questions in your mind and you are wondering
23 and you're speculating and -- but you're saying it could be.

24 THE WITNESS: Yes.

05:11PM 25 THE COURT: Okay.

1 THE WITNESS: It is reasonable to expect that these
2 two products are the same. Beyond that, we don't have any
3 data.

05:11PM 4 THE COURT: And do you agree that other POSAs may not
5 view it quite the way you do.

6 THE WITNESS: It's possible.

7 BY MS. PETERSON:

8 Q. Just to clarify your answer there.

05:11PM 9 Was your answer -- was your opinion that that was what
10 a person of skill in the art would understand?

11 A. Yes.

12 MS. PETERSON: If we could pull up defendant's
13 demonstrative DDX-10-019.

14 BY MS. PETERSON:

05:11PM 15 Q. I recall during Ms. Pensabene's cross-examination, she
16 may have -- or she referred to -- she pulled up this
17 demonstrative, DDX-10-019, and asked you to confirm that you
18 agreed with her that Wakeling 1993 was telling people to
19 conduct further tests for this unproven mechanism.

05:12PM 20 Do you recall that?

21 A. Yes.

22 Q. Are those words "unproven mechanism," here on your
23 demonstrative?

24 A. No. Those were her words.

05:12PM 25 Q. So you do not agree with that?

1 A. No.

2 MS. PETERSON: No further questions.

3 THE COURT: Okay. You get to go home.

4 THE WITNESS: Thank you, Your Honor.

05:12PM 5 THE COURT: Very nice to meet you, safe travels home.

6 Please be careful stepping down. Thank you.

7 MR. PRUGO: Your Honor, just one question about the
8 boards.

9 THE COURT: Yes.

05:12PM 10 MR. PRUGO: I think it's probably clear from the
11 transcript and we don't need the boards necessarily, but do
12 you want us to take a picture of it. How would you like us to
13 handle a couple of the demonstratives here.

14 THE COURT: Well, you have the smaller versions.

05:13PM 15 MS. PENSABENE: Of this one and --

16 MR. PRUGO: Well --

17 MS. PENSABENE: I'm sorry.

18 MR. PRUGO: No, go ahead, please.

19 THE COURT: On the chart here?

05:13PM 20 MR. PRUGO: Yeah, exactly.

21 THE COURT: I think that was okay. I don't think we
22 need a copy of that.

23 MR. PRUGO: And I think this verbally came out.

24 THE COURT: Yes, I think so, yeah.

05:13PM 25 So a question has arisen as to the exhibits. So you

1 folks are welcome to leave the exhibits in the attorney
2 conference rooms. I think Mr. Roney has checked and they are
3 available. So you can just somehow secure them, okay?

4 So are we on schedule? Is it going as the parties had
05:13PM 5 anticipated?

6 MS. PENSABENE: Yes, Your Honor, I think we will be
7 able to complete on schedule.

8 THE COURT: Yes. Do the defendants agree, Mr. Rizzi,
9 do you agree?

05:13PM 10 MR. RIZZI: I would say more or less, Your Honor. I
11 guess one question in terms of the week of August 1st.

12 THE COURT: Yes.

13 MR. RIZZI: Is it your expectation that we would --
14 well, let me ask this, would you like closings?

05:14PM 15 THE COURT: Yes.

16 MR. RIZZI: In addition to post-trial briefing.

17 THE COURT: Yes.

18 MR. RIZZI: So would the closings be deferred, then,
19 until we complete the trial on the extra couple of days?

05:14PM 20 THE COURT: I would like to have closings as to this
21 portion of the trial.

22 MR. RIZZI: Okay.

23 THE COURT: And I would like to have post-trial
24 briefing as to this portion of the trial, because we don't

05:14PM 25 have the date for the, quote, third portion yet, right?

1 MR. RIZZI: That's correct, Your Honor.

2 THE COURT: And so --

3 MR. RIZZI: But the issues do overlap.

4 THE COURT: They do, they do. I'm not suggesting it
05:14PM 5 one way or the other that they don't, but it's all up here and
6 I want to keep it up here as long as I possibly can. So the
7 more that it -- that we can get much of this -- is there a
8 reason why you couldn't do the briefing?

9 Is there a reason why a party might be prejudiced if I
05:14PM 10 required briefing now as to all of the issues, except for the
11 inequitable conduct?

12 MR. RIZZI: I guess it's hard to say in terms -- we
13 don't know obviously what testimony will be elicited from the
14 witnesses who haven't been deposed yet.

05:15PM 15 THE COURT: Right.

16 MR. RIZZI: Obviously, that's geared towards
17 inequitable conduct.

18 THE COURT: Right.

19 MR. RIZZI: It may also be relevant to invalidity.

05:15PM 20 THE COURT: Right.

21 MR. RIZZI: And I can see some logic to deferring at
22 least on invalidity and doing that together with inequitable
23 conduct.

24 MS. PENSABENE: It seems to us, Your Honor, that it
05:15PM 25 makes sense to do the invalidity and infringement briefing now

1 that we're presenting in this portion of the case, and it also
2 could be helpful in narrowing whatever issues there might be
3 left for inequitable conduct.

05:15PM 4 So we would think that briefing now while everything is
5 fresh is best. One other suggestion is to do briefing and
6 then have a short closing at a later date after the briefing,
7 if that makes sense to Your Honor to have a time to ask
8 questions based on the briefing. I know we've done that in
9 some other cases.

05:16PM 10 THE COURT: Yeah, I mean, we could do that. I
11 mean --

12 MR. RIZZI: Would it make sense to --

13 THE COURT: Mr. Rizzi.

05:16PM 14 MR. RIZZI: Would it make sense to do the briefing
15 after August 4th and then defer --

16 THE COURT: The closings?

17 MR. RIZZI: -- closings?

05:16PM 18 THE COURT: Yeah. We can defer the closings, but I
19 would like the briefing and so we can talk about dates for the
20 briefing, but we can defer the closings and so the parties
21 won't need to be prepared for the closings.

22 MR. RIZZI: And then, I mean, if -- depending on time
23 the additional testimony that might come in may allow for
24 supplemental briefing, if that's --

05:16PM 25 THE COURT: Right. Well, see, do the parties have a

1 sense as to when the third phase might occur? Because then
2 you need --

3 MR. RIZZI: I think we're in the process of trying to
4 schedule depositions in the U.K.

05:17PM 5 THE COURT: Yeah, has that gone well?

6 MR. RIZZI: I don't think we have dates. We're
7 trying to do them in September.

8 THE COURT: Okay. In September. Yeah. So --

9 MR. RIZZI: Obviously sometime --

05:17PM 10 THE COURT: -- what we could do is maybe do the
11 closings at that stage as well.

12 MR. RIZZI: Yes. I mean, assuming the depositions
13 happen in September, what was Your Honor thinking about
14 scheduling the last part of trial?

05:17PM 15 THE COURT: Sometime in October, because I have a
16 very long criminal trial in November which will go into
17 December. So I would want to get this done, again, if the
18 testimony is secured by then, I'd want to get this done in
19 October.

05:17PM 20 MR. RIZZI: Understood.

21 THE COURT: That's my hope. Okay.

22 So we will pick up on the week of August 1st. There
23 won't be closings, and then I will talk to you folks about
24 post-trial briefing then, okay?

05:18PM 25 MR. RIZZI: Thank you, Your Honor.

1 THE COURT: Okay. So everyone enjoy some of their
2 summer until I see you back, okay?

3 MS. PENSABENE: You also, Your Honor.

4 THE COURT: All right. Thank you.

05:18PM

5 THE DEPUTY CLERK: All rise.

6 (5:18 p.m.)

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*United States District Court
Camden, New Jersey*