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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:)
IMPAX LABORATORIES, INC,)
a corporation,) Docket No. 9373
Respondent.)
-----)

October 25, 2017
9:52 a.m.
TRIAL VOLUME 2
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C.

Reported by: Josett F. Whalen, Court Reporter

1 APPEARANCES:

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FEDERAL TRADE COMMISSION

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I N D E X

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IN THE MATTER OF IMPAX LABORATORIES, INC.

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TRIAL VOLUME 2

5

PUBLIC RECORD

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OCTOBER 25, 2017

7

8 WITNESS:

DIRECT

CROSS

REDIRECT

RECROSS

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16 EXHIBITS

FOR ID IN EVID IN CAMERA STRICKEN/REJECTED

17 CX

18 (none)

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20 RX

21 (none)

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23 JX

24 (none)

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: Okay. Let's go back on the
4 record.

5 Are you ready to proceed with your
6 examination?

7 MR. HASSI: Yes, Your Honor.

8 JUDGE CHAPPELL: Go ahead.

9 - - - - -

10 Whereupon --

11 ARTHUR ANTHONY KOCH, JR.

12 a witness, called for examination, having been
13 previously duly sworn, was examined and testified as
14 follows:

15 CROSS-EXAMINATION (continued)

16 BY MR. HASSI:

17 Q. Good morning, Mr. Koch.

18 A. Good morning.

19 MR. HASSI: Robert, could we bring up
20 Exhibit CX 2929 that is in evidence and not in camera.

21 JUDGE CHAPPELL: Mr. Meier?

22 Just so we're clear on the record, you had an
23 objection yesterday to the witness testifying to what
24 Mr. Mengler meant, and I have sustained it in part and
25 overruled it in part. Then a few questions later, the

1 witness was telling us what Mr. Mengler meant. I saw
2 you stand up and object, and I said I'm allow- --
3 you know, I'm granting that or I'm sustaining that
4 because I already said he can't tell us what another
5 witness meant.

6 Was that all you had to say? I want to make
7 sure whatever you want to say on the record is on the
8 record. I assume it was based on what happened two
9 questions earlier.

10 MR. MEIER: I just wanted to make sure that the
11 record was clear, but Your Honor clarified that, and
12 that was exactly the reason I had objected.

13 JUDGE CHAPPELL: All right. Thank you.

14 Go ahead.

15 BY MR. HASSI:

16 Q. So if we could start on the second page just
17 to orient the witness, if you could blow up the
18 e-mail.

19 This is an e-mail from Michelle Wong.

20 Can you tell the court who Michelle long is?

21 A. Yes. She's a regulatory affairs analyst for
22 Impax.

23 Q. And what did she report in this e-mail to you
24 and others?

25 A. She's reporting that the company had received

1 tentative approval on its oxymorphone ANDA from the
2 FDA.

3 Q. And was that good news?

4 A. Absolutely.

5 Q. If we could go now to page 1, if we could blow
6 up the e-mail at the top of the page.

7 And Mr. Hsu writes -- he's the CEO of the
8 company at this point in time; right?

9 A. Correct.

10 Q. He writes, "Most likely we will make launch
11 decision based on court decision on the PI."

12 Based on what he wrote here, what was your
13 understanding as to when Impax might consider making a
14 launch decision for oxymorphone?

15 A. Based on this e-mail, when we received a
16 favorable ruling or a ruling from the lower court on
17 the patent litigation.

18 Q. And had the patent trial begun at this point in
19 time, do you know?

20 A. From memory, I believe it had. This is
21 May 2010. I believe it had.

22 Q. Okay. You can take that down.

23 I want to move now to the negotiations related
24 to the two agreements, the settlement agreement and the
25 development and co-promotion agreement.

1 You referenced yourself yesterday as a point of
2 contact in those negotiations.

3 Can you tell the court what you meant when you
4 said you were a point of contact.

5 A. A lead negotiator at a point in time.

6 Q. And who was the other lead negotiation -- lead
7 negotiator from Impax?

8 A. Chris Mengler.

9 Q. At the time you --

10 JUDGE CHAPPELL: Hold on a second.

11 When you say "point of contact," you mean a
12 point of contact from Endo.

13 THE WITNESS: Well, from Impax to Endo and
14 from Endo to Impax. Those were the points of contact.

15 JUDGE CHAPPELL: But if I'm at Endo and I've
16 got a question about negotiations, you're the contact I
17 get in touch with?

18 THE WITNESS: Yes.

19 JUDGE CHAPPELL: Thank you.

20 BY MR. HASSI:

21 Q. And why did Impax designate a point of
22 contact?

23 A. To facilitate the communication between the
24 two companies.

25 Q. Were others at Impax, while not being points of

1 contact, involved in assessing each of those two
2 agreements?

3 A. Yes. A great -- a full team for each
4 agreement.

5 Q. Were there separate teams for each agreement?

6 A. Yes.

7 Q. Who was responsible for, on the brand side, the
8 evaluation of an agreement related to IPX-066?

9 A. That would be Michael Nestor, president of the
10 division, and he relied on Suneel, the vice president
11 of R&D.

12 JUDGE CHAPPELL: You asked a question about
13 "those two agreements," and I don't know if that's
14 clear. It's been -- he was here yesterday. I'd like
15 for the record to be clear what you're talking about
16 when you say "those two agreements."

17 MR. HASSI: Okay.

18 BY MR. HASSI:

19 Q. What was your understanding when I asked you
20 about those two agreements what I was referring to?

21 A. I think you're referring to the settlement and
22 license agreement as the first agreement and the
23 co-promote and joint development agreement as the
24 second agreement.

25 Q. Now, when you began negotiations with Endo, did

1 you have a discussion at the executive committee about
2 evaluating those agreements?

3 A. Yes.

4 Q. And who at Endo would ultimately -- excuse me.

5 Who at Impax would ultimately be responsible
6 for approving entering into one or both of those
7 agreements?

8 A. Ultimately it would be the CEO, Larry Hsu, but
9 he relied on the executive committee in carrying out
10 his duties.

11 Q. And did Mr. Hsu give the executive committee
12 any instructions on the evaluation of either or both of
13 those agreements?

14 A. He was very clear that each agreement should be
15 evaluated on their own merits as a standalone
16 agreement.

17 Q. And did you, as you were evaluating the
18 settlement agreement, evaluate it as a standalone
19 agreement?

20 A. All the time. Yes.

21 Q. Did you evaluate the development and
22 co-promotion agreement as a standalone agreement?

23 A. Yes. All the time.

24 Q. And as the person who signed the settlement
25 agreement for Impax, did you understand the settlement

1 agreement to be a standalone agreement?

2 A. Yes. Absolutely.

3 Q. And as the person who signed the development
4 and co-promotion agreement for Impax, did you
5 understand it to be a standalone agreement?

6 A. Yes.

7 Q. Were you advised by lawyers, just yes or no --

8 A. Yes.

9 Q. -- in terms of those agreements?

10 A. Yes.

11 Q. Who within Impax, what lawyer -- which Impax
12 lawyer assisted you by reviewing the development and
13 co-promotion agreement? I'm just looking for a name
14 here.

15 A. Yeah. Meg Snowden was my contact, and I'm sure
16 she had teams under her, but my contact was Meg.

17 Q. Okay. Did you have a contact for the
18 settlement agreement?

19 A. Same.

20 Q. Ms. Snowden?

21 A. Yes.

22 Q. Was there a point in time where Impax asked
23 Endo for a market degradation trigger?

24 A. I recall that. Yes.

25 Q. And what was Endo's response?

1 A. Categorically no.

2 Q. Did you press the issue with Endo?

3 A. Very hard. Yes.

4 Q. And did they maintain their categorical no?

5 A. It was nonnegotiable.

6 MR. MEIER: Your Honor, I've got to make an
7 objection to that last question and answer. It's
8 ambiguous as to when Mr. Koch said -- answered "Did you
9 press the issue with Endo?" whether "you" means
10 Mr. Koch personally or whether that means the company
11 Impax.

12 And the reason I raise this is because the
13 testimony yesterday from Mr. Koch was that he didn't
14 get involved in the actual negotiations until around
15 June 4, and by the time June 4 came around, this issue
16 had already been taken off the table.

17 JUDGE CHAPPELL: Okay. First of all, I don't
18 need you testifying while you're making an objection.
19 Just make your objection and end it, because you're
20 trying -- this is like a closing argument in the record
21 regarding this issue. We don't need that.

22 MR. MEIER: Yes, Your Honor.

23 JUDGE CHAPPELL: And you need to speak up.
24 We're having trouble hearing you.

25 Do you want to respond to that or do you want

1 to clarify with the witness?

2 MR. HASSI: I'm happy to clarify the question,
3 Your Honor.

4 BY MR. HASSI:

5 Q. When you said "you" in that last answer -- or
6 when I asked "you" in my question, who was the
7 individual who pressed on the issue of market
8 degradation trigger?

9 A. Chris Mengler.

10 JUDGE CHAPPELL: So for now I'm overruling your
11 objection, Mr. Meier. You're free to inquire into that
12 issue when you take the witness back.

13 MR. MEIER: Thank you, Your Honor.

14 MR. HASSI: Your Honor, I want to show the
15 witness a document. The document is in camera. I'm
16 happy to have him -- to not put it up on the screen
17 have him look at it and try to avoid eliciting any
18 in camera testimony.

19 JUDGE CHAPPELL: That's fine with me. Make
20 sure it's clear to opposing counsel what you're talking
21 about.

22 MR. HASSI: Sure.

23 (Pause in the proceedings.)

24 MR. HASSI: Your Honor, may I approach the
25 witness to give him a paper copy?

1 JUDGE CHAPPELL: Yes. Go ahead.

2 MR. HASSI: And would Your Honor like a copy?

3 JUDGE CHAPPELL: I don't need it.

4 Just be sure the document is identified for the
5 record.

6 MR. HASSI: Yes, Your Honor. And what I've
7 just handed the witness is RX 393. The document is in
8 evidence but is in camera.

9 BY MR. HASSI:

10 Q. And so, Mr. Koch, I'm going to ask you about
11 selected portions of this document.

12 A. Yes. Okay.

13 Q. First of all, it's an e-mail from
14 David Paterson to you and Shawn Fatholahi.

15 Can you tell us who Mr. Paterson was at the
16 time at Impax?

17 A. A business development officer for the brand
18 division.

19 Q. And who was Mr. Fatholahi?

20 A. It's pronounced "Fatholahi." And Shawn was
21 like vice president of sales for the brand division.

22 Q. Okay. And what does "business development"
23 mean in this context?

24 A. Evaluating product opportunities, business
25 development.

1 Q. And this e-mail is dated April 21, 2009; is
2 that right?

3 A. Yes.

4 Q. Could you turn to page -- the 14th page of the
5 document, the little number in the bottom right-hand
6 corner.

7 Was -- in April of 2009, were Impax and Endo
8 having discussions about a product called Frova?

9 A. Yes.

10 Q. And Impax was --

11 JUDGE CHAPPELL: Just so the record is clear,
12 are you asking this witness to read from a document or
13 to answer from his own recollection?

14 MR. HASSI: I'm asking for his -- for his
15 recollection, Your Honor.

16 JUDGE CHAPPELL: All right.

17 BY MR. HASSI:

18 Q. Do you recall?

19 A. I don't recall.

20 Q. Does reviewing this document refresh your
21 recollection that Impax and Endo were discussing a
22 migraine drug called Frova?

23 A. Yes.

24 Q. And Impax was interested in licensing Frova
25 from Endo?

1 A. Yes.

2 Q. You can set that aside.

3 You were asked a question by Mr. Meier
4 yesterday that Impax had not talked to Endo about the
5 development and co-promotion agreement before actually
6 entering into the patent settlement negotiations, to
7 which you answered, "Correct."

8 Am I correct that preceding the discussion of
9 what became the development and co-promotion agreement
10 on IPX-203 there were discussions about other business
11 opportunities between Impax and Endo?

12 A. Yes.

13 Q. Now, with respect to -- I want to talk about
14 the development and co-promotion agreement.

15 At the time that you entered into negotiations
16 related to the development and co-promotion agreement
17 with Endo, was Impax looking for a partner in the
18 United States related to IPX-066?

19 A. We were not. We were looking for a partner to
20 market that product outside the U.S.

21 Q. Why were you looking for a partner to market
22 that product outside the U.S.?

23 A. Because we had a sales force or plans to build
24 a sales force for the U.S. market, but we didn't have
25 plans for the market outside the U.S.

1 Q. And why wasn't Impax looking for a partner in
2 the U.S.?

3 A. Because we had the plans to market it
4 ourselves.

5 Q. Did Endo express an interest in marketing
6 IPX-066?

7 A. Yes. They were very interested in the entire
8 Parkinson's franchise.

9 Q. And what was Impax' response to Endo regarding
10 066?

11 A. We weren't interested in Endo or anyone else
12 for marketing in the U.S.

13 Q. Can you describe the relationship between
14 IPX-066 and IPX-06a (sic)?

15 A. IPX-066a or 203 was a line extension, a
16 derivative of IPX-066 or Rytary.

17 Q. And could you just explain what a line
18 extension is in your understanding.

19 A. It's a modification to -- from the parent
20 compound to enhance or in some way improve the next
21 generation of the product.

22 Q. And in your experience in the pharmaceutical
23 industry, what are the odds of a line extension
24 becoming a salable product as compared to, say, a new
25 chemical entity?

1 A. Very high.

2 Q. A line extension has very high odds of being
3 approvable?

4 A. Yes.

5 Q. Do you know at this point in time -- and by
6 that I mean in June of 2010 -- how much money Impax had
7 spent developing IPX-066a, the line extension?

8 A. The line extension was in the very early
9 stages, so it would have been a small amount, in the
10 order of magnitude of \$10 million, from memory.

11 Q. And do you have any understanding as to how
12 much Impax expected the development of 066a to cost
13 it?

14 A. From beginning to end probably somewhere
15 between eighty and a hundred million.

16 Q. And by agreeing to the development and
17 co-promotion agreement with Endo, what did Impax get
18 out of that agreement?

19 A. We got a partner who would fund some of the
20 costs to get IPX-066a approved.

21 Q. And what was Impax offering Endo in exchange
22 for its share of paying those costs?

23 A. A right to market the product to a select set
24 of the market, U.S. market.

25 Q. You spoke yesterday about Mr. Mengler's

1 presentation about oxymorphone to the board in May of
2 2010. And you were asked a question by Mr. Meier. He
3 asked you, "As far as you know, everyone agreed that
4 oxymorphone was a great market opportunity for Impax;
5 correct?" And you said, "Yes."

6 A. Yes.

7 Oh, sorry.

8 Q. That's all right.

9 Did you believe that oxymorphone was a great
10 market opportunity for Impax?

11 A. It could be a great market opportunity, yes.
12 We hadn't made a decision to pursue it, but if we had,
13 it looked like it would be a good -- a great market
14 opportunity.

15 Q. And when you say "a great market opportunity
16 for Impax," what do you mean?

17 A. A potential for high volume of sales, large
18 volume of sales.

19 MR. HASSI: Thank you, Mr. Koch.

20 Your Honor, I have no further questions.

21 JUDGE CHAPPELL: I have a few questions, and
22 then I'll let you ask follow-up if you'd like before we
23 do redirect.

24 Who would you say was the lead negotiator in
25 the settlement agreement for Impax?

1 THE WITNESS: Chris Mengler for most of the
2 time, and I was the lead negotiator for a short period
3 of time right at the end.

4 JUDGE CHAPPELL: And who was the lead
5 negotiator for the deal regarding the new drug, the
6 Parkinson's drug?

7 THE WITNESS: The same.

8 JUDGE CHAPPELL: How did you first learn that
9 there were going to be discussions and negotiations
10 regarding a settlement of the patent case?

11 THE WITNESS: There was an e-mail -- Endo
12 reached out to Impax seeking a discussion on potential
13 settlement.

14 JUDGE CHAPPELL: Do you know when that was?

15 THE WITNESS: I believe the first one was in
16 the fall of 2009.

17 JUDGE CHAPPELL: How did you first learn there
18 was going to be negotiations about an agreement
19 regarding a new drug dealing with Parkinson's?

20 THE WITNESS: In the course of our
21 negotiations on the settlement agreement, they became
22 aware that we had a Parkinson's franchise. They were
23 very interested in our Parkinson's franchise. They
24 had a sales force that was already calling on primary
25 care physicians, and their interest was to expand the

1 portfolio of that sales force, and a Parkinson's drug
2 is often marketed -- often prescribed by general
3 practitioners.

4 JUDGE CHAPPELL: Do you know when you first
5 learned that?

6 THE WITNESS: I don't recall a date, but I
7 would guess in the spring of 2010.

8 JUDGE CHAPPELL: You were on the executive
9 committee?

10 THE WITNESS: Yes.

11 JUDGE CHAPPELL: Are you a hundred percent
12 certain you would be aware of whether or not Impax
13 planned an at-risk launch of Opana ER?

14 THE WITNESS: Absolutely. I would have a key
15 role in that.

16 JUDGE CHAPPELL: Do you know in fact whether
17 Impax intended an at-risk launch of Opana ER?

18 THE WITNESS: Intended? Absolutely not.

19 JUDGE CHAPPELL: I asked if you know. You're
20 saying you didn't know?

21 THE WITNESS: No. I do know.

22 JUDGE CHAPPELL: You do know.

23 THE WITNESS: I do know.

24 JUDGE CHAPPELL: Did they intend to do an
25 at-risk launch of Opana ER?

1 THE WITNESS: No.

2 JUDGE CHAPPELL: Any follow-up?

3 MR. HASSI: No, Your Honor.

4 JUDGE CHAPPELL: Redirect?

5 MR. MEIER: Yes, Your Honor.

6 Good morning, Your Honor.

7 May it please the court.

8 - - - - -

9 REDIRECT EXAMINATION

10 BY MR. MEIER:

11 Q. Mr. Koch, how are you today?

12 A. I'm well. Thank you.

13 Q. Since we recessed yesterday, did you discuss
14 your testimony with anyone?

15 A. No.

16 Q. You testified a few minutes ago about the two
17 agreements, the settlement and license agreement and
18 development and co-promote agreement; correct?

19 A. Correct.

20 Q. And you said that they need to be standalone
21 agreements; correct?

22 A. Yes.

23 Q. And you are aware that the settlement and
24 license agreement in section 9.3 incorporates the
25 development and co-promotion by reference; correct?

1 A. I don't recall that.

2 Q. You don't recall me showing you that at the
3 deposition?

4 A. I don't recall that.

5 Q. All right. You have a bachelor of business
6 administration degree from Temple; correct?

7 A. I do.

8 Q. And you're a certified public accountant?

9 A. I am.

10 Q. And "certified public accountant" is sometimes
11 abbreviated as "CPA"?

12 A. Correct.

13 Q. And as a CPA and a person with more than forty
14 years of experience in finance and public accounting,
15 you're familiar with the Financial Accounting Standards
16 Board; correct?

17 A. I am.

18 Q. And the Financial Accounting Standards Board is
19 sometimes known by the acronym "FASB"; correct?

20 A. Yes.

21 Q. That's F-A-S-B.

22 The Financial Accounting Standards Board, as
23 its name implies, is a standard-setting body; correct?

24 A. It is.

25 Q. And FASB's mission is to establish and approve

1 generally accepted accounting principles within the
2 United States.

3 A. Correct.

4 Q. And "generally accepted accounting principles"
5 is sometimes known by the acronym "GAAP."

6 A. Yes.

7 Q. That's G-A-A-P; correct?

8 A. It is.

9 Q. During your seven years as CFO at Impax, the
10 financial reporting you did for Impax followed
11 generally accepted accounting principles.

12 A. Correct.

13 Q. Are you familiar with FASB's Statement of
14 Financial Accounting Standards Number 5?

15 A. Not from memory. I'd need the title.

16 Q. FASB Statement Number 5 deals with accounting
17 for contingencies?

18 A. Yes.

19 Q. Does that sound correct?

20 A. Yes.

21 Q. And are you familiar -- even if you're not
22 familiar with Statement Number 5 as a name, are you
23 familiar with how you account for contingencies?

24 A. Yes.

25 Q. And during your seven years as CFO at Impax,

1 you sometimes had to account for contingencies;
2 correct?

3 A. Correct.

4 Q. And FASB Statement Number 5 establishes
5 accounting principles for when a company should accrue
6 a charge to income from the estimated loss from a
7 contingency; correct?

8 A. Yes.

9 JUDGE CHAPPELL: Hold on. I don't know how
10 this is within the scope of the cross.

11 MR. MEIER: I'm going to tie it up very
12 quickly, Your Honor.

13 JUDGE CHAPPELL: You need to tie it up --

14 MR. LOUGHLIN: Okay.

15 JUDGE CHAPPELL: -- or I'm cutting this off.

16 MR. MEIER: All right.

17 BY MR. MEIER:

18 Q. In your experience, Impax would follow
19 FASB Statement 5 when accounting for a contingency;
20 correct?

21 A. Correct.

22 Q. And when Impax faced a potential loss from a
23 contingency, it would account for that loss in its
24 financial statements.

25 A. Yes.

1 MR. MEIER: And I have two more questions on
2 this, Your Honor.

3 BY MR. MEIER:

4 Q. As a general matter, a company like Impax would
5 prefer not to accrue a charge against income until it
6 had to.

7 A. Well, I don't really know how to answer that.
8 There's a time when it's required and a time when it's
9 not required, and it wouldn't do it before it was
10 required and it would do it when it is required.

11 Q. Thank you.

12 And so in full compliance with FASB Statement
13 Number 5, a company like Impax could face a potential
14 business loss from a contingency before it would
15 actually take a charge against income in its financial
16 statements; correct?

17 A. I didn't get that. I'm sorry.

18 Q. In full compliance with FASB Statement
19 Number 5, a company like Impax could face a potential
20 business loss from a contingency before it would
21 actually take a charge against income in its financial
22 statements.

23 A. Yes. Any business faces business risks all the
24 time.

25 Q. Business risks aren't necessarily immediately

1 reflected in financial statements; correct?

2 A. Correct.

3 MR. MEIER: I'm going to move on now,
4 Your Honor.

5 BY MR. MEIER:

6 Q. As Impax' CFO, you're responsible for investor
7 relations?

8 A. Yes.

9 Q. And you would regularly speak with stock market
10 analysts and investors?

11 A. Yes.

12 Q. And Impax is a limited liability company?

13 A. Yes.

14 Q. And Impax' owners invest in Impax in the hope
15 of making money.

16 A. Yes.

17 JUDGE CHAPPELL: How is this related to cross?
18 This is beyond the scope. You need to move on.

19 He hasn't told us that he was an auditor for
20 the firm. He hasn't told us that he had anything to
21 do with financial reports of the firm. Granted, he
22 was a CFO. This is beyond the scope. Unless you tie
23 it up -- tie it in immediately, connect it or move on.

24 MR. MEIER: I will tie it up.

25 JUDGE CHAPPELL: We're just starting here, so

1 I'm not going to allow these fishing expeditions that
2 I have continually put up with my entire career here by
3 the government's attorneys. It's not going to happen
4 in this trial.

5 MR. MEIER: Okay, Your Honor. Here's how I
6 intend to tie it up, and I'll put it out there for you,
7 and if you're not happy with it, we'll move on.

8 But yesterday, in questioning from Mr. Hassi,
9 Mr. Koch testified --

10 JUDGE CHAPPELL: You'll need to provide your
11 foundation with the witness, not telling me.

12 MR. MEIER: All right.

13 JUDGE CHAPPELL: He needs to answer questions.

14 MR. MEIER: Thank you, Your Honor.

15 JUDGE CHAPPELL: When someone tells you
16 something is beyond the scope, you need to use the
17 witness to prove it is within the scope or move on.

18 MR. MEIER: All right. Thank you, Your Honor.

19 BY MR. MEIER:

20 Q. Yesterday, in --

21 THE REPORTER: I'm sorry. Mr. Meier, please
22 slow down when you're reading.

23 JUDGE CHAPPELL: You need to slow down or
24 we're going to call in a relief pitcher. That's the
25 third time the court reporter has asked you to slow

1 down, no longer a suggestion.

2 BY MR. MEIER:

3 Q. Yesterday, in questioning from Mr. Hassi, you
4 testified that Impax was a conservative company;
5 correct?

6 A. Yes.

7 Q. But that doesn't mean that Impax would
8 routinely pass up good business opportunities while you
9 were there; correct?

10 A. Correct. Correct.

11 Q. Mr. Koch, I now want to turn back to the
12 discussion of launching at risk.

13 You testified yesterday that Impax never
14 reached a decision to launch generic Opana at risk;
15 correct?

16 A. That's correct.

17 Q. But the Impax board also never reached a
18 decision not to launch generic Opana at risk; correct?

19 A. The Impax board was never asked one way or the
20 other.

21 Q. And Impax couldn't have launched a generic
22 Opana ER until it had final FDA approval to do so;
23 correct?

24 A. That's correct.

25 Q. And Impax didn't get final FDA approval to

1 launch its generic ER product until sometime after
2 Impax' June 8, 2010 settlement of the patent litigation
3 with Endo; correct?

4 A. Correct.

5 Q. So up to the time Impax settled with Endo,
6 Impax was never in a position to legally launch generic
7 Opana ER; correct?

8 A. That's correct.

9 Q. Because Impax settled its patent litigation
10 with Endo before it had final FDA approval to launch
11 generic Opana ER, Impax' board never had to decide
12 whether to launch at risk; correct?

13 A. Impax' board was never asked one way or another
14 on -- with regard to an at-risk launch.

15 Q. And because Impax settled its patent litigation
16 with Endo before it had final FDA approval to launch
17 generic Opana, Impax' board never had to make that
18 decision; correct?

19 A. There's no link between the approval and
20 anything the board did, so I don't know why you're
21 asking that.

22 Q. All right. Based on your seven years at
23 Impax, it would have been unusual for the company to
24 make a final decision to launch a generic product
25 before Impax had the legal authority to do so;

1 correct?

2 A. We would make -- we could make a decision to
3 launch subject to the approval well in advance of the
4 approval.

5 Q. But you would not have launched until you got
6 approval.

7 A. You can't launch until you have approval.

8 Correct.

9 Q. And yesterday you testified that as part of
10 your responsibility as CFO, you would regularly attend
11 Impax' board of directors meetings; correct?

12 A. Yes.

13 Q. And you attended the May 2010 Impax board of
14 directors meeting for which Mr. Hassi showed you a
15 presentation by Mr. Mengler; correct?

16 A. I did.

17 Q. And that was CX 2663.

18 I'm sorry. Let me strike that and start over.

19 As we saw from CX 2663 yesterday, you took
20 minutes at that board meeting in May of 2010.

21 A. I took minutes at every board meeting.

22 Q. And one of the documents Mr. Hassi showed you
23 yesterday is a presentation Mr. Mengler made to the
24 board in May 2010. Do you remember that?

25 A. I do.

1 MR. MEIER: Your Honor, I'm going to ask
2 Ms. Allen in a moment to call up Exhibit 2662 which
3 Mr. Hassi showed yesterday. As Mr. Hassi stated
4 yesterday, this document is on JX 2, it's been admitted
5 into evidence, and it's not subject to your in camera
6 ruling.

7 JUDGE CHAPPELL: All right.

8 MR. MEIER: Ms. Allen, would you please put the
9 second page of CX 2662 up on the screen.

10 Thank you.

11 BY MR. MEIER:

12 Q. CX 2662 is something you've seen before;
13 correct?

14 A. Yes.

15 Q. You saw it yesterday?

16 A. I did.

17 JUDGE CHAPPELL: I have a question. If you're
18 Impax, why does this identify the company as
19 Global Pharmaceuticals?

20 THE WITNESS: The business unit we called the
21 generics business unit had a trade name called
22 Global Pharmaceuticals. It was recognized and
23 well-known in the trade as Global. And Chris often
24 referred to the generics division by its trade name.

25 JUDGE CHAPPELL: But the actual name is Impax.

1 THE WITNESS: The name of the corporation is
2 Impax. And under Impax were two business units, brand
3 and generics. And Chris was president of the
4 generics, and sometimes Chris referred to the generics
5 division or business unit as Global.

6 JUDGE CHAPPELL: Is this a separate
7 subsidiary?

8 THE WITNESS: No.

9 BY MR. MEIER:

10 Q. In addition to seeing CX 2662 yesterday, you
11 also saw it when Mr. Mengler made the presentation to
12 the board in May of 2010; correct?

13 A. Yes, I would have.

14 Q. If we could turn to slide 2662 number 8, 008.

15 Just looking at the heading of page 008, it
16 says "2010 Plan - Assumptions (as presented in
17 February)."

18 What does that mean?

19 A. He's referring back to a presentation he made
20 regarding the 2010 business plan assumption.

21 Q. And the representation -- the reference to
22 "presented in February" would have meant at a board
23 meeting in February of 2010?

24 A. Correct.

25 Q. So it would be referencing a presentation

1 Mr. Mengler might have made to the board in
2 2010 February.

3 A. That's what I understand. Yes.

4 Q. Looking down that page, do you see at the
5 bottom where it says "Oxymorphone"?

6 A. I see that.

7 Q. And do you see it says "No Launch"?

8 A. Right.

9 Q. So is it fair to take from this that in
10 2010 plan assumptions as presented to the board in
11 February there was no launch plan for oxymorphone?

12 A. I wouldn't -- no, I wouldn't say that.

13 Q. What would you say then?

14 A. That oxymorphone was a topic in the February
15 and that the -- I don't know what Chris is referring to
16 as "No Launch."

17 Q. All right. Well, then let's take a look at
18 page 12, please, which Mr. Hassi showed you yesterday.

19 Page 12 has the heading 2010 - Current
20 Assumptions; correct?

21 A. Correct.

22 Q. And can we take from that that "2010 - Current
23 Assumptions" meant current as of the May 2010 board
24 meeting?

25 A. Yes.

1 Q. And that was around May 21st or 22nd?

2 A. 25 and 6 I think.

3 Q. I'm sorry. 25 and 26. Thank you.

4 And this current assumption, if you look all
5 the way down, it says "Oxymorphone At Risk Launch."

6 A. Yes.

7 Q. Correct?

8 A. Correct.

9 Q. So in the three months from Mr. Mengler's
10 presentation to the board in February 2010 to his
11 presentation to the board in May of 2010, the status of
12 the oxymorphone launch changed from no launch to
13 at-risk launch; correct?

14 A. He's describing assumptions at the two
15 different points in time. Yes.

16 Q. He's describing the company's present
17 assumptions at two different times?

18 A. In the generics division, his assumptions,
19 yes.

20 Q. Okay. And this May board meeting, as you said,
21 occurred some -- in twenty -- May 25 or 26, and that
22 was before Impax' June 8, 2010 patent litigation
23 settlement with Endo.

24 A. Correct.

25 Q. Correct?

1 A. Yes.

2 MR. MEIER: Your Honor, may I briefly confer
3 with counsel?

4 JUDGE CHAPPELL: Go ahead.

5 MR. MEIER: I have no further questions,
6 Your Honor.

7 JUDGE CHAPPELL: Just so the record is clear,
8 the document you just questioned the witness about was
9 prepared by Mengler?

10 THE WITNESS: Mengler, yes.

11 MR. MEIER: That was the testimony from
12 yesterday, Your Honor.

13 JUDGE CHAPPELL: Who will be here to testify.

14 MR. MEIER: Correct, Your Honor.

15 JUDGE CHAPPELL: All right. Thank you.

16 Pass the witness?

17 MR. MEIER: Yes, Your Honor.

18 JUDGE CHAPPELL: Anything further?

19 MR. HASSI: Just one or two brief questions,
20 Your Honor.

21 - - - - -

22 RECROSS-EXAMINATION

23 BY MR. HASSI:

24 Q. You were just asked some questions about the
25 timing of FDA approval versus the board meeting.

1 If Impax management was considering
2 recommending an at-risk launch and you were expecting
3 the 30-month stay to expire in June, would you have
4 discussed that with the board at the May meeting or
5 would you have waited till some period in -- some
6 indefinite period in the future?

7 MR. MEIER: Your Honor, I'm going to object
8 that this is speculation. It's a hypothetical.

9 MR. HASSI: Your Honor, the witness testified
10 they wouldn't necessarily wait for FDA approval before
11 asking the board, and I just want to clarify what he
12 meant by that. I'm happy to ask it differently.

13 JUDGE CHAPPELL: Based on the objection, you'll
14 need a better foundation.

15 MR. HASSI: Okay.

16 JUDGE CHAPPELL: Sustained.

17 BY MR. HASSI:

18 Q. What's the -- strike that.

19 As of the time of the May board meeting, you'd
20 received tentative approval; is that right?

21 A. That's correct.

22 Q. And for final approval, is there anything left
23 other than the lapsing of the 30-month stay to get FDA
24 final approval?

25 A. There are steps, questions that the FDA may

1 have, but it's pretty routine and rubber stamp from the
2 time of a tentative approval to final approval.

3 Q. Was -- when Impax received tentative approval,
4 were you anticipating that final approval would be
5 granted in June of 2010?

6 A. Absolutely. Yes.

7 Q. And when you said before -- and I'm not going
8 to quote you verbatim because I didn't get it
9 verbatim. I hope Josett did -- but that you might
10 seek -- you might not wait for FDA approval before
11 asking the board, can you elaborate on that?

12 A. Because the date of approval is pretty well
13 predictable, we would want to be ready -- if we were
14 going to pursue an at-risk launch, we would want to be
15 ready on the date of that approval to make such a
16 launch, so we would never wait for that approval to
17 seek the board's approval to pursue an at-risk launch,
18 we would do it well in advance so that we could
19 accomplish the tasks necessary to prepare,
20 manufacturing product, and so forth.

21 MR. HASSI: Thank you, sir.

22 I have no further questions, Your Honor.

23 JUDGE CHAPPELL: Anything further?

24 MR. MEIER: No, Your Honor. Thank you.

25 JUDGE CHAPPELL: Thank you, sir. You may stand

1 down.

2 THE WITNESS: Thank you.

3 JUDGE CHAPPELL: Next witness.

4 (Pause in the proceedings.)

5 Are you ready?

6 MR. LOUGHLIN: Yes, Your Honor.

7 Complaint counsel calls Margaret Snowden.

8 And Your Honor, my colleague James Weingarten
9 will conduct the examination.

10 JUDGE CHAPPELL: Where is the witness?

11 MR. HASSI: She's in the building, Your Honor.
12 I've sent someone to get her. I hope they'll be here
13 shortly.

14 (Pause in the proceedings.)

15 JUDGE CHAPPELL: You did mean in this building?

16 MR. HASSI: Yes, Your Honor.

17 (Pause in the proceedings.)

18 - - - - -

19 Whereupon --

20 MARGARET MARY SNOWDEN

21 a witness, called for examination, having been first
22 duly sworn, was examined and testified as follows:

23 MR. WEINGARTEN: Good morning, Your Honor.

24 May it please the court.

25 - - - - -

1 DIRECT EXAMINATION

2 BY MR. WEINGARTEN:

3 Q. Good morning, Ms. Snowden.

4 A. Good morning.

5 Q. Would you please state your full name for the
6 record.

7 A. Margaret Mary Snowden.

8 Q. And who is your current employer, Ms. Snowden?

9 A. Impax Laboratories.

10 Q. And you've been employed by Impax since 2004?

11 A. That's correct.

12 Q. And what is your current title at Impax,
13 please?

14 A. Vice president, intellectual property
15 litigation and licensing.

16 MR. WEINGARTEN: Your Honor, pursuant to
17 rule 3.41(d) and Your Honor's October 18 ruling, given
18 the fact that Ms. Snowden is a current employee of
19 respondent, I intend to treat her as an adverse
20 witness.

21 JUDGE CHAPPELL: All right. Thank you.

22 Ms. Snowden, would you talk toward the
23 microphone, but you don't have to lean over. It's a
24 directional mike, so just talk in the direction of the
25 mike.

1 THE WITNESS: Okay.

2 JUDGE CHAPPELL: Thank you.

3 BY MR. WEINGARTEN:

4 Q. Now, Ms. Snowden, you oversee intellectual
5 property matters for Impax; correct?

6 A. Correct.

7 Q. And that includes overseeing patent prosecution
8 matters?

9 A. Correct.

10 Q. And you oversee due diligence?

11 A. Yes.

12 Q. And you oversee licensing?

13 A. Yes.

14 Q. And you work on transactions for Impax.

15 A. Yes.

16 Q. And you oversee litigations for Impax.

17 A. Yes.

18 Q. And the litigations that you oversee include
19 intellectual property and antitrust matters?

20 A. Correct.

21 Q. Now, these responsibilities that we just went
22 over, those were also your primary responsibilities at
23 Impax in 2009 and 2010; correct?

24 A. Yes.

25 JUDGE CHAPPELL: I have a question.

1 You said you oversee litigation and patent
2 matters?

3 THE WITNESS: Yes.

4 JUDGE CHAPPELL: Does that oversight include
5 actually attending trial, being in a courtroom every
6 day?

7 THE WITNESS: Not necessarily every day.
8 There -- I -- for most of this time there's been an
9 attorney who reports to me that handles more of the
10 day-to-day managing of the patent litigation, so
11 sometimes I attend a trial and sometimes not.

12 JUDGE CHAPPELL: Is the litigation handled by
13 in-house lawyers or do you retain law firms?

14 THE WITNESS: We retain outside counsel.

15 JUDGE CHAPPELL: Are you actively involved to
16 the extent that if a decision needs to be made during a
17 trial that you're consulted?

18 THE WITNESS: Not necessarily. Often -- most
19 often I would say that an attorney who reports to me
20 would be more actively involved in instructing outside
21 counsel if there was a decision that needed to be made
22 during trial.

23 JUDGE CHAPPELL: So if I understood you right,
24 either you or someone who reports to you, an attorney
25 at Impax, is actively involved.

1 THE WITNESS: Yes.

2 JUDGE CHAPPELL: Thank you.

3 BY MR. WEINGARTEN:

4 Q. During 2009 and 2010 at Impax, there was no
5 general counsel; correct?

6 A. That's correct.

7 Q. In fact, at that time, 2009 and 2010, you were
8 the highest ranking in-house attorney at Impax?

9 A. That's correct.

10 Q. And in 2009 and 2010, you reported to the CEO
11 at the time, Dr. Larry Hsu?

12 A. Yes.

13 Q. And you were responsible for legal analysis
14 that was presented to Impax' board of directors in
15 2009 and 2010?

16 A. Yes. Not necessarily all legal matters, but
17 yes.

18 Q. And you were responsible for presentations to
19 the board with respect to intellectual property
20 litigation.

21 A. Yes.

22 Q. Impax is comprised of two main businesses, a
23 brand business and a generic business?

24 A. Yes.

25 Q. And that's been the case for as long as you've

1 been at Impax; correct?

2 A. Correct.

3 Q. And you handle intellectual property matters
4 for both the brand and the generic businesses;
5 correct?

6 A. Yes.

7 Q. Now, I'd like to talk to you a little bit about
8 the oxymorphone patent litigation between Impax and
9 Endo.

10 Now, among your main responsibilities working
11 with the generic division at Impax include looking at
12 products to adopt for research and development?

13 A. Yes.

14 Q. And it includes working on intellectual
15 property strategy?

16 A. Yes.

17 Q. Managing litigation, as Your Honor just asked
18 you about?

19 A. Yes.

20 Q. Providing advice and counseling regarding the
21 Hatch-Waxman Act?

22 A. Yes.

23 Q. And the Hatch-Waxman Act, ma'am, that's the
24 federal law that sets out the process by which a
25 generic company can seek and obtain FDA approval for

1 its generic products?

2 A. Correct.

3 Q. Now, let's talk in a little more detail about
4 the circumstances that led to the litigation between
5 Endo and Impax in the District of New Jersey in 2010.

6 Now, when Impax seeks FDA approval for a
7 generic drug, it files what is known as an
8 Abbreviated New Drug Application with the FDA;
9 correct?

10 A. Correct.

11 Q. And an Abbreviated New Drug Application is
12 commonly referred to by its acronym "ANDA"?

13 A. Yes.

14 Q. And sometimes people sound it out as "ANDA"?

15 A. Yes.

16 Q. And we'll try for the court reporter's sake to
17 pronounce it very clearly.

18 An ANDA is abbreviated because it relies on
19 data and information that the brand name company
20 submitted to the FDA as part of its application for its
21 brand name drug; correct?

22 A. Correct.

23 Q. Now, as part of your work at Impax, are you
24 familiar with a publication called the Orange Book?

25 A. Yes.

1 Q. And the Orange Book is an FDA publication that
2 lists the patents that the brand name company has
3 identified as potentially covering its brand name
4 product; correct?

5 A. Correct.

6 Q. And as of 2010, there were three patents listed
7 for Opana ER in the Orange Book; correct?

8 A. That's right.

9 Q. Now, the first patent, ma'am, was
10 Patent Number 5,662,933?

11 A. Okay.

12 Q. If we call it the '933 patent, will you know
13 what I'm referring to?

14 A. Generally.

15 Q. Okay.

16 JUDGE CHAPPELL: I want to make sure the record
17 is clear. She responded, "Okay." That's agreeing with
18 you, but that doesn't tell me she knows that.

19 THE WITNESS: I don't know the patent numbers.

20 BY MR. WEINGARTEN:

21 Q. Okay. Let's do it this way then.

22 Would it help to refresh your recollection
23 potentially if we looked at the Orange Book patent
24 numbers?

25 A. Yes.

1 Q. Okay. Ms. Durand, would you please put
2 CX 301 -- hold on a second.

3 If you look at the binder, ma'am -- you'll see
4 there's a binder next to you, and there's a tab that's
5 labeled CX 301. I'm going to ask you to take a look at
6 that.

7 A. Okay.

8 Q. Let me know when you've had a chance to look at
9 the box there.

10 A. I'm ready.

11 Q. Does looking at that box refresh your
12 recollection as to the patent numbers that applied to
13 Opana ER in 2010?

14 A. Yes.

15 Q. Okay. And so if you -- you can put that aside
16 if you need to, but let me ask you again, the first
17 patent that was listed for Opana ER in the Orange Book
18 in 2010 was Patent Number 5,662,933; correct?

19 A. Correct.

20 Q. Okay. And if I refer to that as the
21 '933 patent, you'll know what we mean?

22 A. Yes.

23 Q. Okay. And the second patent number was
24 Patent Number 5,958,456; correct?

25 A. Correct.

1 Q. And if we call that the '456 patent, you'll
2 understand that's what we're referring to?

3 A. Correct -- yes.

4 Q. Okay. And the '933 and the '456 patents each
5 had an expiration date of September 9, 2013; correct?

6 A. Correct.

7 Q. Okay. And there was a third patent listed as
8 well; correct?

9 A. Correct.

10 Q. And that is the Patent Number 7,276,250;
11 right?

12 A. Yes.

13 Q. Okay. You can put that aside. Thank you.

14 Now, in its ANDA, a generic company may
15 include a patent certification as to patents that a
16 brand company has listed in the Orange Book?

17 A. They're required to include a patent
18 certification. Yes.

19 Q. Okay. And one kind of patent certification is
20 known as a Paragraph IV certification; correct?

21 A. Correct.

22 Q. And it's called Paragraph IV in reference to
23 the paragraph of the Hatch-Waxman Act that explains
24 what that certification is; correct?

25 A. Correct.

1 Q. And a Paragraph IV certification is a
2 certification by the generic company that its generic
3 product will not infringe the brand product and/or
4 that the brand patent is invalid or unenforceable;
5 right?

6 A. Correct.

7 JUDGE CHAPPELL: Are you trying to qualify this
8 witness as a patent expert?

9 MR. WEINGARTEN: I am not, Your Honor.

10 JUDGE CHAPPELL: What's your point?

11 MR. WEINGARTEN: The point is that these are
12 terms that they used in the course of stimulating
13 litigation between Impax and Endo, Your Honor.

14 JUDGE CHAPPELL: I would expect these are also
15 terms the parties can agree to in a joint stipulation
16 I've referenced.

17 MR. WEINGARTEN: And in fact I believe they
18 are, Your Honor.

19 JUDGE CHAPPELL: And if they are, why are we
20 wasting time?

21 MR. WEINGARTEN: I will move faster,
22 Your Honor.

23 BY MR. WEINGARTEN:

24 Q. You have used the term "first to file" in your
25 work at Impax?

1 A. Yes.

2 Q. Okay. The term "first to file" refers to the
3 first generic applicant to file an ANDA with a
4 Paragraph IV certification?

5 A. A substantially complete ANDA. Yes.

6 Q. Okay. Now, you are aware that
7 Endo Pharmaceuticals manufactures and markets a
8 pharmaceutical product called Opana ER?

9 A. Yes.

10 Q. And that oxymorphone is the generic name for
11 Opana?

12 A. Oxymorphone ER I would say is the generic
13 name.

14 Q. And if we refer to it as oxymorphone, you'll
15 understand we're referring to oxymorphone ER?

16 A. Yes.

17 Q. Now, Opana ER was available in multiple dosage
18 forms; correct?

19 A. Correct.

20 Q. And the dosages were 5, 7.5, 10, 15, 20, 30 and
21 40 milligrams?

22 A. That's right.

23 Q. Okay. And Impax filed an Abbreviated New Drug
24 Application for all of those dosage forms; correct?

25 A. Correct.

1 Q. And Impax was the first to file a substantially
2 complete ANDA for all of the dosage forms except the
3 7.5 and 15 milligram dosages?

4 A. Correct.

5 Q. And Impax --

6 JUDGE CHAPPELL: What do you mean by
7 "a substantially complete ANDA"?

8 MR. WEINGARTEN: My understanding, Your Honor,
9 is it may be a term of art, but the --

10 JUDGE CHAPPELL: It was your question.

11 MR. WEINGARTEN: I'll ask the witness.

12 JUDGE CHAPPELL: And if you don't know, the
13 record certainly isn't clear.

14 MR. WEINGARTEN: I will elicit it from the
15 witness if Your Honor prefer.

16 BY MR. WEINGARTEN:

17 Q. Ms. Snowden, by "substantially complete," is
18 that a term of art that the FDA uses when referring to
19 an ANDA?

20 A. Yes. That's referred to in the statute. And
21 in practice, that means the FDA has to review the ANDA
22 and accept it as having all of the information that
23 they require for a substantive review, and that's when
24 they determine that an ANDA is substantially complete.
25 And then they accept it, and that kicks off the

1 process.

2 Q. And having the first substantially complete
3 ANDA for a dosage is what triggers eligibility for
4 first-to-file status?

5 A. Correct.

6 Q. Okay. Now, Impax certified to the FDA that it
7 believed that Endo's existing patents on Opana ER were
8 invalid, unenforceable and/or would not be infringed by
9 Impax' product; correct?

10 A. Yes.

11 Q. And after Impax filed its ANDA for
12 oxymorphone ER, it notified Endo that it had made that
13 Paragraph IV certification to the FDA; correct?

14 A. Yes.

15 Q. Now, in May of 2010, the FDA tentatively
16 approved Impax' ANDA for the dosages of oxymorphone ER;
17 correct?

18 A. Yes. I -- I can't remember if it was all
19 dosages, but I think it might have been.

20 Q. Okay. Well, is it possible I might refresh
21 your recollection if I refer to an e-mail discussing
22 that tentative approval?

23 A. Okay.

24 Q. So if you'd look back to your binder, please,
25 and if you'd look at CX 2929. And if you'd look at the

1 second page of the document.

2 Let me know when you've had a chance to look at
3 the second page, please.

4 (Document review.)

5 Have you had a chance now, ma'am?

6 A. Yes.

7 Q. And does looking at that document refresh your
8 recollection as to the tentative approval status for
9 Impax' ANDA?

10 A. No.

11 Q. I'm sorry.

12 Do you recall receiving an e-mail, ma'am, from
13 Michelle Wong on May 13, 2010?

14 A. I'm sorry. When?

15 Q. Are you looking at CX 2929, ma'am?

16 A. No. I'm in the wrong place.

17 Q. That's okay. Take your time.

18 A. Okay.

19 Q. Okay. So does looking at CX 2929 refresh your
20 recollection about the FDA's tentative approval?

21 A. Yes.

22 Q. Okay. Based on your refreshed recollection,
23 ma'am, is it correct that the FDA tentatively approved
24 Impax' ANDA for all of the strengths for oxymorphone ER
25 in the middle of May 2010?

1 A. Yes.

2 Q. Okay. Thank you. You can put that aside.

3 Now, after receiving Impax' notice letter, Endo
4 filed a patent infringement lawsuit against Impax;
5 correct?

6 A. Yes.

7 Q. Okay. And Endo first sued Impax in the
8 United States District Court for the District of
9 Delaware, yes?

10 A. Yes.

11 Q. And the two patents as to which Endo sued
12 Impax for infringement were the '933 and the
13 '456 patents?

14 A. Yes.

15 Q. And eventually that lawsuit was transferred to
16 the District of New Jersey; correct?

17 A. Correct.

18 Q. And that's where the trial insofar as the trial
19 days were held occurred; correct?

20 A. Correct.

21 JUDGE CHAPPELL: Who transferred the -- who
22 moved to transfer the case, to change venue?

23 THE WITNESS: What was the question?

24 JUDGE CHAPPELL: Who moved to change venue from
25 Delaware to New Jersey?

1 THE WITNESS: Impax did. The -- the case
2 wasn't moving -- the Delaware court was overloaded.
3 They had not enough judges, and our case wasn't moving,
4 so Impax sought to move it to New Jersey in the hopes
5 of getting it moving faster. The other case was
6 already in New Jersey and was moving faster, so Impax
7 sought to move it --

8 JUDGE CHAPPELL: To get an earlier trial date?

9 THE WITNESS: Yes.

10 BY MR. WEINGARTEN:

11 Q. And so as of May and June of 2010, Endo and
12 Impax were engaged in patent litigation in the
13 District of New Jersey?

14 A. I'm sorry. What was the date?

15 Q. As of May and June of 2010 --

16 A. Yes.

17 Q. -- Endo and Impax were engaged in patent
18 litigation in the District of New Jersey.

19 A. Yes, that's correct.

20 Q. And you oversaw that patent litigation?

21 A. Yes.

22 Q. And the case was set for trial to begin in
23 June 2010; correct?

24 A. Yes.

25 Q. And trial of that case in fact began on

1 June 3, 2010?

2 A. Yes.

3 JUDGE CHAPPELL: We talked about in general
4 your level of oversight.

5 What was your level of oversight in this
6 particular case? Did you attend trial? Were you on
7 call if they needed a decision?

8 THE WITNESS: So I -- there was an attorney
9 who reported to me named Huong Nguyen who was the one
10 who was most closely working with outside counsel
11 during the trial, during the preparation for trial,
12 and -- and the run-up to trial. I was at trial when it
13 started.

14 JUDGE CHAPPELL: Did you consider this to be
15 the biggest legal issue on your radar at the time for
16 the company?

17 THE WITNESS: I think it probably was the most
18 pressing at that -- that moment, yes.

19 BY MR. WEINGARTEN:

20 Q. You attended trial on June 3 when it began;
21 correct?

22 A. Now that I say that, I don't think I saw
23 opening statements, but I was there for some of the
24 early witnesses that were put on.

25 Q. Okay. Do you recall attending any other trial

1 days?

2 A. Any other trial days?

3 Q. Uh-huh.

4 A. No.

5 Q. Okay. Now, I'd like to ask you about the
6 resolution of that patent litigation we were just
7 discussing.

8 Endo and Impax settled the patent litigation
9 that was pending in the District of New Jersey?

10 A. Yes.

11 Q. And Endo and Impax executed a settlement and
12 license agreement with an effective date of June 8,
13 2010?

14 A. Yes.

15 Q. And you were involved in the negotiation of
16 that settlement and license agreement with Endo?

17 A. Yes.

18 Q. And you were involved in the negotiations with
19 Endo in May of 2010?

20 A. Yes.

21 Q. Now, Mr. Mengler of Impax was the primary
22 negotiator on Impax' behalf with Endo in May of 2010;
23 correct?

24 A. Yes.

25 Q. And the extent of your involvement in May of

1 2010, ma'am, was an initial conversation with a
2 Mr. Donatiello of Endo and then working with
3 Mr. Mengler during the negotiations?

4 A. I would say yes, the initial conversation with
5 Guy Donatiello and then continued involvement both with
6 internal discussions and occasionally some discussions
7 with Endo --

8 Q. Got it.

9 A. -- Mr. Mengler.

10 Q. So in May and June of 2010, you were involved
11 in internal Impax discussions about the negotiations
12 with Endo to settle the patent case.

13 A. Yes.

14 Q. And in May and June of 2010, you participated
15 in some of the conversations with Endo about settling
16 the patent case.

17 A. Yes.

18 Q. You participated in phone calls with Endo at
19 which settlement was discussed?

20 A. Yes.

21 Q. And you were a recipient of e-mail
22 communications between Endo and Impax about settling
23 the patent case?

24 A. Yes.

25 Q. Now, you yourself did not actually do the

1 drafting of the settlement agreement; correct?

2 A. Correct.

3 Q. Okay. In fact, another in-house Impax lawyer
4 and outside counsel for Impax were responsible for the
5 actual drafting of the settlement; correct?

6 A. They were mostly responsible for the Impax side
7 of the drafting and wording of that agreement.

8 Q. You reviewed the executed settlement; correct?

9 A. Yes.

10 Q. Okay. If you could -- let me ask you about how
11 the negotiations began, ma'am.

12 Now, a gentleman named Guy Donatiello called
13 you in May of 2010 to start discussions about settling
14 the patent litigation?

15 A. Yes.

16 Q. Okay. And you understood Mr. Donatiello was
17 senior vice president of intellectual property for
18 Endo?

19 A. Yes.

20 Q. And in fact, Mr. Donatiello is your counterpart
21 at Endo.

22 A. Yes.

23 Q. And during that call, you and Mr. Donatiello
24 discussed a potential agreed entry date for Impax'
25 generic version of Opana ER; correct?

1 A. I think that's right. I -- as I was thinking
2 about it, I wasn't entirely sure when that conversation
3 happened, if it -- because there were some
4 conversations in 2009, but I think that -- I think
5 you're right.

6 Q. Okay. Well, would it help you, ma'am, if we
7 looked at some of your prior testimony in this case?
8 Might that help you recall or be certain that it was
9 May of 2010?

10 A. I think I reviewed some prior testimony, and it
11 seems like I -- I -- I might have said 2009 and I might
12 have said 2010 in --

13 Q. Well --

14 A. -- my two prior testimonies, so that's why I'm
15 a little bit confused.

16 Q. Understood.

17 Well, I'm going to ask you about a conversation
18 you had with Mr. Donatiello.

19 A. Okay.

20 Q. And my question is, you told Mr. Donatiello
21 that the right way to look at an entry date would be
22 to start with the end of Impax' 30-month stay, because
23 that was the first day Impax would have approval to
24 launch, and you should talk about a settlement date
25 between the end of the 30-month stay and the expiration

1 of the patents at issue; correct?

2 A. Yes.

3 Q. And that conversation happened in May of 2010;
4 correct?

5 A. I'm not entirely sure. It might have.

6 Q. When you and Mr. Donatiello were talking about
7 splitting the date between the expiration of the
8 30-month stay and the expiration of the patents, the
9 patents you were talking about were the '933 and the
10 '456 patents; correct?

11 A. Yes.

12 Q. And you told Mr. Donatiello that the dates you
13 wanted to discuss for an agreed entry for Impax'
14 generic oxymorphone ER were between June 2010 and
15 September of 2013; correct?

16 A. Yes.

17 Q. And you also told Mr. Donatiello an example of
18 when Impax had launched a generic product at risk in
19 the past; correct?

20 A. Yes.

21 Q. And launching at risk means launching prior to
22 a final court decision in favor of the generic
23 company?

24 A. Yes.

25 Q. And the example that you told Mr. Donatiello

1 about was when Impax had launched a generic oxycodone
2 product at risk; correct?

3 A. Yes.

4 Q. And you told Mr. Donatiello -- well, strike
5 that.

6 Mr. Donatiello had a negative reaction to your
7 use of that example; correct?

8 A. Yes.

9 Q. Okay. And you told him, in response to his
10 reaction, that he should think about an entry date
11 between the end of the 30-month stay and the patent
12 expiration because he was wrong to think that Impax
13 never launches at risk; correct?

14 A. Correct.

15 Q. I'm sorry. Was that correct?

16 A. Yes.

17 Q. Thank you.

18 Now, you did not -- strike that.

19 Mr. Donatiello told you that oxycodone was not
20 a good example of an Impax at-risk launch; correct?

21 A. Yes.

22 Q. But you told him that you did not agree that
23 oxycodone was not a good example; correct?

24 A. That's right.

25 Q. Okay. Now, did you -- you never told

1 Mr. Donatiello during this conversation that Impax
2 would not launch a generic version of oxymorphone ER at
3 risk, did you?

4 A. No, I didn't.

5 Q. During the course of any conversations with
6 Mr. Donatiello, you never said that Impax would not
7 launch an oxymorphone product at risk; correct?

8 A. Correct.

9 Q. Okay. Now, after you and Mr. Donatiello spoke,
10 the negotiations between Endo and Impax got under way
11 in earnest; is that fair?

12 A. Yes.

13 Q. And Mr. Mengler then stepped in as the primary
14 negotiator on Impax' behalf?

15 A. Yes.

16 Q. And Endo initially proposed a March 2013 entry
17 date for Impax' generic product; correct?

18 A. Yes.

19 Q. And Impax' representatives counterproposed an
20 entry date of January 2013; correct?

21 A. I don't know.

22 JUDGE CHAPPELL: Hold on a second.

23 If I follow your questioning, Counselor, while
24 they were negotiating, trying to get the best term for
25 the client, you asked her, did she tell the other side

1 that Impax would never make an at-risk launch? You
2 expect her to reveal that while she was negotiating?

3 MR. WEINGARTEN: I'm just trying to elicit the
4 fact that --

5 JUDGE CHAPPELL: I'm just trying to be logical.
6 Go ahead.

7 MR. WEINGARTEN: I'm just eliciting the fact,
8 Your Honor.

9 BY MR. WEINGARTEN:

10 Q. I'm sorry, ma'am. When we left off, Impax'
11 representatives proposed an entry date to Endo of
12 January 1, 2013?

13 A. I don't know.

14 Q. Is it possible I might refresh your
15 recollection if we looked at some of the e-mail
16 correspondence of which you were a participant?

17 Is it possible?

18 A. I -- I could -- I could try, but I think that
19 there were conversations that I wasn't a part of. I
20 know that we wound up at January of 2013, but I -- I
21 don't know if -- and I may never know what exactly
22 Chris proposed in conversations I was not involved in.

23 Q. Understood.

24 Do you have personal knowledge that at some
25 point in time Impax proposed to Endo an entry date of

1 January 1, 2013?

2 A. I know that that's where we wound up. I don't
3 know who proposed it or how the parties got there.

4 Q. Okay. Can I direct your attention in the
5 binder, please, to RX 318. Let's see if this refreshes
6 your recollection.

7 Ms. Durand, can you put RX 318 on the screen,
8 please, and the top e-mail.

9 This is an e-mail from Mr. Mengler; correct?

10 A. Yes.

11 Q. And it's an e-mail to an Endo person; correct?

12 A. Yes.

13 Q. And you are also a recipient of the e-mail;
14 correct?

15 A. Yes.

16 Q. And Mr. Mengler writes, "Launch date:
17 1-1-13 with no authorized generic and certain
18 acceleration triggers."

19 Do you see that?

20 A. Yes.

21 Q. Okay. Does that help refresh you, ma'am, that
22 at some point Impax had proposed a
23 January 1, 2013 entry date?

24 A. It confirms my recollection that there were
25 discussions I wasn't involved in, because earlier in

1 the e-mail chain there -- there's conversations
2 between Chris Mengler and Alan Levin about a
3 discussion.

4 So I -- it looks to me like the last e-mail
5 chain with that January 1, 2013 was a result of those
6 conversations, but I don't know what happened during
7 those conversations.

8 Q. I understand that, ma'am. My question is
9 about the e-mail that you're actually copied on at the
10 top.

11 Mr. Mengler is your colleague at Impax;
12 correct?

13 A. Yes.

14 Q. And you're copied on this e-mail; correct?

15 A. Yes.

16 Q. And Mr. Mengler in the e-mail writes "Launch
17 date: 1-1-13"; correct?

18 A. Yes.

19 Q. So my question to you, ma'am, is, at least as
20 of the date of this e-mail, you were privy to
21 information being transmitted from Mr. Mengler to Endo
22 including a January 1, 2013 launch date.

23 A. Yes.

24 Q. Thank you.

25 And you were also privy to the fact that the

1 proposal included a launch date with certain
2 acceleration triggers; correct?

3 A. Yes.

4 Q. Okay. Thank you. You can put that aside.

5 Now, the entry date agreed to in the final
6 settlement agreement was January 1, 2013; correct?

7 A. That's right.

8 Q. Now, I'd like to talk to you a little bit about
9 Actavis.

10 Actavis is a different pharmaceutical company
11 than either Endo or Impax; right?

12 A. Yes.

13 Q. Okay. And it had filed an ANDA for the 7.5 and
14 15 milligram dosages of Opana ER?

15 A. I believe they filed on all the dosages.

16 Q. Okay. They were the first to file on the
17 7.5 and 15 milligram dosages; correct?

18 A. Yes.

19 Q. Okay. And Endo had sued Actavis for patent
20 infringement?

21 A. Yes.

22 Q. And eventually Actavis and Endo settled;
23 correct?

24 A. Yes.

25 Q. And they settled before Endo and Impax settled;

1 correct?

2 A. Yes.

3 Q. Okay. Now, the date for Actavis' entry to the
4 market with its generic product was a date that you had
5 seen in public reports; correct?

6 A. Yes.

7 Q. Okay. You knew that the date that Actavis had
8 settled for was in mid-2011?

9 A. Yes.

10 Q. In fact, the Actavis entry date was July 15,
11 2011?

12 A. Yes.

13 Q. Okay. Now, during the negotiations with Endo
14 in which you participated, Impax proposed to Endo that
15 Endo give Impax the Actavis entry date; correct?

16 A. Yes.

17 Q. And during the negotiations with Endo, there
18 was a conversation among you, Mr. Koch of Impax, and
19 Endo representatives during which Impax proposed to
20 Endo just a settlement of the Opana ER patent case with
21 no co-development or co-promote deal; correct?

22 A. Yes.

23 Q. And during that conversation when you were
24 talking about a settlement without a co-development
25 deal, Impax proposed the Actavis entry date of

1 mid-2011; correct?

2 A. Yes.

3 Q. Now, I'd like to understand how this proposal
4 to Endo for the Actavis entry date came about.

5 As we saw, Endo had been negotiating for a
6 2013 date; correct?

7 A. Yes.

8 Q. And you understood Mr. Mengler on behalf of
9 Impax was negotiating for some earlier dates?

10 A. Yes.

11 Q. And after the January 2013 entry date had been
12 discussed with Endo, there was an internal Impax
13 management discussion at which you and Mr. Koch were
14 instructed to go back to Endo and seek the Actavis
15 date; correct?

16 A. Yes.

17 Q. And during that internal Impax management
18 discussion, the most recent terms on the table for both
19 the settlement agreement and the development deal were
20 discussed; correct?

21 A. Yes.

22 Q. And the discussion was that you and Mr. Koch
23 should go back to Endo and propose dropping all of that
24 discussion about settlement and co-promotion and enter
25 a simple settlement with the Actavis entry date.

1 A. That's correct.

2 Q. A simple settlement means no development deal;
3 correct?

4 A. That was the instruction.

5 Q. And a simple settlement means no acceleration
6 triggers; correct?

7 A. No.

8 Q. Okay. It could include acceleration triggers?

9 A. It could. Likely. Yes.

10 Q. A simple settlement meant no Endo credit
11 provision; correct?

12 A. I -- I don't think that was discussed.

13 Q. Okay. A simple settlement means no AG?

14 A. I don't think that was discussed.

15 Q. Okay. Let's get back to your conversation that
16 you and Mr. Koch had with the representatives from
17 Endo.

18 Mr. Koch was Impax' CFO at the time?

19 A. Yes.

20 Q. He's an officer of the company?

21 A. Yes.

22 Q. And on June -- in early June 2010, you and
23 Mr. Koch spoke with Alan Levin and Guy Donatiello of
24 Endo; correct?

25 A. Yes.

1 Q. And Mr. Levin was Endo's CFO?

2 A. Yes.

3 Q. And we've established Mr. Donatiello was sort
4 of your in-house counterpart at Endo; correct?

5 A. Yes.

6 Q. And you and Mr. Koch proposed the simple
7 settlement as you'd been directed to do by Impax
8 management.

9 A. Yes.

10 Q. And during that conversation with Endo, Impax
11 communicated to Endo that Impax wanted a settlement of
12 the Opana ER patent case with an entry date for Impax'
13 generic product that was the same as Actavis' entry
14 date; correct?

15 A. Yes.

16 Q. And that date again was July 2011.

17 A. Yes.

18 Q. And Endo refused to agree to the Actavis date
19 of July 2011; correct?

20 A. Correct.

21 Q. And the person at Endo who expressed that
22 refusal was Mr. Levin?

23 A. I think so. Yes.

24 Q. Okay. Mr. Levin insisted on reverting back to
25 a deal similar to the license agreement that he'd been

1 negotiating with Mr. Mengler with a co-promotion deal
2 as well?

3 A. Yes.

4 Q. And you discussed -- you ended up discussing
5 the development and co-promotion agreement during this
6 same conversation in which you had brought up the
7 Actavis entry date; correct?

8 A. I think so.

9 Q. Well, you think so or you are sure or you don't
10 remember?

11 A. I'm -- I -- I'm not sure right now.

12 Q. Okay. Do you recall discussing the development
13 and co-promotion agreement during that same
14 conversation when you brought up the Actavis entry
15 date?

16 A. As I sit here today, I don't recall.

17 Q. Okay. Let's -- let's see if we can look at
18 some deposition testimony that may help refresh your
19 recollection.

20 A. Okay.

21 Q. So in your binder, ma'am, there's a tab, and it
22 says "DEP" for deposition. It's at the front.

23 A. Okay.

24 Q. And if you would please turn so that you're at
25 page 101 lines 6 through 10 of your deposition

1 testimony.

2 And you can read that to yourself. It's 101,
3 6 through 10. And please let me know when you've had a
4 chance to read that to yourself.

5 JUDGE CHAPPELL: Before you go through this
6 exercise, based on my experience, I want you to be
7 doubly sure that the question you're referring her to
8 in the deposition is the very same question you just
9 asked the witness, because too many times to count I
10 have seen us go through this exercise and the question
11 is not the same either in court or in the deposition,
12 which is a big waste of our time.

13 MR. WEINGARTEN: I am very confident,
14 Your Honor, it's the same question.

15 BY MR. WEINGARTEN:

16 Q. Have you had a chance to look at that?

17 A. Yes.

18 Q. I will ask the question.

19 Is it correct that the development and
20 co-promotion deal was also discussed during the same
21 conversation in which you brought up the Actavis entry
22 date, yes or no?

23 A. Yes.

24 Q. Thank you.

25 Now, after Endo refused the Actavis entry date,

1 the conversation then pivoted back to discussing an
2 entry date in 2013; correct?

3 A. In that same conversation?

4 Q. (Counsel nodding.)

5 Yes.

6 A. As I just refreshed my recollection,
7 Alan Levin's response was anger because he had
8 negotiated terms with Chris Mengler and he was angry
9 at Impax for what he called negotiating in bad faith
10 and he -- yes, he expressed -- he expressed anger that
11 Impax would come back and renegotiate terms that he
12 had negotiated with the president of the generics
13 division. And that was the context in which he was not
14 willing to reengage on renegotiating terms that he had
15 negotiated with Chris Mengler.

16 Q. I appreciate that, ma'am.

17 My question is, Mr. Levin then wanted to pivot
18 back -- strike that.

19 My question is, the conversation pivoted back
20 to Mr. Levin wanted to discuss the terms that he'd been
21 discussing with Mr. Mengler; correct?

22 A. Yes.

23 Q. And the terms that he had discussed with
24 Mr. Mengler included an entry date of March or
25 January 2013; correct?

1 A. Correct.

2 Q. And Impax reverted back to discussing the
3 settlement agreement and the co-promotion agreement;
4 correct?

5 A. Yes.

6 Q. Okay. Impax dropped its request for the
7 Actavis entry date?

8 A. After it was refused, yes.

9 Q. Okay. And then Mr. Koch went on to negotiate
10 for better terms in the development and co-promotion
11 deal; correct?

12 A. Possibly.

13 Q. Well, is it that you agree, you disagree or you
14 don't remember, ma'am?

15 A. I think you might be able to refresh my
16 recollection.

17 Q. Okay. I'll ask you this.

18 Do you remember being on the phone call when
19 this was being discussed with -- between you, Mr. Koch
20 and the Endo representatives?

21 A. Yes.

22 Q. Okay. And do you remember that on this phone
23 call that we've been discussing Mr. Koch went on to
24 negotiate for better terms on the co-promotion deal?

25 A. I -- I don't remember, but --

1 Q. Okay. Let me direct you, ma'am, in your
2 deposition again to page 197 line 25, continuing onto
3 to page 198 line 1 -- well, strike that -- line 2.

4 Let me know when you've had a chance to take a
5 look at that.

6 (Document review.)

7 Do you see those three lines, ma'am?

8 A. I'm sorry?

9 Q. Page 197 line 25 through 198 line 2.

10 A. Okay. I see that.

11 Q. Okay. You can put that aside.

12 Does that refresh your recollection, ma'am,
13 that Mr. Koch on that call went on to negotiate for
14 better terms on the co-promote deal?

15 A. Yes.

16 Q. Okay. And that's what happened, Mr. Koch went
17 on to negotiate for better terms on the co-promote
18 deal; correct?

19 A. Correct.

20 Q. Thank you. You can put that aside, please.

21 And in that same conversation, Impax began
22 negotiating for increases to the payments that would be
23 due to Impax under the development and co-promotion
24 agreement; correct?

25 A. Do you want me to --

1 Q. If you need it.

2 A. -- look further?

3 Q. Let me ask the question, and you tell me,
4 ma'am, yes, no, or you don't remember.

5 A. I don't remember.

6 Q. Okay. Let's go back to the deposition, please.

7 Page 198 line 11.

8 If you'd look at 198 lines 11 through 14,
9 ma'am, and let me know when you've had a chance to look
10 at those lines.

11 (Document review.)

12 A. Okay.

13 Q. Does that refresh your recollection, ma'am,
14 that after Mr. Levin rejected the Actavis entry date,
15 Mr. Koch then began negotiating for increases to the
16 payments under the development and co-promotion deal?

17 A. That refreshes my recollection that I
18 responded, it wasn't that direct, but it was later in
19 that conversation, yes.

20 Q. Okay. Your testimony, ma'am -- let me ask you
21 this.

22 When you made that testimony at page 198
23 lines 11 through 14, that was true and accurate at the
24 time you gave it; correct?

25 A. Yes.

1 MR. HASSI: Your Honor, I have an objection
2 here.

3 Ms. Snowden and the deposition that we're
4 referring to was done both -- there were a number of
5 topics that were requested of her as a corporate
6 designee, and she was also deposed in her personal
7 capacity. And while I requested that counsel do them
8 separately so that the transcript could be clear,
9 counsel refused to do that.

10 And so the portion he's refreshing her
11 recollection with starts with questions about "in your
12 capacity as a corporate designee." And I think part
13 of the reason for this witness' confusion relates to
14 the fact that the deposition jumps back and forth
15 between corporate designee and personal capacity, and
16 so it's not clear to me whether the witness has an
17 actual recollection of these events or has a
18 recollection of testifying as corporate designee to
19 certain of these events, and I'd like that made clear
20 for the record.

21 JUDGE CHAPPELL: Response?

22 MR. WEINGARTEN: May I respond, Your Honor?

23 JUDGE CHAPPELL: Go ahead.

24 MR. WEINGARTEN: Your Honor, Ms. Snowden has
25 already testified here today and at her deposition

1 that she was on this phone call and participated, so
2 she has personal knowledge. I am simply attempting to
3 refresh her recollection with her prior testimony.

4 If it doesn't refresh her recollection, she can
5 tell me that, but if it refreshes it, then I believe
6 I'm entitled to inquire as to her personal knowledge
7 having been refreshed.

8 JUDGE CHAPPELL: And she's also entitled to
9 know what portion of the deposition you're referring
10 to.

11 The objection is sustained.

12 MR. WEINGARTEN: Okay.

13 BY MR. WEINGARTEN:

14 Q. Ms. Snowden, in your personal knowledge, you
15 participated on that phone call with Mr. Koch and the
16 Endo representatives; correct?

17 A. Yes.

18 Q. And I asked you a question that started off
19 about your corporate capacity; correct, at your
20 deposition?

21 A. Yes.

22 Q. Okay. Having seen that question, does that
23 refresh your personal recollection about the contents
24 of the call?

25 A. No.

1 Q. Okay. So your testimony today is you don't
2 remember during that call Mr. Koch negotiating for
3 increases to the milestone fees due under the
4 development and co-promotion agreement.

5 A. Not today. I'm sorry.

6 Q. Okay. Do you have any reason to doubt the
7 testimony that you provided during your deposition?

8 A. No.

9 Q. Okay. You were truthful and accurate when you
10 gave that testimony; correct?

11 A. Yes.

12 Q. And it was sworn testimony.

13 A. Yes.

14 Q. And you had in fact a chance to review the
15 testimony and provide an errata if you wanted to;
16 correct?

17 A. Yes.

18 Q. And you didn't provide an errata as to this
19 sentence --

20 A. Correct.

21 Q. -- in your testimony, did you?

22 A. No, I didn't.

23 Q. Now, I'd like to direct your attention to the
24 provision in the settlement agreement that is called
25 the Endo credit.

1 A. Okay.

2 JUDGE CHAPPELL: Mr. -- is it "Koch" or "Koch"?

3 MR. WEINGARTEN: I believe it's pronounced
4 "Koch," Your Honor.

5 JUDGE CHAPPELL: And you're asking this witness
6 questions about a phone call or a meeting that included
7 Mr. Koch; right?

8 MR. WEINGARTEN: Yes, Your Honor.

9 JUDGE CHAPPELL: Were these same questions
10 asked of Mr. Koch while he was here in the witness
11 chair?

12 MR. WEINGARTEN: I don't believe so,
13 Your Honor.

14 JUDGE CHAPPELL: I don't either.

15 Go ahead.

16 BY MR. WEINGARTEN:

17 Q. Now, you participated personally in phone calls
18 about the concepts that eventually became the Endo
19 credit provision in the settlement; correct?

20 A. Yes.

21 Q. And you're aware there is a term in the
22 settlement called Endo credit?

23 A. Yes.

24 Q. Okay. And it's section 4.4 of the settlement
25 agreement?

1 A. Yes.

2 Q. Okay. Now, you had no personal involvement in
3 the actual drafting of the language of the Endo credit
4 provision; correct?

5 A. That's right.

6 Q. Okay. Now, during the negotiations, Impax
7 negotiated for protections in case Endo moved the
8 market away from the original formulation of Opana ER;
9 correct?

10 A. Yes.

11 Q. And the first form of protection that Impax
12 proposed were acceleration triggers for the entry
13 date.

14 A. That's right.

15 Q. And "acceleration triggers" means if a
16 specified condition precedent occurs, then the date of
17 entry for Impax gets moved up; correct?

18 A. Yes.

19 Q. Now, Endo rejected the idea of an acceleration
20 trigger?

21 A. Yes.

22 Q. And after Endo had rejected the idea of an
23 acceleration trigger, the parties agreed to the concept
24 that eventually became the Endo credit.

25 A. Yes.

1 Q. Now, you were on a phone call during a
2 conversation between Mr. Levin of Endo and Mr. Mengler
3 of Impax about negotiating the figures that became part
4 of the Endo credit provision; correct?

5 A. Yes.

6 Q. And during that call, Mr. Mengler said to Endo
7 that Impax would accept the alternative of a credit
8 instead of an acceleration trigger, but all the
9 assumptions in the credit would be in Impax' favor;
10 correct?

11 A. Yes.

12 Q. Mr. Mengler said, if Impax was going to agree
13 to this structure for protection from market
14 degradation, then Endo would have to agree to
15 aggressive numbers for the Endo credit; correct?

16 A. Yes.

17 Q. And the Endo credit was intended to be an
18 incentive for Endo not to move the market and to
19 protect Impax; correct?

20 A. Correct.

21 Q. And the Endo credit results in a cash payment
22 from Endo to Impax if in fact the market for Opana ER
23 declined in certain circumstances; correct?

24 A. Correct.

25 Q. Now, on January 18, 2013, you wrote a letter to

1 Endo, telling Endo that the Endo credit provision had
2 been triggered; correct?

3 A. Yes.

4 Q. And you wrote that that section of the
5 settlement agreement required Endo to pay approximately
6 \$102 million to Impax?

7 A. Yes.

8 Q. And you provided the backup with the basis for
9 the payment you requested; correct?

10 A. Yes.

11 Q. Okay. Let's take a look.

12 Ms. Durand, can you put CX 332 on the screen,
13 please.

14 Can you go to page 1, please, Ms. Durand.

15 It's also in your binder, but whichever is
16 easier for you, Ms. Snowden.

17 This is a cover e-mail from a lady named
18 Huong Nguyen. Her last name is spelled N-G-U-Y-E-N.

19 Ms. Nguyen worked for you at Impax?

20 A. Yes.

21 Q. And it's an e-mail to Mr. Donatiello of Endo;
22 correct?

23 A. Yes.

24 MR. HASSI: Can I just interrupt. What's the
25 record number?

1 MR. WEINGARTEN: I'm so sorry.

2 MR. HASSI: The record showed up as 332, and
3 that's not it.

4 MR. WEINGARTEN: No, it is. I'm asking about
5 this, 332.

6 (Pause in the proceedings.)

7 BY MR. WEINGARTEN:

8 Q. And you were copied on this e-mail from
9 Ms. Nguyen; correct?

10 A. Yes.

11 Q. And the e-mail is transmitting your letter to
12 Mr. Donatiello; correct?

13 A. Yes.

14 Q. Okay. Let's turn to the letter.

15 Ms. Durand, if you would put up page 7,
16 332-007.

17 This is in fact your letter to Mr. Donatiello;
18 correct?

19 A. Yes.

20 Q. And it's addressed to both the president and
21 the chief legal officer of Endo Pharmaceuticals?

22 A. Yes.

23 Q. Okay. You wrote this letter?

24 A. Yes.

25 Q. Okay. And if we could go to page 008, please,

1 Ms. Durand.

2 There we go. Thank you.

3 If you can highlight the paragraph that's
4 numbered 2 and then the rest of it, 2 through the
5 signature, please.

6 So it says "2. Endo Credit" all the way down.

7 And then the number 2, please, ma'am.

8 There you go. Perfect. Thank you.

9 So in your letter, you wrote, "The data shows
10 the Endo Credit to be \$102,049,199.64"; correct?

11 A. Yes.

12 Q. And in number 3 you wrote -- I'm sorry.

13 In number 2, you wrote, "Attachment 1 sets
14 forth the data to determine, and calculates the
15 Endo Credit," and then you go through the calculation;
16 correct?

17 A. Correct.

18 Q. And you also wrote, "Attachment 2 shows the IMS
19 data used in the calculations"; correct?

20 A. Correct.

21 Q. So you provided Mr. Donatiello with your
22 calculation and the backup for the calculation.

23 A. Correct.

24 Q. Yes?

25 I'm sorry, ma'am. I didn't --

1 A. Correct.

2 Q. Thank you.

3 And in the last paragraph of your letter or
4 second to last, you write, "Pursuant to Section 4.4,
5 since the Pre-Impax Amount (3.47 percent) is less than
6 the Trigger Threshold (50 percent), Endo is to pay
7 Impax \$102,049,199.64 (the 'Endo Credit'). This
8 payment is due within 90 days of receipt of this
9 letter."

10 You wrote those words?

11 A. Yes.

12 Q. You sent this letter to Endo?

13 A. Yes.

14 Q. Okay. And in fact, you also provided wire
15 instructions so Endo could wire the money to Impax;
16 correct?

17 A. Yes.

18 Q. Okay. You can take that down, Ms. Durand.
19 Thank you.

20 Now, Endo paid the \$102 million to Impax;
21 correct?

22 A. Yes.

23 Q. In fact, Endo paid the exact amount you
24 requested, \$102,049,199.64, to the penny; correct?

25 A. I think so.

1 Q. And Endo paid that amount to Impax by wire
2 transfer in April of 2013?

3 A. Yes.

4 Q. Ms. Snowden, do you remember testifying in your
5 deposition that you don't recall ever hearing anyone
6 use the term "stick" to refer to the Endo credit during
7 the negotiations with Endo?

8 A. I could say today I don't recall anybody using
9 that term.

10 Q. Even better.

11 So you don't recall sitting here today anyone
12 using the term "stick" during the negotiations with
13 Endo to refer to the Endo credit?

14 A. Right.

15 Q. Okay. And you don't recall anyone internally
16 at Impax using the phrase "carrot and stick" during the
17 time period of the negotiations?

18 A. Correct.

19 Q. Thank you.

20 Now, you're familiar with the term
21 "no-authorized-generic clause"?

22 A. Yes.

23 Q. It's sometimes abbreviated as a no-AG clause?

24 A. Yes.

25 Q. And you understand it means that there will not

1 be a generic sold under the brand company's
2 New Drug Application?

3 A. Correct.

4 Q. In other words, the brand name company agrees
5 not to sell a generic version of its product during a
6 generic company's 180-day exclusivity period; correct?

7 A. Yes.

8 Q. And the final settlement agreement between Endo
9 and Impax includes a no-AG clause; correct?

10 A. Correct.

11 Q. And if there's no authorized generic and Impax
12 maintained its exclusivity, then Impax would be the
13 only generic product on the market during its 180 days
14 of exclusivity; correct?

15 A. Correct.

16 Q. Thank you.

17 Now, I'd like to talk to you a little bit about
18 the license provision in the settlement.

19 A. Okay.

20 Q. A patent holder has the right to grant a
21 license for use of its patents?

22 A. Yes.

23 Q. Okay. And a patent holder can do so on a
24 royalty-free basis; correct?

25 A. Yes.

1 Q. Or the patent holder can obtain value by
2 seeking a royalty for the use of its patents; correct?

3 A. Yes.

4 Q. The settlement agreement with Endo includes a
5 license from Endo to Impax; correct?

6 A. Yes.

7 Q. Okay. And the license is a royalty-free
8 license unless Opana ER sales grew to a certain trigger
9 level; correct?

10 A. Yes.

11 Q. Impax never ended up having to pay any royalty
12 to Endo pursuant to that license provision; correct?

13 A. No.

14 I have to caveat. There was a royalty dispute
15 with Endo, and in solving that dispute, Impax does pay
16 a royalty to Endo.

17 Q. Let me ask you this question, ma'am.

18 Pursuant to the provision in section 4.1 of the
19 agreement as it was executed on June 8, 2010, Impax
20 never paid a royalty to Endo; correct?

21 A. I -- I -- I -- like I said, there was a
22 royalty dispute with Endo because there's another
23 provision that Endo said did require a royalty. Impax
24 disputed that, and we -- and they sued us, and we
25 settled that litigation, and we do pay a royalty.

1 Q. I see.

2 It was Impax' belief that this section 4. --
3 strike that.

4 A. That section does say "royalty-free."

5 Q. Okay. The license was royalty-free unless
6 certain trigger thresholds were met.

7 A. It -- that provision says it was royalty-free
8 unless certain trigger thresholds were met, and I will
9 caveat that with Endo believed that there was another
10 provision that also required royalties, and they didn't
11 agree that it was entirely royalty-free.

12 Q. I understand, ma'am. I appreciate that. My
13 questions are really directed to the settlement
14 agreement as executed and the language --

15 A. That language that you're looking at, yes, says
16 "royalty-free."

17 Q. Thank you.

18 JUDGE CHAPPELL: Wait a minute. I want to make
19 sure the record is clear.

20 The dispute where Endo demanded a royalty you
21 referred to, is it arising from this same agreement?

22 THE WITNESS: Yes.

23 JUDGE CHAPPELL: And did I hear you say that
24 you are paying a royalty to Endo?

25 THE WITNESS: Yes.

1 JUDGE CHAPPELL: But I also heard you say 4.1,
2 the provision he was trying to focus on, does not
3 require a royalty.

4 THE WITNESS: Right. The language in 4.1, it
5 says the -- that the license is royalty-free except
6 for the certain provision that he was referring to
7 where Impax would pay a royalty if Opana ER sales
8 grew.

9 And the dispute between Impax and Endo that
10 came up later was a different provision of the
11 contract, where Endo said that this other provision
12 that required a negotiation was a negotiation for
13 royalties, and we had a dispute about that. And when
14 we settled that dispute, Impax agreed to pay Endo a
15 royalty.

16 JUDGE CHAPPELL: Okay. But there was never any
17 assertion that the triggering event in 4.1 ever
18 required a royalty.

19 THE WITNESS: That's correct.

20 JUDGE CHAPPELL: All right.

21 MR. WEINGARTEN: Thank you, Your Honor.

22 BY MR. WEINGARTEN:

23 Q. Outside of their court filings, ma'am, in the
24 patent case, during the negotiations of the settlement
25 agreement, Endo and Impax never communicated about the

1 merits of the patent litigation that Endo had brought
2 against Impax; correct?

3 A. That's right.

4 Q. Now, you're familiar with the process at Impax
5 for authorizing an at-risk launch of a generic
6 product?

7 A. Yes.

8 Q. And you've participated in presentations to
9 the Impax board of directors about a potential at-risk
10 launch of an Impax product?

11 A. Yes.

12 Q. And in your experience, when senior Impax
13 management discussed potential at-risk launches with
14 the board, senior management was accurate in the
15 information it presented?

16 A. Yes.

17 Q. And you can't recall any instances in which
18 information presented to the board about a potential
19 at-risk launch was inaccurate when it was presented;
20 correct?

21 A. Correct.

22 Q. Thank you.

23 Now, in your experience with at-risk launch at
24 Impax, Impax' board of directors had on at least one
25 occasion authorized Impax management to sell a drug at

1 risk but subject to a dollar limit on the amount that
2 management could sell; correct?

3 A. Yes.

4 Q. And by doing that, by placing a dollar limit on
5 the amount management could sell, the board could limit
6 the potential damages liability for the at-risk launch;
7 correct?

8 A. Yes.

9 Q. So, for example, in 2008, Impax' board of
10 directors authorized an at-risk launch of a generic
11 product called Solodyn with a capped damages exposure;
12 correct?

13 A. Yes.

14 Q. All right. I'd like to talk to you a little
15 bit about the development and co-promotion agreement
16 that Endo and Impax entered into.

17 You participated in internal discussions at
18 Impax in May and June of 2010 about entering a
19 potential joint development agreement with Endo?

20 A. Yes.

21 Q. And Endo and Impax in fact executed a
22 development and co-promotion agreement on or about
23 June 7 or 8, 2010?

24 A. Yes.

25 Q. And you worked more on the development

1 agreement than you did on the settlement agreement;
2 correct?

3 A. Yes.

4 Q. In fact, you were the lead in-house counsel at
5 Impax for the drafting of the development agreement?

6 A. Yes.

7 Q. If you could turn in your binder, please,
8 ma'am, to RX 365, sort of towards the back.

9 And Ms. Durand, you can put this one up on the
10 screen on page 1.

11 This is the executed development and
12 co-promotion agreement between Endo and Impax?

13 A. Yes.

14 Q. Okay. If you flip to the back, there's
15 signatures on behalf of the various parties?

16 A. Okay.

17 Q. And just to be complete, if you look in your
18 tab at RX 364, that's a copy of the executed
19 settlement and license agreement between Endo and
20 Impax; correct?

21 A. Yes.

22 Q. Okay. My questions are going to focus on 365.

23 Now, the development and co-promotion agreement
24 involved a product at Impax that was referred to
25 internally as IPX-203?

1 A. Yes.

2 Q. And that was Impax' internal designation for
3 the next generation of a product that was called
4 IPX-066.

5 A. Yes.

6 Q. And sometimes it was called 203 and sometimes
7 it was called 66a; correct?

8 A. Yes.

9 Q. Now, the development and co-promotion agreement
10 provides for certain payments to Impax by Endo;
11 correct?

12 A. Yes.

13 Q. Well, let's please turn to the relevant section
14 of the development and co-promotion agreement regarding
15 the payments, so if you would please turn to
16 RX 365.0009.

17 Are you there, ma'am?

18 A. Yes.

19 Q. And Ms. Durand, could you please put that on
20 the screen.

21 And can you highlight, Ms. Durand,
22 section 3.1 and 3.2.

23 Now, section 3.1 of the agreement calls for an
24 upfront payment from Endo to Impax; correct?

25 A. Yes.

1 Q. And it says, "Endo shall pay Impax a payment of
2 Ten Million U.S. dollars within five business days
3 after the Effective Date"; is that right?

4 A. Yes.

5 Q. And so the only trigger for that payment was
6 the execution of the agreement; correct?

7 A. Correct.

8 Q. And in fact, Endo made that \$10 million payment
9 to Impax?

10 A. Yes.

11 Q. Okay. And we'll talk a little bit about those
12 other milestone fees in a minute.

13 Now, the settlement agreement and the
14 development and the co-promotion agreement, they were
15 executed on or about the same day; correct?

16 A. Yes.

17 Q. And in fact, Mr. Koch, Impax' CFO, executed
18 both within a few hours of each other; correct?

19 A. Yes.

20 Q. Now, during the negotiations, both Impax and
21 Endo expressed to each other that they wanted to move
22 quickly; is that correct?

23 A. Yes.

24 Q. And in fact, while you were at the trial in
25 New Jersey, Mr. Donatiello of Endo told you that Endo

1 wanted to settle the litigation by June 8 to avoid
2 having its expert witness cross-examined during the
3 trial; correct?

4 A. Yes.

5 Q. And Mr. Donatiello told you that in a
6 face-to-face conversation between you and him in
7 New Jersey.

8 A. Yes.

9 Q. I'd like to ask you a little bit about the
10 product that's part of the development agreement.

11 So as of May 2010, IPX-066 was in Phase III
12 clinical trials; correct?

13 A. I think that's right, yeah.

14 Q. And as of May 2010, IPX-203, by contrast, was
15 in the early stages of development; correct?

16 A. Yes.

17 Q. If you could turn in the development agreement,
18 ma'am, to page RX 365.0006.

19 And you can put that on the screen, please,
20 Ms. Durand.

21 And I'm directing you specifically to the
22 definition of the term "Product."

23 This is the part of the agreement that defines
24 the product that is the subject of the agreement;
25 correct?

1 A. Yes.

2 Q. And the product is defined as being the product
3 as described in the first investigational New Drug
4 Application and, after submission, the NDA for such
5 product filed by Impax; is that right?

6 A. Yes.

7 Q. So the definition refers to a potential filing
8 by Impax to provide the rest of the definition of the
9 product; right?

10 A. Yes.

11 Q. And it's referring to an investigational
12 New Drug Application that had not been filed as of the
13 date of this agreement; correct?

14 A. Yes.

15 Q. And in fact, the investigational New Drug
16 Application had not been drafted as of the date of this
17 agreement; correct?

18 A. I don't think I'd be the one to know.

19 Q. Okay. To your knowledge, Impax had not begun
20 investigating -- sorry. Strike that.

21 To your knowledge, Impax had not begun drafting
22 an investigational New Drug Application for the product
23 described here at the time that this agreement was
24 executed.

25 A. That's true.

1 Q. Okay. You can take that down, please,
2 Ms. Durand.

3 Let me ask you a little bit about the
4 due diligence process, ma'am, that led to the execution
5 of this agreement.

6 You're familiar with the concept of a data
7 room?

8 A. Yes.

9 Q. Okay. And a data room is an electronic setup
10 where confidential documents can be stored and
11 confidential access given to parties to review those
12 documents?

13 A. Yes.

14 Q. It's sort of the electronic way people share
15 information now instead of actually exchanging paper?

16 A. Yes.

17 Q. Okay. Impax had created a data room for
18 IPX-066; correct?

19 A. Yes.

20 Q. And that's not the product that ended up being
21 in the development agreement; right?

22 A. Right.

23 Q. And Impax had set up that data room for
24 product 66 before its negotiations with Endo began;
25 correct?

1 A. Yes.

2 Q. And it had set up that data room because it was
3 engaged in negotiations with other companies about 66;
4 correct?

5 A. Correct.

6 Q. Impax never set up a data room for IPX-203
7 before this agreement was signed; correct?

8 A. Correct.

9 Q. And you don't have any personal knowledge of
10 any conversations between Endo and Impax about creating
11 a data room for IPX-203; correct?

12 A. I don't have any knowledge of that, correct.

13 Q. Okay. Now, to your knowledge, Impax provided
14 to Endo the information about 66 that was in the data
15 room; correct?

16 A. Yes.

17 Q. Okay. And apart from forecasts, financial
18 forecasts, regarding 66 that were in that data room,
19 you don't have any knowledge of any financial forecasts
20 for 2013 being sent to Endo as part of the
21 due diligence; correct?

22 A. Correct.

23 Q. Okay. And to your knowledge, Endo never
24 requested any specific financial information about
25 IPX-203 from Impax other than the info they already got

1 in the data room.

2 A. Correct.

3 Q. Impax and Endo never conducted a face-to-face
4 presentation about IPX-203; correct?

5 A. I think that's right.

6 Q. And you don't have any knowledge of any
7 internal conversations at Impax about what
8 due diligence should be provided to Endo regarding
9 IPX-203; correct?

10 A. Could you repeat the question.

11 Q. I'll withdraw the question.

12 Now, the development agreement required Impax
13 to develop the product in consultation with a joint
14 development committee; correct?

15 A. Yes.

16 Q. Okay. And there's a separate section of the
17 agreement that actually addresses the composition and
18 responsibilities of this joint development committee;
19 correct?

20 A. Yes.

21 JUDGE CHAPPELL: Do you know when negotiations
22 switched from IPX-66 to IPX-203?

23 THE WITNESS: My -- my recollection is that
24 Impax had always been proposing that the deal be
25 around IPX-203. Endo was interested in the

1 Parkinson's space and wanted the deal to cover both
2 products, the original IPX-066 and the follow-on
3 product, but Impax wasn't interested in doing the deal
4 on IPX-066.

5 So there wasn't actually -- there wasn't a
6 switch as much as Endo was trying to negotiate for
7 both product rights and Impax was only interested in
8 doing product rights on the one product.

9 JUDGE CHAPPELL: Was there ever a draft
10 agreement prepared that included IPX-66?

11 THE WITNESS: Endo had sent a term sheet that
12 included them both. Yes.

13 JUDGE CHAPPELL: But Impax never drafted an
14 agreement including IPX-66?

15 THE WITNESS: That's right.

16 BY MR. WEINGARTEN:

17 Q. Just turning back to the joint development
18 committee, ma'am, the joint development committee was
19 supposed to have six members, three each from Impax and
20 Endo; is that right?

21 A. I think that's right.

22 Q. Okay. And the development and co-promotion
23 agreement required that while Impax was developing this
24 product that we saw the definition of, the joint
25 development committee was supposed to meet at least

1 four times each year; correct?

2 A. I think that's right.

3 Q. Okay. And to your knowledge, the joint
4 development committee met only one time; is that
5 right?

6 A. That's right.

7 Q. And in fact, that one time didn't occur until
8 2015; correct?

9 A. I think that's right.

10 Q. And you attended that meeting?

11 A. Yes.

12 Q. But you were not a member of the joint
13 development committee.

14 A. Correct.

15 Q. And shortly after that meeting -- well, strike
16 that.

17 After that meeting, in 2015, the development
18 and co-promotion agreement was terminated.

19 A. Correct.

20 Q. And in 2015, Endo and Impax agreed to terminate
21 the development and co-promotion agreement.

22 A. Correct.

23 Q. And it was Endo that first raised the idea of
24 terminating the agreement?

25 A. Yes.

1 Q. Let's go back to those milestone payments if
2 you don't mind, ma'am. It's RX 365.0009.

3 And Ms. Durand, if you can put that on the
4 screen, please.

5 Section 3.2. Thank you.

6 Do you have that in front of you?

7 A. Yes.

8 Q. This section sets forth the payments that are
9 due from Endo to Impax if Impax successfully completes
10 certain milestones on the way to commercializing this
11 product; correct?

12 A. I'm sorry. Repeat the question.

13 Q. Sure.

14 This section sets forth payments due from Endo
15 to Impax as Impax completes certain steps on the way to
16 commercializing the product; correct?

17 A. Yes.

18 Q. Okay. Impax never achieved any of the
19 milestones listed there before the agreement was
20 terminated; correct?

21 A. Correct.

22 Q. Impax never refunded the \$10 million that Endo
23 had paid pursuant to section 3.1, did it?

24 A. No.

25 Q. Okay. You can put that aside. Thanks.

1 Impax never proposed reaching an agreement on
2 the development and co-promotion deal without also
3 reaching a settlement on the pending patent litigation;
4 correct?

5 A. Correct.

6 JUDGE CHAPPELL: Let me go back to one of your
7 previous questions.

8 Is it the government's position that the
9 agreement required Impax to refund the \$10 million --

10 MR. WEINGARTEN: No, Your Honor.

11 JUDGE CHAPPELL: -- that there was any term in
12 the agreement that ever required that?

13 MR. WEINGARTEN: No, Your Honor.

14 BY MR. WEINGARTEN:

15 Q. And Endo never proposed to Impax doing the
16 development deal on its own without also settling the
17 patent litigation; correct?

18 A. I think that's right.

19 Q. And Impax and Endo had never entered into any
20 other development agreements prior to executing this
21 agreement that we have been discussing; correct?

22 A. I think that's correct.

23 Q. And Endo and Impax have not entered into any
24 other development agreements since they executed the
25 June 2010 development agreement; correct?

1 A. Correct.

2 Q. Just briefly on the license, after the
3 settlement agreement was executed, Endo later
4 communicated to Impax that Endo believed the license it
5 had granted was terminated; correct?

6 A. Yes.

7 Q. And in fact, Endo brought a lawsuit against
8 Impax for allegedly breaching the terms of the
9 settlement agreement; correct?

10 A. Yes.

11 Q. And Endo sued Impax again in the District of
12 New Jersey?

13 A. Yes.

14 Q. And they sued Impax for patent infringement?

15 A. For breach of contract, and they added patent
16 infringement because they alleged that the license had
17 been terminated.

18 Q. So in the suit that Endo brought later after
19 this agreement was executed, they alleged that Impax
20 was infringing certain Endo patents; correct?

21 A. Yes.

22 Q. Okay. And Impax moved to dismiss that
23 lawsuit?

24 A. Yes.

25 Q. And Endo's suit survived that motion to

1 dismiss?

2 A. Yes.

3 Q. And then later on, Endo and Impax eventually
4 reached a settlement of that new litigation about the
5 license; correct?

6 A. Yes.

7 Q. Okay. And during the course of the
8 negotiations, you never heard the license and the
9 settlement agreement referred to as a universal
10 license; correct?

11 A. I'm not sure I heard those words, no.

12 MR. WEINGARTEN: Okay. Nothing further at this
13 time, Your Honor. Thank you.

14 JUDGE CHAPPELL: Will there be any cross?

15 MR. HASSI: Yes, Your Honor.

16 JUDGE CHAPPELL: Go ahead.

17 MR. HASSI: May I approach the witness with a
18 binder, Your Honor?

19 JUDGE CHAPPELL: Go ahead.

20 - - - - -

21 CROSS-EXAMINATION

22 BY MR. HASSI:

23 Q. I was going to say good afternoon, but it's
24 good morning, Ms. Snowden.

25 A. It's still morning.

1 Q. You talked a little bit more about
2 Hatch-Waxman, and I want to start there to make sure
3 that we have a background.

4 As a generic company, to bring a product to
5 market, is filing a Paragraph IV one of the ways you do
6 that?

7 A. Yes.

8 Q. And is that required if there are patents
9 listed in the Orange Book?

10 A. It's required if you want approval for your
11 generic product before patent expiration.

12 Q. And in the Paragraph IV, if it's a
13 Paragraph IV certification, you may allege things such
14 as the patent is either invalid or not infringed; is
15 that right?

16 A. That's right.

17 Q. Have you had occasion in your time at Impax to
18 file a Paragraph IV indicating that patents are
19 invalid and infringed and have district courts differ
20 with your conclusion that patents are not invalid or
21 not infringed?

22 A. I think you misspoke, but --

23 Q. I think I did, too.

24 A. -- yes, we have alleged our position that the
25 patents were invalid or not infringed and had district

1 courts disagree with us and find the opposite.

2 Q. And you mentioned an ANDA.

3 What sort of information does an ANDA contain?

4 A. It contains the data that the FDA requires for
5 approval, so it -- it's typically data that shows that
6 the generic product is bioequivalent to the brand
7 product, as well as the additional requirements that
8 FDA needs to see to approve the product for marketing.
9 There's what's called the chemistry, manufacturing and
10 controls section, those sorts of things.

11 Q. Okay. As it relates to oxymorphone, did Impax
12 file a Paragraph IV certification?

13 A. Yes.

14 Q. And who did it notify that it had filed a
15 Paragraph IV certification?

16 A. It sent the notifications to Endo and to
17 Penwest. Under the statute, you're required to send
18 the notice to the patent owner and the owner of the
19 NDA.

20 Q. And who is Penwest?

21 A. Penwest was the patent owner and the licensor
22 to Endo.

23 Q. And was Penwest involved in the subsequent
24 litigation between Impax and Endo?

25 A. Yes.

1 Q. They were a plaintiff in that litigation?

2 A. Yes.

3 Q. And do you recall when Impax filed for an
4 ANDA?

5 A. I believe it was in 2007.

6 Q. Did other companies file ANDAs for Opana ER?

7 A. Yes.

8 Q. Did they file before or after Impax?

9 A. As we've discussed, Impax was first to file for
10 all of the dosage strengths except the 7.5 and
11 15 milligram and Actavis was first on those, and then
12 other generics filed after both Actavis and Impax.

13 Q. And what benefit did Impax get for being first
14 to file on certain dosages?

15 A. Under the statute, the first filer is entitled
16 to 180 days of generic exclusivity.

17 Q. And during that 180 days, can any other ANDA
18 filer market the generic drug, in this case Opana ER?

19 A. No. The statute doesn't allow FDA to give
20 approval to any other ANDA filer.

21 Q. Are there ways where Impax could have lost or
22 forfeited that exclusivity?

23 A. Yes.

24 Q. And can you explain some of those ways?

25 A. One way is, after patent expiration, if you

1 haven't used it and the patent expires, you lose your
2 exclusivity, which would happen, say, if you lost the
3 patent case and had to wait until patent expiration.

4 One way that's kind of common is, a generic
5 needs to get tentative approval from the FDA for their
6 ANDA within 30 months of submission, with certain
7 exceptions, and if you don't have that tentative
8 approval within 30 months, then you would forfeit your
9 exclusivity.

10 And then there's a third provision that's very
11 complicated, but it requires the generic to launch the
12 generic product within 75 days of certain events that
13 are keyed off of the patent litigation and certain
14 regulatory events, so you have to actually get the
15 product launched or lose it.

16 Q. So if Impax lost the patent litigation with
17 Endo, it would have likewise lost its first-to-file
18 exclusivity?

19 A. Actually, I don't think that would be true in
20 this case. As we --

21 Q. Why not?

22 A. Because we went through Endo sued Impax on the
23 two patents that expire in 2013 but not the
24 '250 patent, and Impax had certified Paragraph IV
25 against all three of those patents, so Impax would have

1 still had exclusivity after 2013 because all of the
2 patents would not be expired in 2013.

3 Q. I see.

4 Do you have any understanding as to why Endo
5 didn't sue on the '250 patent?

6 MR. WEINGARTEN: Your Honor, I object. That
7 calls for speculation. He's asking her opinion about
8 what Endo thought about suing or not suing on a
9 patent.

10 MR. HASSI: I'm just asking her opinion as
11 someone who supervised the litigation, Your Honor. She
12 may or may not know.

13 MR. WEINGARTEN: Her lay opinion about what
14 Endo thought in its litigation is not foundation,
15 Your Honor.

16 JUDGE CHAPPELL: I'll sustain the objection to
17 the extent you're asking for speculation. If you want
18 to ask the witness what she knows, I'll allow that.

19 MR. WEINGARTEN: Thank you.

20 BY MR. HASSI:

21 Q. Do you know why Endo didn't sue on the
22 '250 patent?

23 A. No, I don't.

24 Q. We were talking about the 180-day exclusivity.

25 Once it starts, is there a way to stop the

1 clock, the 180-day clock?

2 A. No. No. As soon as a generic sells one
3 bottle, the clock will start ticking, and there's no
4 way to stop it.

5 Q. And we've heard about tentative approval from
6 the FDA.

7 Can you just describe what the significance of
8 tentative approval is?

9 A. Tentative approval is the FDA saying that the
10 application would be ready -- satisfies all the FDA
11 requirements and would be ready for approval according
12 to FDA if not for some patent or exclusivity reason why
13 they can't grant final approval.

14 So they -- because of some patent or
15 exclusivity they can't grant final approval, they grant
16 tentative approval.

17 And the significance, as I mentioned, is, under
18 the Hatch-Waxman Act, a generic company that's first to
19 file needs to get tentative approval within 30 months
20 in order to not forfeit exclusivity.

21 Q. And so with respect to your ANDA on
22 oxymorphone ER, you received tentative approval during
23 the 30-month period?

24 A. Yes.

25 Q. And does that suggest that Impax was almost

1 certain to get final approval at the conclusion of the
2 30-month stay?

3 A. Yes.

4 Q. You mentioned a moment ago that Actavis was
5 first to file on a couple of strengths of Opana ER; is
6 that right?

7 A. Right.

8 Q. Do you know what the indications or particular
9 uses for those strengths are?

10 A. I think the indication is the same for all of
11 the strengths.

12 Q. Do those -- strike that.

13 You discussed this morning settlement
14 negotiations with Endo, and there were two periods of
15 time, the fall of 2009 and spring of 2010; is that
16 right?

17 A. That's right.

18 Q. Was there a meeting in the fall of 2009?

19 A. Yes.

20 Q. And do you recall who attended that meeting?

21 A. I recall that it was Chris Mengler and me and
22 Impax' outside counsel. We met at a law firm with I
23 believe it was Guy Donatiello and a couple other people
24 from Endo.

25 Q. And do you recall what was discussed at that

1 meeting?

2 A. That meeting was kind of a high-level
3 discussion of the business interests of the two
4 parties, both parties discussing areas of interest,
5 what they're interested in from a business
6 perspective, what their capabilities were, and sort of
7 explored areas that might be interesting to work
8 together.

9 Q. You referred also this morning to a call
10 between you and Mr. Donatiello in which entry dates
11 were described. Do you recall that?

12 A. Yes.

13 Q. Can you tell us, who called who?

14 A. Guy Donatiello called me.

15 Q. And what did he say to you in that call?

16 A. In that discussion of dates, he said that
17 Endo's thinking about settle -- a settlement entry
18 date was the following, that Endo looked at it that
19 you would take the date that Impax could get final
20 appellate court decision and the date of patent
21 expiration and look for an entry date between those two
22 time periods.

23 Q. And what was your response to him?

24 A. That's when I responded that I didn't think
25 that was the right way to look at it, that a more

1 appropriate way to look at it would be to take the
2 date that's the end of Impax' 30-month stay and patent
3 expiration and use that time period to find a date in
4 between for the entry date, because if you looked at it
5 that way, then that would incline towards an earlier
6 date.

7 Q. Did you raise the Actavis entry date that we
8 talked about this -- that you talked about this morning
9 with Mr. Donatiello?

10 A. I -- I'm certain that I did, but I can't
11 remember if it was that same conversation or not.

12 Q. And tell us about the conversation in which you
13 raised the Actavis date, the 2011 date, with
14 Mr. Donatiello.

15 A. I can't remember more than us wanting the
16 Actavis date and him not agreeing. And that may have
17 been with -- he -- his focus was -- and I can't --
18 again, I can't remember if it was the same
19 conversation, but I know that he was talking about you
20 look at the end of the appellate court decision to
21 patent expiration and split that time period.

22 JUDGE CHAPPELL: We're going to take a short
23 break. We'll reconvene at 12:20.

24 We're in recess.

25 (Recess)

1 JUDGE CHAPPELL: Proceed.

2 MR. HASSI: Thank you, Your Honor.

3 BY MR. HASSI:

4 Q. Ms. Snowden, before the break, we were talking
5 about your entry date conversations with
6 Mr. Donatiello, and I just want to make sure I
7 understand.

8 Whether it was in the conversation where you
9 talked about Endo's view of the beginning and end dates
10 that you should be thinking about an entry date in
11 between or in some other call, you had a call with
12 Mr. Donatiello in which you asked him to agree that
13 Endo should give Impax the same entry date that it gave
14 Actavis; is that right?

15 JUDGE CHAPPELL: Before you answer that,
16 Mr. Donatiello, that's a guy named Guy?

17 THE WITNESS: Yes. That's Guy Donatiello.

18 JUDGE CHAPPELL: And I noticed earlier there
19 was an e-mail from the Huong Nguyen?

20 THE WITNESS: Yeah.

21 JUDGE CHAPPELL: Works for you.

22 THE WITNESS: Huong Nguyen works for --

23 JUDGE CHAPPELL: And I noticed her e-mail said
24 "Dear Guy." They were that tight, they were on a
25 first-name basis?

1 Was that a little less formal than it should
2 have been?

3 THE WITNESS: No. That was -- that was
4 normal. Our conversations were typically on a
5 first-name basis.

6 JUDGE CHAPPELL: So that was -- they were on a
7 first-name basis.

8 THE WITNESS: Yes.

9 JUDGE CHAPPELL: Did they work together on
10 anything other than this agreement?

11 THE WITNESS: No.

12 JUDGE CHAPPELL: Go ahead.

13 There's a question pending. Would you like her
14 to read it?

15 MR. HASSI: I think that would be best. Yes,
16 Your Honor.

17 (The record was read as follows:)

18 "QUESTION: Ms. Snowden, before the break, we
19 were talking about your entry date conversations with
20 Mr. Donatiello, and I just want to make sure I
21 understand.

22 "Whether it was in the conversation where you
23 talked about Endo's view of the beginning and end
24 dates that you should be thinking about an entry date
25 in between or in some other call, you had a call with

1 Mr. Donatiello in which you asked him to agree that
2 Endo should give Impax the same entry date that it gave
3 Actavis; is that right?"

4 THE WITNESS: Yes.

5 And so I think what I was saying was I couldn't
6 remember if it was in the same call or a different
7 call. Where he discussed what we've called the
8 bookends and the discussion about the Actavis date, I
9 can't remember if those were the same call or a
10 different call.

11 BY MR. HASSI:

12 Q. Okay. But to be clear, there were at least
13 two occasions on which Impax asked Endo for the same
14 entry date that Actavis received; is that right?

15 A. Yes.

16 Q. And both times, the answer from Endo was no?

17 A. Correct.

18 Q. Going back to the conversation with
19 Mr. Donatiello where he told you how he was thinking
20 about it, how Endo was thinking about the entry dates,
21 you may have said this already, but how did you --
22 what did you tell him about how Impax was thinking
23 about it?

24 A. Right. I responded that the better way to
25 think about it was to think about taking the time

1 period from the end of Impax' 30-month stay until
2 patent expiration and splitting that time period,
3 because then Impax' 30-month stay was the first time
4 Impax would be able to launch its product.

5 Q. And at the end of the 30-month stay, if Impax
6 were to launch its product at that point, would that
7 necessarily be a launch at risk?

8 A. Yes, that would have been.

9 Q. And Mr. Donatiello's response to your
10 suggesting that you should be thinking about the
11 earliest date as being at the end of the 30-month stay,
12 what was his response?

13 A. He laughed at me. He laughed and said, Impax
14 never launches at risk.

15 Q. And --

16 A. That's not a realistic date.

17 Q. And what did you say to him in response?

18 A. That's when I said in response that -- I
19 brought up the example of oxycodone where Impax had
20 launched at risk once before.

21 Q. Was that the only launch at risk that Impax had
22 engaged in at this point in time in 2010?

23 A. Yes.

24 Q. And what was Mr. Donatiello's response when you
25 brought up the example of oxycodone?

1 A. He laughed again and said, Oh, we know all
2 about oxycodone. That doesn't count.

3 Q. Did you have an understanding as to why he
4 would know about oxycodone?

5 A. Yes. I knew that Endo was another generic
6 filer in the oxycodone case and that -- so he would be
7 very, very familiar with the oxycodone case.

8 Q. Did Endo launch at risk in the oxycodone case,
9 do you know?

10 A. No.

11 Q. Did anyone other than Impax launch at risk?

12 A. Teva.

13 Q. And who was the first filer in that case?

14 A. Endo was the first filer for many strengths,
15 and Teva was the first filer for the 80 milligram
16 strength, which is why after Teva launched and their
17 180 days Impax had the ability to launch 180 days after
18 Teva for just the one strength.

19 Q. And what was the status of the underlying
20 litigation at the time that Impax launched?

21 A. The patents had been held unenforceable at the
22 district court level.

23 Q. And so you launched at risk following a
24 favorable district court decision and following Teva's
25 launch?

1 A. Yes.

2 JUDGE CHAPPELL: The district court decision
3 involved your company or another company?

4 THE WITNESS: All of the generics were
5 involved in that litigation that held the patents
6 unenforceable.

7 JUDGE CHAPPELL: So you were a part --

8 THE WITNESS: In the oxycodone case, yes.

9 JUDGE CHAPPELL: Impax was a party to that
10 action.

11 THE WITNESS: Yes.

12 BY MR. HASSI:

13 Q. And Endo was a party to that action?

14 A. Yes.

15 Q. And Teva was a party to that action?

16 A. Yes.

17 Q. Did that oxycodone launch at risk require board
18 approval?

19 A. Yes.

20 Q. Did you provide Mr. Donatiello any other
21 examples of times where Impax had launched at risk?

22 A. No.

23 Q. Why not?

24 A. There weren't any.

25 Q. Other than the discussion about the Actavis

1 date, did you have any other discussion about specific
2 entry dates with Mr. Donatiello?

3 A. No.

4 Q. If we could bring up Exhibit CX 320, please.

5 And if you want to look at it, this is in
6 evidence. It's -- the court will have seen it before.
7 It should be tab 2 in your binder if you want to look
8 at a paper copy.

9 A. Okay.

10 Q. And do you recognize Exhibit CX 320?

11 A. Yes.

12 Q. And what is this document?

13 A. It's a cover e-mail from Guy Donatiello to
14 Chris Mengler in which he attached term sheets.

15 Q. And these are the first term sheets that Impax
16 received from Endo?

17 A. That's correct.

18 Q. If you look at page - -- you may need to
19 look -- start by looking at page -4.

20 (Pause in the proceedings.)

21 Go to -- I'm sorry. It's page -6.

22 What is -- what is this attachment from
23 Mr. Donatiello's e-mail starting at page -6?

24 A. That's the term sheet for the settlement and
25 license agreement.

1 Q. Okay. And then if you look at page -9, is that
2 part of the settlement agreement?

3 A. Yes.

4 Q. And focusing on paragraph 1(b), what entry date
5 did Endo propose in the first term sheet that it sent
6 over?

7 A. They proposed a date-certain launch date of
8 March 10, 2013.

9 Q. Okay.

10 A. And then an acceleration clause for a court
11 decision.

12 JUDGE CHAPPELL: You need to speak up.

13 THE WITNESS: They proposed a date-certain
14 launch date of March 10, 2013 and an acceleration
15 clause for a court decision.

16 BY MR. HASSI:

17 Q. Okay. If you go a little further down the
18 page, let's look at paragraph 2(a), please.

19 Is this what was referred to earlier this
20 morning as a no-authorized-generic term?

21 A. Yes.

22 Q. And am I correct that Endo proposed this term
23 in the first term sheet it sent over to Impax?

24 A. Yes.

25 Q. And as someone involved in the discussions, do

1 you recall any discussion between Impax and Endo over
2 the no-authorized-generic term?

3 A. No, I don't.

4 Q. Was there an authorized generic in the final
5 agreement?

6 A. There was a no-AG term in the final agreement.

7 Q. What was Impax' priority in the negotiations
8 with Endo?

9 MR. WEINGARTEN: Your Honor, I'm going to have
10 to object to this one. I'm concerned that he's delving
11 into the privilege at this point if he's asking
12 in-house counsel about what Impax' priorities were
13 going into contract negotiations.

14 MR. HASSI: And Your Honor, I'm not seeking to
15 elicit any privileged conversation. I'm asking and I
16 can make clear that I'm asking strictly for business
17 priorities.

18 JUDGE CHAPPELL: My ruling is that any answers
19 that were not allowed during the deposition in
20 discovery will not be allowed in court.

21 MR. HASSI: Understood, Your Honor.

22 JUDGE CHAPPELL: So if that applies, the
23 objection is sustained; if that doesn't apply, it's
24 overruled.

25 MR. HASSI: Understood.

1 MR. WEINGARTEN: Thank you, Your Honor.

2 BY MR. HASSI:

3 Q. And Ms. Snowden, to be clear, in all of my
4 questions today, I'm not asking you to divulge any
5 Impax privileged information.

6 Were you privy to Impax' business priorities in
7 the settlement negotiations with Endo?

8 A. Yes.

9 Q. And what was its first priority?

10 A. The top business priority was to get the
11 earliest entry date possible and then to protect the
12 market for that entry date.

13 Q. Okay. In this first term sheet that was
14 received from Endo, is there any version of what you
15 were describing, what was described to you earlier this
16 morning as an Endo credit?

17 A. No.

18 Q. And before I show you the next document, the
19 date of this term sheet was May 26, is when you
20 received it from Endo; is that right?

21 A. That's right.

22 Q. If we could bring up RX 318, please. And focus
23 on the top e-mail if you would.

24 Showing you what is in evidence as RX 318, is
25 this Mr. Mengler's response to Endo in response to the

1 term sheet a day later?

2 A. It appears to be. Or else -- I can't tell if
3 there was a phone conversation in between.

4 Q. Well, let's --

5 A. Or if the phone conversation was earlier.

6 JUDGE CHAPPELL: Can you have the witness
7 explain what you mean by "term sheet" on the record.

8 MR. HASSI: Certainly, Your Honor.

9 BY MR. HASSI:

10 Q. I've asked you some questions about a term
11 sheet.

12 Can you tell us what the meaning of
13 "term sheet" is?

14 A. It's generally understood to be sort of an
15 outline of the major terms of the agreement between the
16 parties.

17 MR. HASSI: Is that sufficient, Your Honor?

18 JUDGE CHAPPELL: Not a draft contract but a
19 list of terms like high points?

20 THE WITNESS: Correct. Correct. Just a list
21 of the key terms and not a draft contract.

22 BY MR. HASSI:

23 Q. Okay. In Mr. Mengler's e-mail on May 27, the
24 top of the second paragraph, he references "certain
25 acceleration triggers, including market degradation to

1 any alternate product."

2 Do you see that?

3 A. Yes.

4 Q. And do you know what the "market degradation to
5 any alternate product" was a reference to?

6 A. Yes. He's using that in the context of an
7 acceleration trigger, so that would mean that the
8 launch date that's proposed here could become earlier
9 if the market for Opana ER degraded by some amount to
10 be agreed.

11 Q. And what was Endo's response to Impax' request
12 for certain acceleration triggers, including a market
13 degradation to any alternate product?

14 A. They never did agree to a market degradation
15 acceleration trigger.

16 Q. Following that, did Endo make a proposal that
17 led to the Endo credit?

18 A. Yes.

19 Q. Were you on a call in which Mr. Levin and
20 Mr. Mengler discussed that?

21 A. Yes.

22 Q. Can you tell us what you remember about that
23 call?

24 A. I remember Chris was negotiating for what he
25 called this protection in case Endo moved the market

1 for Opana ER to another form, and Alan Levin's
2 response was: You don't have to worry about that.
3 We're not going to do that. We have every intention
4 of putting a lot of resources behind marketing this
5 product. You should be grateful, by the time you
6 launch, it's going to be an even bigger and more
7 robust opportunity for you, and you should pay us a
8 royalty because it's going to be such a big
9 opportunity for you after we, you know, continue to
10 promote it.

11 And Chris responded, That's great. If you're
12 right and it does grow, I'll be happy to pay you a
13 royalty if it's greater than that, but I still need
14 downside protection in case that's not what happens.

15 Q. And specifically downside protection for what?

16 A. For the market for the generic Opana ER
17 degrading before we get to launch.

18 Q. Why was Impax concerned that Endo might degrade
19 the market?

20 A. Impax didn't have any specific information
21 about what Endo was planning to do but just by being in
22 the industry had seen that kind of thing happen with a
23 number of brand companies try to introduce a
24 next-generation product and move the market over to the
25 next-generation product so that the product that the

1 generic launches into is much reduced for the generic
2 launch.

3 Q. What specifically is the impact on Impax if
4 Endo were to move to a next-generation product?

5 A. That the market opportunity for Impax' generic
6 product would be much reduced or zero.

7 Q. How did Impax respond to Mr. Levin's proposal
8 of a royalty and some form of downside protection?

9 A. As I said, I think it was Chris who said, If
10 you're right and the market grows like that, we'll be
11 happy to pay you a royalty for the increased growth,
12 but I still need protection from the downside.

13 And that's what led into the discussion of
14 what became the Endo credit for the downside
15 protection.

16 Q. And when the Endo credit was being discussed,
17 did Chris take a position on what the terms -- what the
18 terms would be and whether they would favor Endo or
19 Impax?

20 A. Once it was agreed that the trigger would be
21 set at 50 percent, Chris then said that all the other
22 assumptions had to go his way. He said, In case
23 you're lying, we're going to make these aggressive
24 assumptions and you're going to agree -- I know
25 they're aggressive, but this is the way it's going to

1 be.

2 And he sort of walked through some of the
3 assumptions that were going to be built into the
4 calculation in terms of assuming a generic penetration
5 rate and a generic price.

6 Q. And were those assumptions built into
7 something that eventually became known as the Endo
8 credit?

9 A. Yes.

10 Q. You saw a letter this morning, dated 2013, that
11 you wrote, asking Endo to pay the Endo credit. Do you
12 recall that?

13 A. Yes.

14 Q. If I asked you to, could you explain to the
15 court how the Endo credit works based on that letter?

16 A. Somewhat. It's a very complicated formula, but
17 I can --

18 MR. WEINGARTEN: Your Honor, I apologize for
19 interrupting. I object.

20 Ms. Snowden testified under my questioning that
21 she had no involvement in drafting the Endo credit, so
22 asking her now for her interpretation or her
23 understanding of how it worked, it seems like there's a
24 lack of foundation.

25 MR. HASSI: Ironically, counsel put in front

1 of Ms. Snowden a letter that she wrote saying how the
2 Endo credit should be calculated and how it should be
3 paid and put that letter into evidence. I'm asking
4 this witness, using that letter as a foundation, to
5 explain how the Endo credit works.

6 JUDGE CHAPPELL: She wrote the letter enforcing
7 the credit; therefore, I'll allow this line of
8 questioning. Overruled.

9 MR. WEINGARTEN: Understood, Your Honor.

10 BY MR. HASSI:

11 Q. And to be clear, Ms. Snowden, I'm not asking
12 you any questions about the drafting of the Endo
13 credit. I'm asking, in 2013, when it came due, how was
14 the number calculated.

15 A. Okay.

16 Q. So if we could pull up CX 332. And the letter
17 starts on page -7, but I think the calculations that
18 are of interest are probably the ones on page -8.

19 And Robert, if you could do the paragraph above
20 that as well, it would make it easier.

21 And Ms. Snowden, I'm just looking for sort of a
22 high level, your understanding as the person who
23 drafted the letter seeking payment from Endo, to give
24 us an understanding of the operation of the Endo credit
25 as you understood it in 2013.

1 A. Okay. So at a high level, it called for
2 determining the quarterly peak, which was the calendar
3 quarter in which Opana ER sales were the highest
4 during the relevant time period. And based on this
5 letter, we determined that the quarterly peak was
6 fourth quarter of 2011. And all of this was based on
7 IMS data.

8 We calculated the quarterly peak. And the
9 calculation also requires determining what's called the
10 pre-Impax amount, which is the sales of Opana ER in the
11 fourth quarter of 2012, the sales right before Impax
12 was to launch its generic product.

13 So you compare the quarterly peak number to
14 the pre-Impax amount. And if the pre-Impax amount is
15 less than 50 percent, which was called the trigger
16 threshold, if the Impax amount -- the pre-Impax amount
17 is less than the trigger threshold, then the payment
18 is triggered, and then you go through the calculation
19 of multiplying the differences between these amounts by
20 the factors that was determined to get to the final sum
21 that is the Endo credit.

22 Q. When the settlement agreement was entered into
23 in 2010, was the quarterly peak or what would become
24 the quarterly peak a known quantity at that point in
25 time?

1 A. No.

2 Q. Could you have known what the quarterly peak
3 would be in 2010?

4 A. No.

5 Q. And in terms of the trigger threshold, could
6 that have been known at the time in 2010?

7 A. The trigger threshold was 50 percent. It
8 couldn't be known whether it would be hit.

9 Q. Right.

10 How about the pre-Impax amount, which was
11 calculated to be 3.47 in your letter? Could that be
12 known at the time?

13 A. No.

14 Q. And that was only determined come 2013; is that
15 right?

16 A. That's right.

17 Q. Thank you.

18 At the time that Impax signed the settlement
19 agreement, did it have any expectation of being paid
20 pursuant to the Endo credit?

21 A. No.

22 MR. WEINGARTEN: I'm sorry, Your Honor. Now
23 he's asking what their expectation was with respect to
24 how a contract provision would work in the future.
25 That is definitely legal advice, and he's now eliciting

1 it here for the first time at trial.

2 MR. HASSI: It's not legal advice, Your Honor.
3 I'm only asking, as I made clear --

4 JUDGE CHAPPELL: First of all, you can't ask
5 this witness whether Impax had any expectation. You
6 can ask this witness, at the time it was signed, did
7 this witness have any expectation based on her
8 involvement. I'll allow that.

9 MR. WEINGARTEN: Thank you, Your Honor.

10 BY MR. HASSI:

11 Q. Based on your involvement -- and I'm not asking
12 for any privileged information -- did you have any
13 expectation that Impax was going to receive a payment
14 pursuant to the Endo credit?

15 A. No.

16 Q. To which patents did Impax ultimately receive a
17 license under the settlement and license agreement?

18 A. Impax received a license to all the patents
19 owned or controlled by Endo and Penwest.

20 JUDGE CHAPPELL: Do you mean at the time of the
21 agreement or in perpetuity?

22 THE WITNESS: All the ones that would ever be
23 owned by them that would cover the Impax product, so
24 the patents that existed at the time as well as future
25 patents.

1 JUDGE CHAPPELL: Can you explain in a nutshell
2 how the various patents that were acquired later
3 enabled Endo to block other entrants, other generic
4 companies who wanted to sell this drug?

5 THE WITNESS: Yes.

6 JUDGE CHAPPELL: In a nutshell?

7 THE WITNESS: I'll try to do it in a nutshell,
8 because it got to be kind of complicated.

9 After -- after all of the cases that were
10 pending in 2010 -- and I think in addition to Impax and
11 Actavis, Endo settled with all of the other generic
12 filers, which included Sandoz and Teva and Watson or
13 Par, so all of the generic filers settled that. And
14 within a couple years, Endo's pending patent
15 applications turned into issued patents.

16 In the meantime, Endo had come out with its
17 crush-resistant formulation so that there was another
18 round of litigation that started around 2013 based on
19 the new patents. And Endo asserted the new patents
20 against both filers who had tried to file a generic to
21 the new formulation of Opana ER, so that included
22 Impax, as well as all of the other generics that they
23 had settled with in 2010 for the original Opana ER.
24 They sued everybody based on their new patents.

25 And there was some litigation with Actavis,

1 because they were on the market with the two lower
2 strengths, where Actavis tried to argue that under
3 their 2010 license that they had an implied license to
4 the future patents, but they lost that. The
5 Federal Circuit said no, you clearly don't, you don't
6 have a license.

7 So that case proceeded in New York, and like I
8 say, it was against a whole group of generics,
9 including Impax for the new formulation but not the
10 original formulation. And the district court in
11 New York ultimately determined that those patents were
12 valid and infringed.

13 In the meantime, they filed another suit in
14 Delaware based on a couple other patents. One of
15 those was found invalid, but the other one which
16 covers -- it covers a purified oxymorphone. That was
17 also asserted against generic filers to both original
18 and to new Opana ER, except for Impax.

19 And many generics stayed their case, but three
20 of them did litigate based on that new purified
21 oxymorphone patent. And again, the district court in
22 that case found that that patent was valid and
23 infringed by the generics that litigated that.

24 So -- so all of the generics that litigated
25 are now enjoined until patent expiration, and those

1 cases are up on appeal.

2 JUDGE CHAPPELL: So even though the original
3 Opana ER patent has expired, Endo has blocked generic
4 entry based on these after-acquired or newly approved
5 patents.

6 THE WITNESS: Right. Yeah.

7 Some of the early patents that were litigated
8 in 2010 I think, like I said, those were Penwest
9 patents, and they related to a certain kind of
10 formulation platform that Penwest had developed.

11 In the meantime, Endo had filed additional
12 patent applications for their oxymorphone
13 extended-release, and those were the ones that emerged
14 from the Patent Office later and were litigated later.

15 JUDGE CHAPPELL: All right. Thank you.

16 BY MR. HASSI:

17 Q. Just sticking with that, let's talk first --
18 you said Impax acquired some patents. Can you tell us
19 what you mean by that?

20 A. I think I said Endo.

21 Q. Endo. I'm sorry.

22 Endo acquired some patents. What did you mean
23 by that?

24 A. Endo had some pending applications that then
25 later issued as patents. And then the patent that I

1 referred to as the purified oxymorphone patent, they
2 acquired the rights to enforce that through a deal they
3 had with Mallinckrodt.

4 I know that there were also some
5 Johnson Matthey patents, but I think that got resolved
6 in the shuffle between Johnson Matthey and
7 Mallinckrodt.

8 Q. Okay. So let's take them one by one. I think
9 the first one to arrive on the scene was the
10 Johnson Matthey patent. Do you recall that?

11 A. Yes.

12 Q. And do you recall what that patent addressed
13 generally?

14 A. Generally it was, again, to a purified type of
15 oxymorphone. We call it the low-ABUK patent.

16 ABUK is a particular impurity that FDA wanted
17 to reduce out of -- out of some of these products, so
18 they had a patent to produce a purified form of
19 oxymorphone that had less of that impurity, so
20 sometimes it's called the low-ABUK patent.

21 Q. And after Johnson Matthey, after that patent
22 was approved and Johnson Matthey had the patent, did it
23 contact Impax?

24 A. Yes.

25 Q. And did you understand them to be wanting Impax

1 to obtain a license to their patent?

2 A. I -- I think that's right.

3 Q. They were contacting you to --

4 A. To inform us of their patent on that
5 oxymorphone, yes.

6 Q. The Johnson Matthey patent, did it stay with
7 Johnson Matthey or did they sell it to somebody?

8 A. I believe there was an interference between
9 Johnson Matthey and Mallinckrodt, and ultimately it was
10 the Mallinckrodt patent that Endo ultimately sued
11 people on.

12 JUDGE CHAPPELL: What you're talking about now,
13 being contacted by I guess Endo to license a patent,
14 was this before or after the settlement agreement we're
15 litigating now?

16 THE WITNESS: It was after the settlement
17 agreement and before Impax launched its generic
18 product.

19 BY MR. HASSI:

20 Q. And did Endo -- prior to Endo acquiring the
21 Mallinckrodt patent, did Endo acquire the
22 Johnson Matthey patent, do you recall?

23 A. My understanding is yes.

24 Q. And subsequent to that, the Patent Office
25 approved a number of Endo patents; is that right?

1 A. Yes.

2 Q. And some of those patents were asserted in a
3 litigation in the Southern District of New York?

4 A. Yes.

5 Q. And was Impax a defendant in the litigation
6 that Endo brought on those patents in the
7 Southern District of New York?

8 A. Yes.

9 Impax was a defendant because Impax had filed
10 an ANDA against the new crush-resistant form of
11 Opana ER, but Impax' original formulation of Opana ER
12 was not part of that lawsuit, because of Impax'
13 license.

14 Q. And so Impax' license protected it as to
15 original Opana ER, but the license didn't cover the
16 reformulated Opana?

17 A. That's right.

18 JUDGE CHAPPELL: And does that mean that Impax
19 is enjoined, like the other companies, from
20 introducing the tamper-resistant or crushproof
21 version?

22 THE WITNESS: Yes.

23 BY MR. HASSI:

24 Q. What was the outcome -- did Your Honor have a
25 question? I thought you might have a -- what was the

1 outcome of the patent litigation in the
2 Southern District of New York?

3 A. That was the outcome on those patents, that
4 they were held valid and infringed by all of the
5 generics that were party to that lawsuit.

6 There were a couple other patents that only
7 applied to the crush-resistant form, and those patents
8 were held invalid, but those patents that expire in
9 2023 were held valid and infringed by everyone.

10 JUDGE CHAPPELL: Are you aware of whether or
11 not any company, with a patent or without a patent,
12 license or without a license, could sell the crushproof
13 version of Opana right now?

14 THE WITNESS: I am aware. That had a -- it had
15 a whole other story.

16 Ultimately FDA asked Endo to remove that
17 product from the market, and Endo agreed, and they --
18 so they said that they were going to cease sales of
19 that product effective as of September 1 of this year,
20 so that product is being removed from the market by
21 Endo because of FDA's request. And all of the generics
22 will also get removed from the market because the
23 brand --

24 JUDGE CHAPPELL: So had anyone been in the
25 market as a generic, they would also not be able to

1 sell that product at this time?

2 THE WITNESS: I'm sorry. Say that again.

3 JUDGE CHAPPELL: Well, there was no generic
4 equivalent, was there, of the crushproof?

5 THE WITNESS: There were ANDA filers, but no
6 one was approved and no one --

7 JUDGE CHAPPELL: But even if they were
8 approved, because of the FDA recall, no one could sell
9 that product at this time; correct?

10 THE WITNESS: That's -- that's what it looks
11 like, right, because FDA asked Endo to remove it for
12 safety reasons.

13 JUDGE CHAPPELL: Are you aware of whether or
14 not that is something that's supposed to change soon,
15 or is that pretty much something that's permanent, if
16 you know? The prevention of selling the crushproof
17 version.

18 THE WITNESS: Endo announced that they weren't
19 going to fight the FDA. They could have, you know,
20 gone through mechanisms to challenge FDA's decision,
21 and they announced that they weren't. They announced
22 that they were just going to remove it from the
23 market, and so there won't be any further, you know,
24 process there for them to determine whether the FDA was
25 really right or not.

1 And just, as it turns out, yesterday, Impax
2 got a letter saying, you need to withdraw the ANDA that
3 goes to the crush-resistant version because the brand
4 is being removed, so the ANDA should be withdrawn
5 also.

6 JUDGE CHAPPELL: So we're not going to see
7 that product again.

8 THE WITNESS: Correct.

9 BY MR. HASSI:

10 Q. And to be clear on that last part, you said
11 Impax received a letter yesterday.

12 Who was that letter from?

13 A. FDA.

14 Q. So FDA has asked Impax to withdraw its ANDA as
15 to reformulated.

16 A. Correct.

17 Q. At the --

18 JUDGE CHAPPELL: Is that really the FDA asking
19 or the FDA demanding?

20 MR. HASSI: You're closer to this than I am.

21 THE WITNESS: It's the FDA. They asked, and
22 they also said if -- they also put in, you know, how
23 to discuss or dispute with them if you thought that
24 was inappropriate, so it's not -- not written as a
25 demand.

1 BY MR. HASSI:

2 Q. Do you expect Impax to withdraw its ANDA as to
3 reformulated?

4 MR. WEINGARTEN: Your Honor, I'm going to
5 caution against getting into legal advice of Impax
6 about the question of what they're going to do in
7 response to an FDA letter. I don't think Mr. Hassi
8 really wants to go there.

9 MR. HASSI: I'm not asking to waive any
10 privilege if the answer is privileged.

11 JUDGE CHAPPELL: I'm concerned that I got us
12 going down a rabbit hole, and I'm cutting it off now.
13 That's sustained.

14 MR. WEINGARTEN: Thank you, Your Honor.

15 MR. HASSI: Thank you.

16 JUDGE CHAPPELL: Not that it's totally
17 irrelevant. I consider it valid background
18 information, but I think we have enough.

19 MR. HASSI: Understood, Your Honor.

20 BY MR. HASSI:

21 Q. At the time of the Southern District
22 litigation -- I'm going to call it the second wave of
23 litigation brought by Endo -- were any of the generics
24 selling generic Opana, Opana ER, in other words?

25 A. Actavis was selling the two lower strengths,

1 the 7.5 and the 15 milligram strengths, when that case
2 started, and Impax was selling all of the strengths.

3 Q. And do I understand correctly Actavis, along
4 with the other ANDA filers, has been enjoined by the
5 court in the Southern District of New York?

6 A. That's correct.

7 Q. And to your knowledge, has Actavis withdrawn
8 its product from the market?

9 A. They -- they stopped selling it after they were
10 enjoined. Yes.

11 Q. You mentioned a third wave of litigation in
12 Delaware.

13 That's on yet additional subsequently acquired
14 patents?

15 A. Yes.

16 Q. And I've been using "subsequently acquired."

17 Would it be better for me to say that those
18 were subsequently issued by the Patent Office?

19 A. There's -- there's two patents, and one of
20 them was the patent that Endo acquired rights to from
21 Mallinckrodt and one I believe that is an Endo patent.

22 Q. Is Impax a defendant in the Delaware cases,
23 patent cases brought by Endo?

24 A. Yes. Only with respect to the ANDA to the
25 crush-resistant form but not to original Opana ER.

1 Q. Do those cases address both original and
2 reformulated as to some of the other ANDA filers?

3 A. Those patents were asserted against ANDAs to
4 both original and the crush-resistant form.

5 Q. And what is the status of the lawsuits in
6 Delaware?

7 A. Some of them are stayed, but three companies
8 have litigated, Actavis and Teva and Amneal. And in
9 those cases -- there's a patent that expires in
10 2027 that was invalidated, but a patent expiring in
11 2029, which is what I call the low-ABUK patent about
12 the purified oxymorphone, that patent was held valid
13 and infringed.

14 And I -- and a number of the generics that
15 stayed their litigation agreed to be bound by the
16 finding of validity in the cases that were litigated.

17 Q. In the New York litigation, did Actavis make
18 arguments about whether or not its launch of the
19 strengths that Impax was first to file on was at risk?

20 MR. WEINGARTEN: Your Honor, I'm going to
21 object to him asking about arguments made in another
22 case by a different pharmaceutical company for which
23 Ms. Snowden is not employed.

24 JUDGE CHAPPELL: The relevance?

25 MR. HASSI: The relevance, Your Honor, relates

1 to the fact that they launched at risk but under
2 particular circumstances on this drug, and Ms. Snowden
3 has supervised counsel in those litigations which Impax
4 is a party to and so has knowledge of the arguments
5 that Actavis has made.

6 JUDGE CHAPPELL: The arguments Actavis has made
7 are not relevant.

8 Sustained.

9 MR. WEINGARTEN: Thank you, Your Honor.

10 BY MR. HASSI:

11 Q. Did the judge in the New York litigation rule
12 that Actavis' launch was at risk?

13 MR. WEINGARTEN: Your Honor, I'm going to rise
14 again here on this one. The judge's ruling as to a
15 pharmaceutical company that is not before Your Honor is
16 not relevant here.

17 MR. HASSI: Your Honor, it's relevant to the
18 facts underlying the market. If we can get a
19 stipulation that Actavis' sales in the market are not
20 relevant, I'll withdraw it and move on.

21 JUDGE CHAPPELL: You're saying this goes to the
22 overall market for the drug?

23 MR. HASSI: It goes to the overall market and
24 it goes to who was in and who was out and why they were
25 in and why they were out. Yes, Your Honor.

1 JUDGE CHAPPELL: I'll allow this, but you need
2 to cut it off soon.

3 Overruled.

4 MR. HASSI: Understood.

5 BY MR. HASSI:

6 Q. Do you need the question read back?

7 A. Well, I think there was no dispute that Actavis
8 did not have a license so that their sales were in the
9 absence of a license and those sales were found to be
10 infringing.

11 Q. Did the district court rule that Actavis had an
12 implied license?

13 MR. WEINGARTEN: Your Honor, now we're getting
14 into a certain level of hearsay about Actavis'
15 proceedings before the district court where the witness
16 is going to be asked to testify about the contents of a
17 ruling by another judge as to Actavis.

18 JUDGE CHAPPELL: If this was a public case, to
19 the extent the ruling is relevant, you can offer that
20 under certain rules of procedure here, rules of
21 evidence. Sustained.

22 MR. WEINGARTEN: Thank you, Your Honor.

23 MR. HASSI: Understood, Your Honor.

24 BY MR. HASSI:

25 Q. I want to talk now about Endo and Impax'

1 discussions about working together on co-development.

2 When is the first time that you recall Impax
3 and Endo discussing a possible collaboration?

4 A. I remember a conversation in early 2009.
5 Because our brand division is focused on neurology,
6 they were interested in working with Endo on a product
7 that they had for migraine that was called Frova, so
8 they tried to initiate conversations with Endo in early
9 2009 on a product called Frova.

10 Q. And who at Impax expressed an interest in
11 working with Endo on Frova?

12 A. Shawn Fatholahi. He was our head of sales and
13 marketing for the brand division.

14 Q. And were you involved in reaching out to Endo
15 on behalf of Mr. Fatholahi to --

16 A. Yes.

17 Q. -- sponsor those conversations?

18 A. Yes.

19 Q. What happened with respect to those
20 discussions?

21 A. They didn't succeed in reaching a deal.

22 Q. In the fall of 2009, when you began settlement
23 discussions with Endo, did Mr. Fatholahi contact you
24 again about Frova?

25 A. I believe he did.

1 Q. And what was the purpose -- for what purpose
2 did he contact you?

3 A. He was still interested in doing some kind of
4 deal with Endo around Frova and wanted to see if Impax
5 could discuss something around Frova with Endo.

6 Q. And did you put him in touch with anyone at
7 Endo?

8 A. I don't remember if that happened again in the
9 fall.

10 Q. Do you recall the parties entering into -- the
11 parties.

12 Do you recall Impax and Endo entering into a
13 confidentiality agreement?

14 A. Yes.

15 Q. Could we bring up CX 1816, which is in
16 evidence.

17 It's tab 9 in your binder if you want to take a
18 look at it.

19 This is an e-mail from Mr. Donatiello to you
20 and others, dated May 19, 2010.

21 Do you see that?

22 A. Yes.

23 Q. And he sends you an attachment dated
24 October 13, 2009.

25 Do you see that?

1 A. Yes.

2 Q. And what do you understand that attachment to be?

3 A. It's a confidentiality agreement between Impax
4 and Endo.

5 Q. And when did Impax and Endo enter into that
6 confidentiality agreement?

7 A. In October of 2009.

8 Q. And why did Impax and Endo enter into that
9 confidentiality agreement in October of 2009?

10 A. Because they intended to discuss potential
11 business relationships and intended to share
12 confidential information.

13 Q. Could Endo -- could Endo's Frova have been one
14 of the products discussed?

15 A. Yes.

16 Q. You mentioned this morning that Endo expressed
17 an interest in 066. Do you recall that?

18 A. Yes.

19 Q. And what was your reaction to Endo's interest
20 in 066?

21 A. My reaction?

22 I didn't -- I didn't have a reaction. I know
23 that the business folks had not intended to do a deal
24 on 066 with Endo.

25 Q. Why did you understand that the Impax business

1 folks didn't want to do a deal with 066 -- with Endo on
2 066?

3 A. They weren't looking for a U.S. business
4 partner on IPX-066.

5 Q. Were they looking for an overseas business
6 partner?

7 A. Yes.

8 Q. Other than 066, did Impax have any other
9 publicly announced branded product candidates at this
10 time?

11 A. No.

12 Q. Can you describe the relationship between
13 IPX-066 and IPX-203?

14 MR. WEINGARTEN: Your Honor, I'm going to
15 object to a lack of foundation. I don't believe
16 Ms. Snowden is a scientist or part of the R&D team at
17 Impax, and I'm not sure she's got the foundation to
18 describe --

19 JUDGE CHAPPELL: Well, I don't think she needs
20 to be a scientist, but we don't have a proper
21 foundation that she has any idea of what these are, so
22 sustained.

23 MR. WEINGARTEN: Thank you, Your Honor.

24 BY MR. HASSI:

25 Q. Do you know what IPX-066 is?

1 A. Yes.

2 Q. What is IPX-066?

3 A. It's Impax' Parkinson's drug which is now on
4 the market and called Rytary, and it is a product that
5 contains carbidopa and levodopa.

6 Q. What is IPX-203?

7 A. IPX-203 is an investigational product under
8 development by Impax that's designed to be an
9 improvement over Rytary.

10 Q. And when you say "an improvement over Rytary,"
11 does it bear any similarities to Rytary?

12 A. Yes. It also contains carbidopa and levodopa,
13 but it's designed to improve some dramatic control of
14 Parkinson's better.

15 Q. And what is it -- and I'm not looking for any
16 confidential information, but what's the status of
17 IPX-203 today?

18 A. It has completed one Phase II clinical trial
19 and it's in a second Phase II clinical trial.

20 Q. You testified this morning about the
21 termination of the development and co-promotion
22 agreement.

23 Were you involved in that?

24 A. Yes.

25 Q. If we could bring up RX 221, which is in

1 evidence.

2 And it's tab 11 of your binder if you'd like to
3 look at it.

4 And if we could start on the second page,
5 there's an e-mail -- if you could bring up the e-mail
6 from David Ailinger?

7 A. "Ailinger."

8 Q. And what was Mr. Ailinger's role at Impax in
9 October of 2015?

10 A. He's a senior director of business development
11 for the brand division.

12 Q. And you're copied on this e-mail?

13 A. Yes.

14 Q. And he's sending an amendment to the
15 development and co-promotion agreement to Endo; is that
16 right?

17 A. Yes.

18 Q. Was it Impax' expectation at this time that
19 Impax and Endo were going to amend the development and
20 co-promotion agreement?

21 A. Yes.

22 Q. And why were you -- high level, why were you
23 amending the development and co-promotion agreement?

24 A. The original development and co-promotion
25 agreement was -- we looked at the product definition

1 earlier. The product definition was a levodopa ester
2 and carbidopa. And as Impax worked with that, that --
3 Impax wasn't able to get the improvement that it hoped
4 to get by using the levodopa ester, but it did get the
5 improvement it hoped to get by working with levodopa
6 itself in a new formulation.

7 So when we shared those results with Endo,
8 Endo had said yes, they agreed they wanted to continue
9 with the program, but we needed to amend the contract
10 to change the definition of "Product" to apply to the
11 levodopa-carbidopa product and not the levodopa ester,
12 so we had started the process of amending the
13 agreement.

14 Q. If we could turn back to the first page and
15 let's start with the e-mail at the bottom of the first
16 page.

17 This is an e-mail from Doug Macpherson at Endo
18 to you and others at Impax; is that right?

19 A. Yes.

20 Q. And who was Doug Macpherson at Endo at this
21 point in time?

22 A. He was a lawyer for Endo.

23 Q. And he indicated in this e-mail that Endo has
24 decided after all not to amend the existing agreement;
25 is that right?

1 A. That's right.

2 Q. And he further indicated that Endo would not be
3 participating in the program going forward?

4 A. Correct.

5 Q. And what was your reaction to that?

6 A. I was surprised.

7 Q. Okay. Let's look at your e-mail, the one above
8 that.

9 And why -- can you tell us why you were
10 surprised?

11 A. I was surprised because fairly recently they --
12 they had said the opposite, that they were interested
13 in continuing forward with the program and amending the
14 agreement.

15 Q. Did Impax and Endo agree to terminate the
16 agreement?

17 A. Yes.

18 Q. Did Impax receive any further milestones from
19 Endo under the agreement --

20 A. No.

21 Q. -- milestone payments?

22 A. No.

23 Q. You mentioned earlier that Impax at the time in
24 2010 had done one at-risk launch; is that right?

25 A. Yes.

1 Q. Have you been involved in the consideration of
2 other at-risk launches during your time at Impax?

3 A. Yes.

4 Q. And do you recall participating in evaluating
5 an at-risk launch related to a product called
6 azelastine?

7 A. Yes.

8 Q. And what were the circumstances under which
9 Impax considered launching azelastine at risk?

10 A. Azelastine was a product that Impax had a
11 partnership deal with a company called Perrigo.
12 Perrigo was the ANDA holder and the marketer of the
13 product. Impax had shared in the development costs
14 and the litigation costs and were sharing in the
15 profits.

16 Perrigo had notified Impax of its intent to
17 launch the product at risk. And under the terms of our
18 agreement with Perrigo, Impax was able to either
19 participate in the risk and the profits of the product
20 or not participate, in which case Perrigo would bear
21 all of the risk and keep all of the profits, so Impax
22 was to make that decision about whether they would
23 participate or not.

24 Q. When did this take place?

25 A. I think it was in 2014.

1 Q. Did Impax' management make a recommendation to
2 its board about this at-risk launch?

3 A. Yes.

4 Q. Let's bring up CX 2689. That's a document
5 that's in evidence, not in camera, and it's tab 14 in
6 your binder.

7 And if we -- let's just focus on the top for a
8 second.

9 Do you recognize this document?

10 A. Yes.

11 Q. And can you tell us what it is?

12 A. It's the minutes of a special meeting of the
13 board of directors.

14 Q. And when did this meeting take place?

15 A. In March of 2014.

16 Q. Did you attend the meeting?

17 A. Yes.

18 Q. If we go a little further down, is that
19 reflected in the minutes?

20 If we can go to the next group.

21 And let's go to the next couple paragraphs
22 down.

23 What was the purpose of this special meeting of
24 the board of directors?

25 A. It was a special meeting to determine if Impax

1 was going to participate with Perrigo in this at-risk
2 launch. This refers to gAstepro, which is the brand
3 name. Azelastine is the generic name of the product.

4 Q. And was there a presentation made to the board
5 regarding this launch at risk?

6 A. Yes.

7 Q. And who made -- who participated in making that
8 presentation?

9 A. Carole Ben-Maimon, who was the president of the
10 generics division at the time --

11 Q. Did you participate --

12 A. Carole Ben-Maimon, who was the president of the
13 generics division at the time, made a presentation.

14 In addition, Mark Schlossberg, who is the
15 general counsel, and I participated in the
16 presentation.

17 Q. In the third paragraph up here, it says, "She,"
18 a reference to Dr. Ben-Maimon, "concluded by
19 recommending that the Company participate in the
20 'at-risk' launch up to 150,000 units."

21 Can you tell us what was discussed at the board
22 with regard to that, and I'm not asking for any
23 privileged information.

24 A. The sentence before it refers to
25 Carole Ben-Maimon reviewing potential exposure, so the

1 board looked at what the potential risk to the company
2 is, and so the limit on 150,000 units was a way to
3 limit the amount of sales and therefore the potential
4 exposure of the company.

5 Q. And why would the board want to limit the
6 number of units that would be sold pursuant to this?

7 MR. WEINGARTEN: Your Honor, I'm going to
8 object for a lack of foundation. I don't think
9 Ms. Snowden is prepared to testify on behalf of
10 collectively the board members of Impax.

11 BY MR. HASSI:

12 Q. Was there a discussion -- I'll withdraw.

13 Was there a discussion at the board regarding
14 this particular limit?

15 A. Yes.

16 Q. And what was the result of that discussion?

17 A. The discussion was that Impax could participate
18 in the at-risk launch up to that limit of
19 150,000 units.

20 Q. And you were present for that discussion?

21 A. Yes.

22 Q. And do you have an understanding, based on that
23 discussion, why Impax limited its participation to up
24 to 150,000 units?

25 A. Yes.

1 Q. And can you tell us what your understanding of
2 why that limitation was placed on Impax' management?

3 A. 150,000 units was how much Perrigo had
4 manufactured and how much they intended to launch
5 immediately, and in order -- the board, in order to
6 limit Impax' exposure, asked that Impax' participation
7 in the at-risk launch be limited to those
8 150,000 units.

9 Q. If you go to the next page, was a resolution
10 placed before the board?

11 Was a resolution placed before the board?

12 A. Yes.

13 Q. Thank you.

14 And did the board vote on the idea, on
15 management's recommendation to launch at risk?

16 A. Yes.

17 Q. And did the board in this case in
18 March of 2014 approve the launch at risk?

19 A. Yes.

20 Q. And did Impax and its partner Perrigo launch
21 azelastine at risk?

22 A. Yes.

23 Q. And do you recall how long you were on the
24 market together for selling azelastine?

25 A. Just a couple days.

1 Q. And what happened after that?

2 A. The parties negotiated a settlement agreement
3 with the brand company.

4 Q. I want to talk about dutasteride.

5 Did the board -- did Impax consider launching
6 dutasteride at risk?

7 A. Yes.

8 Q. And did the board ultimately approve an at-risk
9 launch of dutasteride?

10 A. I think the board approved manufacturing the
11 lots of product that would be necessary for an at-risk
12 launch.

13 This was a product that was also partnered with
14 another company called Banner, and Impax needed to
15 submit a purchase order for that number of products and
16 asked the board for permission to do that. And at the
17 same time, that was in contemplation of a potential
18 at-risk launch after a district court decision.

19 Q. Okay. Let's take a look at CX 3223, and that
20 document is in evidence and it's not in camera.

21 And these are minutes from a
22 July 5, 2013 meeting of the Impax board of directors;
23 is that right?

24 A. Yes.

25 Q. And did you attend that meeting?

1 A. Yes.

2 Q. And do you recall what the purpose of this
3 meeting was?

4 A. This was, as I discussed, to discuss preparing
5 for a potential at-risk launch of dutasteride.

6 Q. If we could go to the second page and focus on
7 the paragraph at the top or the two paragraphs at the
8 top of the page.

9 You mentioned that the launch would be
10 dependent on a court decision. And the first sentence
11 reads, "Dr. Ben-Maimon discussed that any launch would
12 be dependent on the court decision and its
13 interpretation, and that she anticipated at least two
14 other competitors could be in a position to launch at
15 the same time."

16 So what limitations were placed on management
17 in terms of the launch -- this launch at risk by the
18 board?

19 A. I believe the first page says Impax was just at
20 this stage authorized to prepare the batches, but any
21 decision to launch those would then be dependent on
22 this favorable court decision.

23 Q. And why did the Impax board want to make a
24 launch conditional on a favorable decision by the
25 district court?

1 MR. WEINGARTEN: Your Honor, I'm going to
2 object again on lack of foundation. Ms. Snowden
3 cannot testify as to what the collective Impax board
4 thought or why it wanted to make a certain decision.

5 MR. HASSI: I'll lay a foundation, Your Honor.

6 BY MR. HASSI:

7 Q. Was there a discussion of this issue at the
8 board?

9 A. Yes.

10 Q. Were you present for that discussion?

11 A. Yes.

12 Q. Did the board discuss placing a requirement on
13 management that there would be a favorable court
14 decision prior to permitting management to launch at
15 risk?

16 A. That was management's recommendation to the
17 board and the board agreed.

18 Q. And why did management recommend that to the
19 board?

20 A. There were two reasons. Impax had already
21 agreed in the court proceedings that it would not
22 launch prior to the court issuing its decision in the
23 case, and then of course to mitigate risk, it needed to
24 be a favorable court decision before there would be a
25 launch.

1 Q. Thank you.

2 Did Impax ever launch dutasteride at risk?

3 A. No.

4 Q. Why not?

5 A. The court decision wasn't favorable.

6 Q. And when the -- well, strike that.

7 Are you aware of any recommendation from
8 management to the Impax board relating to a launch at
9 risk of Opana ER?

10 A. No.

11 Q. Would you be involved in making any such
12 recommendation had it been made?

13 A. Yes.

14 Q. And what would your role be?

15 A. I get involved in prevent- -- presenting to
16 the board an analysis of the patent case, and I also
17 get involved in presenting to the board the potential
18 risk exposure.

19 Q. Absent board approval, under what
20 circumstances could Impax have launched Opana ER
21 before a final, nonappealable decision resolving the
22 patent litigation?

23 A. It wouldn't do it without board approval.

24 Q. Did management ever make a recommendation to
25 launch Opana ER at risk?

1 A. No.

2 Q. You mentioned a moment ago the district court
3 asking for -- asking Impax to promise not to launch at
4 risk on dutasteride pending a decision; is that right?

5 A. Yes.

6 Q. In Opana, in the Opana litigation with Endo,
7 was there any discussion with the court about an
8 at-risk launch?

9 A. Yes.

10 Q. Can you describe the circumstances of that
11 discussion.

12 MR. WEINGARTEN: Your Honor, I'd like to object
13 on a lack of foundation. We need to know if
14 Ms. Snowden was present for that discussion.

15 BY MR. HASSI:

16 Q. Ms. Snowden, were you present for a discussion
17 with the court regarding a launch at risk?

18 A. No.

19 Q. Were you supervising outside counsel who had a
20 discussion with the court about a launch at risk?

21 A. Yes.

22 Q. And do you understand the district court in
23 New Jersey to have asked Impax not to launch at risk
24 pending trial -- pending the trial of the case against
25 Endo?

1 A. Yes.

2 Q. And what did Impax inform the court in that
3 regard?

4 A. Impax informed the court that it agreed that
5 it would not launch its product at risk during trial.

6 Q. Could we bring up RX 251, please.

7 And if you could -- well, just looking at this,
8 can you identify this letter?

9 A. Yes.

10 Q. And it's dated May 20, 2010; is that right?

11 A. Yes.

12 Q. And it's to the Honorable Katharine Hayden.

13 Is that the judge who was presiding over the
14 case between Impax and Endo, the patent case?

15 A. Yes.

16 Q. And if you look at the second paragraph, did
17 you authorize your lawyers to write, "In light of
18 Your Honor's comments during the May 18, 2010
19 telephonic hearing, we write to advise the Court that
20 Impax will not launch its ANDA product (generic
21 oxymorphone HCl extended-release tablets) through and
22 including the last trial day as presently scheduled"?

23 Did you authorize your lawyers to say that to
24 the court?

25 A. Yes.

1 Q. Did you intend -- did Impax intend to keep its
2 promise to the judge?

3 A. Yes.

4 Q. Thank you.

5 JUDGE CHAPPELL: I've heard you answer a
6 number of questions saying that something is your
7 understanding. I don't like to hear about somebody's
8 understanding. I like to know what someone knows or
9 doesn't know.

10 When you say something is your understanding,
11 what does that mean?

12 THE WITNESS: Sometimes I've been asked
13 questions that I know from other -- other people at
14 Impax, and so I say that it is my understanding that
15 it's the case.

16 I don't know if you could read back one of
17 the -- if you could read back one of the questions
18 where I said it was my understanding, I might be able
19 to explain more.

20 JUDGE CHAPPELL: Not my job.

21 Thank you.

22 BY MR. HASSI:

23 Q. If you could, Robert, bring up RX 364. It's in
24 evidence.

25 It's in your binder, but in the white binder

1 that complaint counsel gave you, on a tab toward the
2 end, RX 364 (indicating).

3 A. I'm sorry. What number?

4 Q. RX 364.

5 A. You said RX 364.

6 Q. It's one of the last documents in there,
7 RX 364.

8 A. Oh, 364?

9 Q. Yes.

10 A. Okay.

11 Q. And this is the settlement and license
12 agreement between Impax and Endo?

13 A. Yes.

14 Q. There was some discussion earlier about the
15 patent license that you obtained.

16 Could you identify that in this document.

17 A. I believe it was section 4.1.

18 Q. So it's on page -9, Robert, and it's the bottom
19 of the page.

20 And I'd like you to just identify -- the court
21 asked you some questions about what you obtained a
22 license to, and could you identify in this paragraph
23 the description of the patents to which Impax received
24 a license in the settlement with Endo.

25 A. Right. The patents that Impax obtained a

1 license to is -- are described starting right after the
2 parenthetical that defines the term "License." The
3 patents that are licensed are described as the licenses
4 "under the Opana ER Patents," which is a defined term,
5 "and any continuations, continuations in part, or
6 divisionals thereof, and any patents and patent
7 applications owned by Endo or Penwest (or their
8 respective Affiliates) to the extent that Endo and/or
9 Penwest has the right to grant a sublicense to such
10 patents and applications that cover or could
11 potentially cover the manufacture, use, sale, offer for
12 sale, importation, marketing or distribution of
13 products (or any components thereof) that are the
14 subject of the Impax ANDA."

15 And it goes on to define the -- in that group
16 of patents those that are issued are called the
17 existing patents and the pending -- and the patents
18 that issue from the pending patent applications are
19 called the pending applications.

20 Q. So did the license include a license from
21 Penwest in addition to Endo?

22 A. Yes.

23 Q. And there was reference to a contract
24 litigation between Impax and Endo.

25 Did Endo in that litigation deny giving you

1 this license?

2 A. No.

3 Q. Did they deny that the license covered any of
4 Endo's patents?

5 A. No.

6 Q. Do I understand correctly that Endo's
7 allegations were that Impax had breached the license
8 and --

9 A. Yes.

10 Q. And Endo alleged that Impax breached that
11 license by not paying a royalty?

12 A. Correct.

13 Q. And Endo claimed in that litigation that as a
14 result, it had the power and was terminating the
15 license?

16 A. That's what they said in that litigation.
17 Yes.

18 Q. Was Impax ever removed from the market by Endo
19 or by an order of the court?

20 A. No.

21 Q. Did Impax ever stop selling Opana ER?

22 A. No.

23 Q. Did there come a time when Endo filed a
24 citizens petition with the FDA related to Opana?

25 A. They filed a couple.

1 Q. They filed a couple of citizens petitions?

2 A. Yes.

3 Q. Let's look at CX 3203. It's in evidence and
4 it's tab 20 in your binder.

5 And I'm sorry I --

6 A. I'm sorry. What was the number again?

7 Q. Tab 20.

8 JUDGE CHAPPELL: How much more time do you
9 think you need?

10 MR. HASSI: Probably only about 15 minutes,
11 although I, candidly, if we took the lunch break now,
12 probably could streamline just make sure that we get it
13 done quickly.

14 JUDGE CHAPPELL: Go ahead.

15 MR. HASSI: Keep questioning? Okay.

16 BY MR. HASSI:

17 Q. Can you identify this document or these
18 documents?

19 A. No. Not the cover e-mail.

20 MR. WEINGARTEN: Your Honor, I'm going to
21 object to the extent he's asking -- lack of foundation.
22 He's asking Ms. Snowden about a document that is an
23 Endo e-mail between what I think are two Endo people
24 and Ms. Snowden is not on it.

25 MR. HASSI: And Your Honor, I don't really care

1 about the cover e-mail. I'm happy to focus on the
2 citizens petition and if we'll jump to the page -30.

3 MR. WEINGARTEN: Then I just ask he lay a
4 foundation for the questions about the petition,
5 Your Honor.

6 BY MR. HASSI:

7 Q. Ms. Snowden, did you review the citizens
8 petitions that Endo filed with the FDA related to
9 Opana ER?

10 A. Yes.

11 Q. And focusing on the one that starts at
12 tab 30 -- excuse me -- at page -30, is this one of the
13 citizens petitions that Endo filed with the FDA?

14 A. Yes.

15 Q. And you reviewed it at the time?

16 A. Yes.

17 Q. And what did -- what was your understanding --
18 it's me asking the question about your understanding,
19 Your Honor, which is -- what was the purpose of this
20 citizens petition?

21 MR. WEINGARTEN: Your Honor, I'm going to
22 object to a lack of foundation. Ms. Snowden cannot
23 testify as to what Endo's purpose was in filing a
24 citizens petition.

25 MR. HASSI: I didn't ask Endo's purpose,

1 Your Honor.

2 BY MR. HASSI:

3 Q. Let's back up a second.

4 What's the purpose of a citizens petition?

5 MR. WEINGARTEN: Sorry, Your Honor. If he's
6 asking about what the purpose of a citizens petition in
7 general is, I have no objection.

8 JUDGE CHAPPELL: That's what he said,
9 "a citizens petition."

10 MR. WEINGARTEN: Thank you.

11 BY MR. HASSI:

12 Q. What's the purpose of a citizens petition?

13 A. It's to request the FDA to take particular
14 actions.

15 Q. And what action was Endo requesting that the
16 FDA take with respect to this citizens petition?

17 A. They asked -- they asked FDA to make -- to do
18 three things.

19 They asked FDA to determine that the original,
20 non-crush-resistant version of Opana ER was
21 discontinued for reasons of safety and could no longer
22 serve as a reference listed drug for an ANDA
23 applicant.

24 They asked FDA to refuse to approve any
25 pending ANDA for a generic version of the original,

1 non-crush-resistant version of Opana ER.

2 And they asked FDA to withdraw the approval of
3 an ANDA referencing the original, non-crush-resistant
4 version of Opana ER.

5 Q. And what did Impax do in response to this
6 citizens petition?

7 A. Impax filed a response to the citizen petition
8 with FDA.

9 Q. Why did Impax file a response to the citizens
10 petition with the FDA?

11 A. Because Impax disagreed with what Endo wrote in
12 the citizens petition and Impax was trying to fight
13 this argument that the approval of Impax' ANDA should
14 be withdrawn, which would have prevented Impax' launch
15 in January of 2013.

16 Q. And do you recall that Endo was arguing that
17 Opana ER should be withdrawn for safety reasons?

18 A. They argued that their original version of
19 Opana ER should be determined to be -- have been
20 withdrawn for reasons of safety because they argued
21 that their new crush-resistant version of Opana ER was
22 safer.

23 Q. Did this citizens petition lead to litigation
24 with the FDA?

25 A. I wouldn't say it led to it, but there was

1 parallel litigation.

2 Q. And did -- what was that parallel litigation?

3 A. Endo sued FDA, seeking the same relief in
4 court, asking the court to order FDA in effect to
5 withdraw approval of Impax' ANDA before Impax' launch
6 date in January of 2013.

7 Q. Did Impax intervene in that litigation?

8 A. Yes.

9 Q. And what was the outcome of that litigation?

10 A. The court sided with Impax and the FDA, which
11 was to deny Endo's motion and allow FDA to use its
12 normal process to determine whether the original
13 Opana ER was discontinued for reasons of safety.

14 MR. HASSI: May I confer with counsel?

15 JUDGE CHAPPELL: Go ahead.

16 (Pause in the proceedings.)

17 BY MR. HASSI:

18 Q. Ms. Snowden, was the settlement and license
19 agreement filed with the Federal Trade Commission?

20 A. Yes.

21 Q. And when was it filed with the
22 Federal Trade Commission?

23 A. Shortly after it was executed in June of 2010.

24 Q. When you say "shortly after," within a month?

25 A. Yes.

1 Q. And did you hear from the
2 Federal Trade Commission in response to that filing?

3 A. No.

4 Q. When was the first time that you heard anything
5 from the Federal Trade Commission with regard to the
6 settlement and license agreement?

7 A. In 2014 when they issued a CID.

8 Q. And I suspect the court knows, but can you tell
9 us what a CID is?

10 A. Civil investigative demand.

11 Q. And between June of 2010 when you filed it and
12 2014 when Impax first received that CID, did you have
13 any communications with the Federal Trade Commission
14 regarding the settlement and license agreement?

15 A. No.

16 Q. Any communications regarding the development
17 and co-promotion agreement?

18 A. No.

19 Q. And when was the Actavis case decided?

20 A. I think that was 2013.

21 MR. HASSI: Thank you. I have nothing further,
22 Your Honor.

23 JUDGE CHAPPELL: Anything else?

24 MR. WEINGARTEN: I will have some questions,
25 Your Honor, so I don't know if you prefer to take a

1 lunch break.

2 JUDGE CHAPPELL: No. You're going to go now.

3 We're going to finish this witness.

4 MR. WEINGARTEN: Okay. It might be some time,

5 Your Honor. I'll do my best.

6 JUDGE CHAPPELL: Well, it's going to have to
7 be within the scope of the examination we just heard.

8 MR. WEINGARTEN: Absolutely, Your Honor.

9 - - - - -

10 REDIRECT EXAMINATION

11 BY MR. WEINGARTEN:

12 Q. Good afternoon, Ms. Snowden.

13 A. Good afternoon.

14 Q. You talked a little bit on your examination by
15 Mr. Hassi about when occasionally district courts
16 disagree with Impax when Impax has filed a Paragraph IV
17 certification; correct?

18 A. Correct.

19 Q. And sometimes district courts agree when Impax
20 files a certification that a patent is invalid or
21 otherwise unenforceable; correct?

22 A. Correct.

23 Q. In fact, patent litigation is uncertain, would
24 you agree?

25 A. Yes.

1 Q. You were asked several questions about
2 forfeiture of a 180-day exclusivity period; correct?

3 A. Yes.

4 Q. Okay. Impax did not forfeit its 180 days, did
5 it?

6 A. No.

7 Q. Thank you.

8 We spent some time on my examination and
9 during Mr. Hassi's examination discussing a call you
10 had with Mr. Donatiello in -- about what dates you
11 should think about for when the entry date should be.
12 Do you remember those questions?

13 Okay.

14 A. Part of what you just said I didn't catch, so
15 if you would start over, that would be great.

16 Q. Sure.

17 Mr. Hassi and I both asked you about a
18 telephone call with Mr. Donatiello during which you
19 discussed dates within which the two parties might
20 agree to an entry date for oxymorphone; correct?

21 A. Yes.

22 Q. Okay. And you put on the table to
23 Mr. Donatiello that you thought the dates in between
24 which an entry date would be acceptable would be the
25 end of the 30-month stay for Impax' product and the

1 expiration of the patents at issue; correct?

2 A. Yes.

3 Q. And the date of the end of the 30-month stay
4 was June in 2010; correct?

5 A. Yes.

6 Q. And the date the patents expired that were at
7 issue was September 2013; correct?

8 A. Correct.

9 Q. So you told Mr. Donatiello an acceptable entry
10 date should be one in between those two dates.

11 A. Yes.

12 Q. Thank you.

13 That conversation with Mr. Donatiello occurred
14 in May of 2010; correct?

15 A. I think I've testified that I'm not sure. It
16 might have been.

17 Q. Okay.

18 A. We went through this. I -- I think I said a
19 couple different things, which is one of the reasons
20 why I'm not sure.

21 Q. Okay. Mr. Hassi asked you a little bit about
22 the at-risk launch of oxycodone by Impax. Do you
23 recall that?

24 A. Yes.

25 Q. Okay. Impax launched a dosage of oxycodone at

1 risk; correct?

2 A. Yes.

3 Q. And you did not agree -- strike that.

4 When you raised that example with

5 Mr. Donatiello during your phone call, Mr. Donatiello

6 said it was not a good example of an at-risk launch;

7 correct?

8 A. Yes.

9 Q. And you disagreed with him and told him that it

10 was a good example of a time Impax had launched at

11 risk; correct?

12 A. Yes.

13 Q. You also mentioned that Endo also had its own

14 generic version of oxycodone at the same time that

15 Impax had its; correct?

16 A. Yes.

17 Q. Okay. And you mentioned on your response to

18 Mr. Hassi that Endo did not launch its version of

19 oxycodone at risk; correct?

20 A. I said that, but I think I should clarify my

21 answer. The -- in that case what happened was the

22 district court found the patents unenforceable, and

23 that's when Teva launched the 80 milligram strength,

24 and Impax launched sometime after Teva's 180 days.

25 What happened was, on appeal, the

1 Federal Circuit affirmed the finding of patent
2 unenforceability, and then Endo launched.

3 In the meantime, Purdue had requested
4 reconsideration, and then on reconsideration, the
5 Federal Circuit reversed and remanded. And therefore,
6 Endo in a sense thought it was not launching at risk
7 because it launched after the appellate court decision,
8 but then after reconsideration and the appellate court
9 changed its mind, Endo found itself on the market at
10 risk after all.

11 Q. I appreciate that explanation.

12 So my question is, Impax launched after a court
13 decision but before an appeal had been decided;
14 correct?

15 A. Yes.

16 Q. And that is an at-risk launch; correct?

17 A. Yes.

18 Q. And Impax knew it was at risk when it launched;
19 correct?

20 A. Yes.

21 Q. Endo, by contrast, waited until an appellate
22 decision in its favor; correct?

23 A. Yes.

24 Q. So in that circumstance of oxycodone, Impax
25 launched at risk, Endo did not.

1 A. Right. With the caveat that I just gave
2 about --

3 Q. Okay.

4 A. -- the court changing --

5 Q. Even if Endo later found, because of later
6 action by the court of appeals, that it in fact was at
7 risk, at the time it launched, it was not at risk;
8 correct?

9 A. I think that's a funny way of saying things.
10 There's the day that you launch.

11 Q. Yes.

12 A. And then for any time after that that there's
13 patent uncertainty, if you're continuing to sell the
14 product, you're at risk while you're continuing to sell
15 the product.

16 So if you want to focus on the day of launch,
17 that would be true. After the court changed its mind,
18 then they're on the market at risk.

19 Q. In any event, the day that Impax launched, it
20 knew it was launching at risk.

21 A. Yes.

22 Q. Okay. I'd like you to look at -- I believe
23 it's CX 320. These are the term sheets.

24 Can you pull that up, Ms. Durand.

25 This is something Mr. Hassi showed you.

1 A. I might be in the wrong binder.

2 Q. Do you remember Mr. Hassi asked you questions
3 about the term sheets that Endo sent over to Impax?

4 A. Yes.

5 Q. Okay. And if you could please, Ms. Durand,
6 take us to 320- -- I believe it's 002.

7 And if you could highlight, please, Ms. Durand,
8 the box that says "Product."

9 The product in the term sheet that Endo sent to
10 Impax was IPX-066; correct?

11 A. This is what I said. They -- their term sheet
12 included both because it was IPX-066 and all
13 improvements, modifications, derivatives, formulations
14 and line extensions thereof, so I -- I described that
15 as their original term sheet had included both
16 products.

17 Q. Okay. So the original term sheet from Endo
18 included IPX-066 and any follow-ons or extensions
19 thereof.

20 A. Correct.

21 Q. Thank you.

22 You can take that down, please, Ms. Durand.
23 Thanks.

24 You testified, in response to questions from
25 Mr. Hassi, about the business priorities for the

1 settlement with Endo. Do you remember that?

2 A. Yes.

3 Q. Okay. And you testified I believe that getting
4 the earliest entry date possible was a business
5 priority for Endo; correct?

6 A. For Impax.

7 Q. Strike that. Yes.

8 Getting the earliest entry date possible was a
9 business priority for Impax; correct?

10 A. Yes.

11 Q. Okay. And protecting the market for that entry
12 date was a priority for Impax; correct?

13 A. Yes.

14 Q. And you -- strike that.

15 And you accomplished that in the settlement
16 that was ultimately signed with Endo; correct?

17 A. I'd say Impax believed it did. Yes.

18 Q. Thank you.

19 If you could please refer back to CX 332. This
20 is your letter to Mr. -- well, to the president and
21 chief legal officer of Endo about the Endo credit.

22 Ms. Durand, if you could put it on the screen,
23 please.

24 Do you remember both Mr. Hassi and I asked you
25 about this e-mail and the letters?

1 A. Yes.

2 Q. The letter?

3 And if you could please scroll forward,
4 Ms. Durand, to page 7 of this document.

5 This is the letter; correct?

6 A. Yes.

7 Q. Okay. And Mr. Hassi asked you that Impax
8 followed the formula that was set forth in the
9 settlement agreement to calculate the Endo credit;
10 correct?

11 A. Yes.

12 Q. And Endo did not dispute the calculation that
13 you sent over, did it?

14 A. No.

15 Q. And Endo paid the amount that you calculated
16 using that formula to the penny; correct?

17 A. Yes.

18 Q. Thank you.

19 In response to a question about (sic) Mr. Hassi
20 about your expectations of the credit, you said you
21 didn't -- you said, "No." I want to get clarity on
22 that.

23 You didn't have an expectation one way or the
24 other about how the credit would turn out; is that
25 fair?

1 A. I think that's fair.

2 Q. You didn't expect the credit to be worth --
3 strike that.

4 At the time you entered this deal, you didn't
5 have an expectation that the credit was worth zero, did
6 you?

7 A. I had no expectation at all.

8 Q. One way or the other about the event.

9 A. Correct.

10 Q. Let me ask you a few questions about the
11 license provision.

12 Mr. Hassi asked you about pending applications
13 and various patents that came later, Johnson Matthey
14 and otherwise. Do you remember that?

15 A. Yes.

16 Q. The patents that we've been referring to today
17 as later obtained or later issued, none of those had
18 been issued by the Patent Office to Endo when you
19 signed this deal; correct?

20 And by "this deal" I mean the settlement and
21 license agreement.

22 A. I -- right. Right. I think that's correct. I
23 think it's -- those are the ones referred to in the --
24 in the license as pending applications, although it --
25 you're right. And it also covers later-acquired

1 patents.

2 Q. Okay. And some of the decisions that you
3 talked about with Mr. Hassi going on in the
4 Southern District of New York or the
5 District of Delaware, some of those decisions came out
6 in Endo's favor; correct?

7 A. Yes.

8 Q. And some of those decisions in Endo's favor are
9 on appeal; correct?

10 A. Yes.

11 Q. And so the parties who lost in the district
12 court are asserting the district court got it wrong?

13 A. That's correct.

14 Q. Let me ask you a few questions about a product
15 that Mr. Hassi mentioned called Frova, F-R-O-V-A.

16 JUDGE CHAPPELL: Let me ask you something about
17 at risk.

18 Are you aware of whether or not it matters,
19 regarding the damages you're subjected to, if you have
20 a district court ruling in your favor and you launch a
21 product and then that decision is later reversed on
22 appeal? Are you aware of whether that will reflect --
23 or will affect the amount of damages you would be
24 subject to?

25 THE WITNESS: I believe the common view is it

1 won't affect the amount of damages, direct damages.

2 It does matter. Patent damages could be
3 trebled for willfulness, and I think it's -- there's a
4 view that if there's a district court in your favor,
5 there's not a chance that the infringement would be
6 found willful, so there wouldn't be a chance of
7 trebling the damages.

8 JUDGE CHAPPELL: So your risk would still be
9 actual damages but not those damages trebled.

10 THE WITNESS: Correct.

11 BY MR. WEINGARTEN:

12 Q. Talking about Frova now, Mr. Hassi asked you
13 about a meeting between Impax and Endo representatives
14 that you attended regarding Frova, F-R-O-V-A. Do you
15 remember that?

16 A. I don't think I said I attended a meeting.

17 Q. Okay. Did you have any -- do you recall
18 discussing with Mr. Hassi conversations between Impax
19 and Endo about Frova in 2009?

20 A. Yes. I said that our head of sales and
21 marketing on the brand side came to me because he was
22 interested in Frova, and I put him in touch with
23 somebody at Endo, but I don't think I was involved in
24 any discussions about Frova.

25 Q. So you had no personal foundation for any

1 discussion about Frova between Endo and Impax?

2 A. Only that the conversations took place.

3 Q. Okay. Do you know whether Frova is an Endo or
4 an Impax product?

5 A. Frova was an Endo product.

6 Q. Okay. And the development deal, the
7 development and co-promotion deal, that was for an
8 Impax branded product; correct?

9 A. Yes.

10 Q. Not an Endo branded product.

11 A. Correct.

12 Q. And to your knowledge, the Frova discussions
13 between Endo and Impax never went anywhere; correct?

14 A. They never succeeded in reaching a deal.
15 Correct.

16 Q. Okay. We talked a little bit -- strike that.

17 Mr. Hassi asked you a few questions about the
18 development status of IPX-203. Do you remember that?

19 A. Yes.

20 Q. And you testified that you've neared completion
21 of Phase II; is that correct?

22 A. I said one Phase II was completed and a second
23 Phase II is underway.

24 Q. So it's seven years since the development and
25 co-promotion agreement between Endo and Impax was

1 signed, and IPX-203 is still in Phase II trials;

2 correct?

3 A. Correct.

4 Q. And after you complete Phase II trials, if
5 that's successful, then to market the product, Impax
6 would have to complete Phase III trials; correct?

7 A. Correct.

8 Q. And to market the product if those work out,
9 Impax would then have to file a New Drug Application
10 with the FDA; correct?

11 A. Correct.

12 Q. And as of today, you can't say with certainty
13 whether the product that is called IPX-203 will in fact
14 ever be marketed; correct?

15 A. Correct.

16 Q. I'd like to direct you if I could to RX 221.
17 Mr. Hassi asked you some questions about that
18 document.

19 Ms. Durand, if you could put that on the
20 screen, please.

21 And Ms. Durand, can you highlight the bottom
22 e-mail on this page. Actually, it's the one from
23 Mr. Macpherson. Thank you.

24 Do you see that bottom e-mail, ma'am?

25 A. Yes.

1 Q. And that's the one that Mr. Hassi asked you
2 some questions about; correct?

3 A. Yes.

4 Q. Okay. Mr. Macpherson wrote, "Endo has decided
5 not to amend the existing agreement"; correct?

6 A. Yes.

7 Q. And he wrote, "Since your existing program does
8 not meet the definition of Product in the agreement, we
9 will not be participating in that program."

10 Do you see that?

11 A. Yes.

12 Q. So the IPX-203 that exists today is a different
13 program than the one that was agreed to in the
14 development and co-promotion agreement in 2010;
15 correct?

16 A. Impax didn't consider it a different program.
17 Impax kept calling it IPX-203 the whole time, but you
18 are correct that it was no longer the levodopa ester.

19 Q. It's a fair point. I'll ask you this one.

20 The product that is IPX-203 today at Impax is
21 not the same product that was defined in the
22 development agreement between Endo and Impax in 2010;
23 correct?

24 A. Correct.

25 Q. Thank you.

1 You can put that aside, please, Ms. Durand.

2 Thank you.

3 Mr. Hassi asked you some questions about
4 at-risk launches and the history of going to the board
5 to discuss at-risk launches at Impax. Do you remember
6 that?

7 A. Yes.

8 Q. Okay. And he showed you some board minutes for
9 several discussions about launches at risk. Do you
10 recall that?

11 A. Yes.

12 Q. And in at least one of those cases, the board
13 approved limiting the risk that Impax could face from
14 an at-risk launch. Do you remember that?

15 A. Yes.

16 Q. So on at least one occasion, the board
17 understood it could authorize an at-risk launch -- or
18 strike that.

19 So on at least one occasion, the board approved
20 an at-risk launch with a risk limit that would protect
21 Impax from potential damages if they lost a patent
22 suit?

23 A. Yes.

24 Q. Okay. In the examples that Mr. Hassi asked you
25 about, in each of those cases, management came to the

1 board with a recommendation regarding the at-risk
2 launch; correct?

3 A. Yes.

4 Q. And in each of those cases the board approved
5 management's recommendation; correct?

6 A. Yes.

7 Q. Okay. Regarding a potential at-risk launch of
8 oxymorphone, Mr. Hassi asked you whether there had
9 been a management recommendation. Do you remember
10 that?

11 A. Yes.

12 Q. There had not been a recommendation either way
13 to the board whether to launch or not; correct?

14 A. Correct.

15 Q. And the board had not decided against launching
16 at risk; correct?

17 A. Correct.

18 Q. Okay. And once Endo and Impax entered into
19 their settlement agreement, then the topic of an
20 at-risk launch no longer needed to be presented to the
21 board of directors of Impax; correct?

22 A. That's true.

23 Q. Thank you.

24 Mr. Hassi showed you a letter regarding the
25 preliminary -- strike that.

1 Mr. Hassi showed you a letter written by Impax'
2 counsel to the court in New Jersey. Do you remember
3 that?

4 A. Yes.

5 Q. And in the letter, Impax' counsel memorialized
6 that Impax would agree not to launch at risk during
7 trial in the District of New Jersey. Do you remember
8 that?

9 A. Yes.

10 Q. Okay. Trial was set to end in the middle of
11 June 2010; correct?

12 A. Yes.

13 Q. So in effect the promise was simply not to
14 launch at risk until the middle of June 2010?

15 A. Yes. In the context of Endo was not going to
16 ask the court to hear a preliminary injunction motion
17 during trial. The implication is that somehow that
18 date would come and go without anybody asking. I
19 wouldn't agree with that.

20 Q. Mr. Hassi also asked you about the litigation
21 that came several years later after 2010 between Endo
22 and Impax about the license in the settlement
23 agreement.

24 Do you remember that?

25 A. Yes.

1 Q. Okay. And Endo asserted that license was
2 terminated; correct?

3 A. Yes, they did.

4 Q. And so absent a license, if the court --
5 strike that.

6 And the action in which Endo asserted that the
7 license was terminated also included claims for patent
8 infringement against Impax; correct?

9 A. Yes.

10 Q. Now, Mr. Hassi asked you about whether the
11 settlement agreement at issue in this case was filed
12 with the FTC. Do you remember that?

13 A. Yes.

14 Q. And you said you hadn't heard from the FTC, but
15 you must have meant other than when the FTC began
16 investigating this case; correct?

17 A. Yes.

18 Q. So the FTC began investigation into this
19 settlement agreement; correct?

20 A. Yes.

21 Q. And that's why we're all here today; correct?

22 A. Yes.

23 MR. WEINGARTEN: Okay. Thank you.

24 Nothing further, Your Honor.

25 JUDGE CHAPPELL: Anything else?

1 MR. HASSI: I have a few questions,
2 Your Honor.

3 JUDGE CHAPPELL: Go ahead.

4 - - - - -

5 RE-CROSS-EXAMINATION

6 BY MR. HASSI:

7 Q. The FTC began investigating what led to this
8 case in 2014; right?

9 A. I believe so. I believe that's correct, yes.

10 Q. And that was almost four years after you first
11 filed the settlement with the FTC; right?

12 A. Right.

13 Q. You were asked a minute ago about going to the
14 board, making a recommendation to the board, and the
15 board limiting the risk associated with an at-risk
16 launch.

17 In the case of Opana ER, where you were first
18 to file, would that be a good strategy, for management
19 to ask the board to limit the risk at launch?

20 MR. WEINGARTEN: Your Honor, I'm going to have
21 to object.

22 JUDGE CHAPPELL: Basis?

23 MR. WEINGARTEN: There's no way she can answer
24 this question without getting into privilege. If he
25 can ask her if she can do it without discussing legal

1 advice that she would give the company or --

2 JUDGE CHAPPELL: Are you asking her about a
3 legal strategy or a business strategy?

4 MR. HASSI: Business strategy, Your Honor.

5 JUDGE CHAPPELL: Overruled.

6 MR. HASSI: You've got six months first to
7 file -- sorry.

8 BY MR. HASSI:

9 Q. Would it be a good business strategy for Impax
10 to risk its very valuable first-to-file exclusivity
11 with a limited launch of Opana ER?

12 A. I don't think so. Without even getting into
13 the patent merits, what we've seen in this industry
14 is, when a generic launches at risk, being enjoined is
15 quite, quite possible, and so if you launch at risk
16 and then you get enjoined, the 180-day clock will keep
17 ticking, as we discussed earlier, and so the generic
18 company loses the value of the 180-day exclusivity
19 period.

20 MR. WEINGARTEN: Your Honor, I don't mean to
21 interrupt, but I'm going to object to this answer as
22 being speculative and lacking in foundation.

23 She's talking about what we've seen in the
24 industry when a generic launches at risk. This is not
25 based on her personal knowledge apparently, so I move

1 to strike the response.

2 BY MR. HASSI:

3 Q. Was your answer based upon your personal
4 experience as an IP litigator with more than twenty
5 years of experience in this industry?

6 A. Yes.

7 JUDGE CHAPPELL: Overruled.

8 BY MR. HASSI:

9 Q. The court asked you a question about the
10 difference between a launch at risk after a favorable
11 district court opinion. Do you recall that?

12 A. Yes.

13 Q. What would the effect be of a district court
14 injunction after a favorable district court ruling,
15 had you launched at risk, on your 180-day exclusivity?

16 A. I think that's what I was referring to.

17 MR. WEINGARTEN: I'm sorry. I don't mean to
18 interrupt the witness, Your Honor. Now he's asking for
19 her legal advice.

20 MR. HASSI: No, Your Honor. I'm asking about
21 her experience, and I'm happy to connect it to an
22 experience that she can speak to that happened in this
23 industry.

24 MR. WEINGARTEN: If he wants to talk about a
25 past experience that she observed, that's one thing,

1 but asking her what the effect would be in the future
2 hypothetically with the interplay with the regulatory
3 regime --

4 JUDGE CHAPPELL: Rephrase.

5 MR. HASSI: Yes, Your Honor.

6 BY MR. HASSI:

7 Q. Are you aware of a situation in which Mylan
8 launched at risk following a favorable district court
9 decision only to find themselves enjoined by that same
10 district court?

11 A. Yes.

12 Q. And was Mylan the first to file in that case?

13 A. Yes.

14 MR. WEINGARTEN: Your Honor -- I'm sorry. I
15 don't mean to interrupt you, Mr. Hassi.

16 MR. HASSI: You do.

17 MR. WEINGARTEN: Now we're on the relevance
18 question, Your Honor. I don't understand the relevance
19 of Mylan, which is also not before Your Honor, and its
20 experience with an unnamed drug.

21 JUDGE CHAPPELL: Why are we asking about
22 Mylan?

23 MR. HASSI: Your Honor, you asked for a
24 foundation for what might happen -- I'm explaining --
25 having the witness explain what might happen to

1 first-to-file exclusivity in the event of a favorable
2 district court decision where Impax were to launch at
3 risk, and the Mylan experience speaks to that.

4 Mylan did exactly that. They launched at risk
5 following a favorable district court opinion, they were
6 enjoined, and they lost the benefit of their
7 first-to-file exclusivity.

8 This witness is aware of that and wanted to
9 share that experience with the court.

10 JUDGE CHAPPELL: Complaint counsel asked a
11 line of questions regarding going ahead and launching
12 while something may still be on appeal, and that to me
13 opens the door for what the repercussions would be and
14 what's happened in the real world.

15 Overruled.

16 BY MR. HASSI:

17 Q. Can you tell us what happened in the Mylan
18 experience.

19 A. Right. Mylan did win at the district court
20 level and launched at risk after that, and then they
21 were enjoined, and that -- their 180-day clock had
22 started ticking with the launch, and so they lost the
23 value of their 180-day exclusivity.

24 Q. And so would Impax management recommend a
25 limited launch at risk even after a favorable district

1 court opinion on Opana ER?

2 MR. WEINGARTEN: Your Honor, I have to object.
3 This is speculation. Now he's asking her to speak on
4 behalf of all Impax management. He's asking --

5 JUDGE CHAPPELL: That's sustained.

6 MR. WEINGARTEN: -- a hypothetical.

7 Thank you, Your Honor.

8 BY MR. HASSI:

9 Q. And as a member of Impax management who's
10 involved in counseling the executive committee and the
11 board on these issues -- and I'm not asking for legal
12 advice -- just from a business risk standpoint, would
13 you counsel Impax to launch at risk following a
14 favorable district court decision and put at risk its
15 180-day exclusivity?

16 MR. WEINGARTEN: Objection, Your Honor. Calls
17 for speculation. He's basically asking for lay expert
18 opinion now.

19 MR. HASSI: No, Your Honor, I'm not.

20 MR. WEINGARTEN: It's a hypothetical.

21 JUDGE CHAPPELL: It's a hypothetical. You can
22 ask the witness what has happened in the past, what
23 she's aware of, but not to speculate. Sustained.

24 BY MR. HASSI:

25 Q. Have you ever recommended that Impax launch at

1 risk on a product where it was first to file?

2 A. No.

3 Q. And so I take it you've never asked management
4 or asked the board to approve a limited launch at risk
5 where Impax was first to file.

6 A. No.

7 Q. You made a comment about the judge -- about
8 Impax' promise to the judge regarding not launching at
9 risk during the trial.

10 Had the judge renewed that request following
11 the trial, what would you have recommended your lawyers
12 do?

13 MR. WEINGARTEN: Your Honor, objection. This
14 is again a hypothetical.

15 JUDGE CHAPPELL: Sustained.

16 BY MR. HASSI:

17 Q. In your experience, have you ever been asked by
18 a judge not to launch at risk and told the judge --
19 violated the judge's request and gone ahead and
20 launched at risk?

21 A. No.

22 Q. Have you been asked by judges before not to
23 launch at risk?

24 A. Yes.

25 MR. HASSI: Thank you.

1 I have no further questions.

2 MR. WEINGARTEN: I just have one follow-up,
3 Your Honor.

4 JUDGE CHAPPELL: Go ahead.

5 - - - - -

6 REDIRECT EXAMINATION

7 BY MR. WEINGARTEN:

8 Q. Mr. Hassi just asked you about recommendations
9 to the board about launching at risk, and you said
10 you've never made a recommendation to the board to
11 launch at risk; is that correct?

12 JUDGE CHAPPELL: That's one question.

13 MR. WEINGARTEN: I apologize.

14 BY MR. WEINGARTEN:

15 Q. Do you remember testifying that you never made
16 a recommendation to the board about launching at risk?

17 A. I think that wasn't the exact question. I
18 think it was about a first-to-file product.

19 Q. Okay. At Impax, it's -- are you the one who
20 makes a rec- -- who seeks a rec- -- an authorization
21 from the board to launch at risk?

22 A. No.

23 MR. WEINGARTEN: Okay. Thank you.

24 MR. HASSI: I'm sorry, Your Honor. I have to
25 follow up.

1 JUDGE CHAPPELL: You could end this.

2 MR. HASSI: I'm trying.

3 - - - - -

4 RE CROSS-EXAMINATION

5 BY MR. HASSI:

6 Q. Are you a member of the team that makes
7 recommendations to the board with regard to launches at
8 risk?

9 A. Yes.

10 MR. HASSI: I'm ending it, Your Honor.

11 JUDGE CHAPPELL: Anything further?

12 - - - - -

13 REDIRECT EXAMINATION

14 BY MR. WEINGARTEN:

15 Q. Your role on that team, ma'am, is to provide
16 legal advice; correct?

17 A. Yes.

18 MR. WEINGARTEN: Nothing further, Your Honor.
19 Thank you.

20 JUDGE CHAPPELL: Anything else? Going once.

21 - - - - -

22 RE CROSS-EXAMINATION

23 BY MR. HASSI:

24 Q. I don't want to be accused of waiving, so do
25 you provide business advice as well where you think

1 management might be making a mistake?

2 A. I would.

3 MR. HASSI: Thank you, Your Honor.

4 MR. WEINGARTEN: I have nothing further,
5 Your Honor. Thank you for your patience.

6 JUDGE CHAPPELL: Thank you. You may stand
7 down.

8 We're going to take an afternoon -- or we're
9 going to take a lunch break. Have the next witness
10 ready in the courtroom when we return. We'll reconvene
11 at 3:20.

12 We're in recess.

13 (Whereupon, at 2:20 p.m., a lunch recess was
14 taken.)

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1 Q. Did you say it's a specialty pharma company?

2 A. Yes.

3 Q. Does that include generics?

4 A. Yes.

5 Q. Now, before Cuda, you worked at

6 Impax Laboratories; correct?

7 A. Yes.

8 MR. LOUGHLIN: Your Honor, I'll note for the
9 record that pursuant to Your Honor's October 18 order,
10 Mr. Mengler has been designated as an adverse witness.

11 JUDGE CHAPPELL: Okay.

12 BY MR. LOUGHLIN:

13 Q. Now, Mr. Mengler, you were president of Impax'
14 generics division; correct?

15 A. Yes.

16 Q. And that is sometimes referred to as
17 Global Pharmaceuticals?

18 A. Yes.

19 Q. And you were president of Impax' generics
20 division from January 2009 until October of 2010?

21 A. Yes.

22 Q. Now, you gave a deposition in this case. Do
23 you recall that?

24 A. Yes.

25 Q. That was in May of this year?

1 A. If you say so, I believe it.

2 Q. It was earlier this year.

3 A. Yes.

4 Q. You recall that. Okay.

5 And you were represented by Mr. Hassi at the
6 deposition?

7 A. Yes.

8 Q. And Mr. Hassi is with the O'Melveny & Myers law
9 firm?

10 A. Yes.

11 Q. That's the law firm that represents Impax in
12 this case; correct?

13 A. Yes.

14 Q. And you met with counsel the day before your
15 deposition?

16 A. Yes.

17 Q. And that was for about eight or nine hours;
18 correct?

19 A. I guess so, yeah.

20 Q. And you reviewed documents with counsel in
21 preparation for the deposition; correct?

22 A. Yes.

23 Q. And you were paid by Impax for your time
24 preparing for the deposition; correct?

25 A. Yes.

1 Q. You were paid \$500 an hour?

2 A. Yes.

3 Q. You were also paid for your time testifying in
4 the deposition; correct?

5 A. Yes.

6 Q. And that was also \$500 per hour?

7 A. Yes.

8 Q. Now, do you recall that you also gave testimony
9 in what's called an investigational hearing?

10 A. Yes.

11 Q. And you were represented by O'Melveny & Myers
12 in that hearing as well; correct?

13 A. Probably.

14 Q. You don't recall --

15 JUDGE CHAPPELL: Did you have an attorney
16 there?

17 THE WITNESS: Yeah. I'm sure I did. I don't
18 recall who it was. It was a while ago.

19 JUDGE CHAPPELL: Do you recall if your attorney
20 had a right to ask you any questions?

21 THE WITNESS: Pardon me?

22 JUDGE CHAPPELL: Do you recall if your attorney
23 asked you any questions?

24 THE WITNESS: At the first hearing -- I don't
25 think so.

1 JUDGE CHAPPELL: I'm trying to jog your
2 memory, sir, on the difference between this so-called
3 investigational hearing transcript versus a real
4 deposition where your attorney actually has a right to
5 question you.

6 Does that jog your memory that you weren't
7 asked anything by your own lawyer?

8 THE WITNESS: You know, it was a while ago. I
9 remember that it happened and I remember it was --
10 because it was in the other building, but the details
11 escape me.

12 BY MR. LOUGHLIN:

13 Q. Well, Mr. Mengler, you have a binder sitting
14 next to you.

15 Do you see that?

16 A. Yes.

17 Q. If you look in there, you see a tab that says
18 "IH"?

19 A. Yep.

20 Q. If you'd turn to page 218 of your IH.

21 A. Okay.

22 Q. Do you see line 6?

23 A. Yes.

24 Q. Where Mr. Meier is asking you -- where
25 Mr. Meier says, "I don't have any other questions. I

1 don't know if you have anything you want to ask or any
2 clarifying questions," and Mr. O'Rourke says, "Not at
3 this time," do you see that?

4 A. Yes.

5 Q. Was Mr. O'Rourke your attorney?

6 A. I don't know who Mr. O'Rourke is, or I don't
7 remember who Mr. O'Rourke is.

8 Q. Well, let me ask you to turn to the front of
9 this transcript.

10 JUDGE CHAPPELL: Do you know who Mr. O'Rourke
11 is? Maybe you can tell me. We've been spinning the
12 wheels on this for a while.

13 MR. LOUGHLIN: Yes, Your Honor. Mr. O'Rourke
14 is a partner at O'Melveny & Myers.

15 BY MR. LOUGHLIN:

16 Q. Does that refresh your recollection that your
17 counsel was offered the opportunity to ask you
18 questions?

19 A. No.

20 Q. Did you prepare in advance of that hearing with
21 your counsel?

22 A. Probably, yes.

23 Q. Do you recall whether you were paid for your
24 time preparing with counsel for that investigational
25 hearing?

- 1 A. I'm sure I was.
- 2 Q. Was that \$500 an hour?
- 3 A. Probably.
- 4 Q. Do you recall whether you were paid for your
5 time testifying in the investigational hearing?
- 6 A. I'm sure I was.
- 7 Q. Was that also \$500 per hour?
- 8 A. Probably, yes.
- 9 Q. Now, did you prepare for your testimony today?
- 10 A. Yes.
- 11 Q. Did you prepare with counsel?
- 12 A. Yes.
- 13 Q. Who did you prepare with?
- 14 A. There was a whole bunch of people.
- 15 Q. People from O'Melveny & Myers?
- 16 A. Yes.
- 17 Q. Okay. How long did you spend preparing for
18 your deposition?
- 19 A. About six hours.
- 20 Q. And are you being paid for that time spent
21 preparing?
- 22 A. Yes.
- 23 Q. Are you being paid for your time testifying in
24 the court today?
- 25 A. Yes.

1 Q. And is that \$500 per hour?

2 A. Yes.

3 Q. Now, before you started working at
4 Impax Laboratories, you had worked at other
5 pharmaceutical companies; correct?

6 A. Yes.

7 Q. And you have worked at both branded
8 pharmaceutical companies and generic pharmaceutical
9 companies; correct?

10 A. Yes.

11 Q. And altogether, you've worked in the
12 pharmaceutical industry for about 25 years.

13 A. Yes.

14 Q. Now, during your time at Impax as president of
15 Impax' generics division, you had general management
16 oversight of the generics division; correct?

17 A. Yes.

18 Q. You were involved in deciding what generic
19 products to develop; correct?

20 A. It was a team, but I was -- had a significant
21 role.

22 Q. You were involved in overseeing the actual
23 development of generic products at Impax; correct?

24 A. Yes.

25 Q. You were involved in overseeing the

1 manufacturing of generic products at Impax; correct?

2 A. Indirectly.

3 Q. But you were involved in overseeing that
4 process; correct?

5 A. Not to be technical, it was more of a
6 dotted-line-type relationship, but yes. I had an
7 important role, yes.

8 Q. And you were involved in deciding when to
9 launch a generic product at Impax; correct?

10 A. Depending on circumstances, yes.

11 Q. And you oversaw the sales and marketing of
12 generic products at Impax; correct?

13 A. Yes.

14 Q. And you were involved in pricing generic
15 products; correct?

16 A. Yes.

17 Q. And in your role as president of the generics
18 division, you reported directly to the CEO of Impax;
19 correct?

20 A. Yes.

21 Q. And at the time, that was Dr. Larry Hsu?

22 A. Yes.

23 Q. Are you familiar with the term "AB-rated" as it
24 applies to generics?

25 A. Yes.

1 Q. Can you just tell us what AB rating means as it
2 applies to generic pharmaceuticals?

3 A. AB rating refers to a determination by the FDA
4 that a generic drug is therapeutically equivalent and
5 interchangeable with a brand reference drug.

6 Q. And if a generic has an AB rating, that means
7 the pharmacist can substitute the generic for the brand
8 without having to call the prescribing physician;
9 right?

10 A. Well, there's 52 jurisdictions that rely on the
11 AB rating in some way in the United States area,
12 including D.C. and Puerto Rico, so generic
13 substitution laws vary by state. But in general, an
14 AB rating confers this connotation of -- not
15 connotation -- confers the guarantee or the ruling from
16 the FDA that the drugs are therapeutically
17 interchangeable.

18 Q. And that means that for the most part, in your
19 experience, a pharmacist can substitute the generic
20 product for the branded product; right?

21 A. Well, the way you're saying it is not -- I
22 think as a practical matter you're on the right path.
23 You're not stating it exactly right because it's not
24 the pharmacist.

25 The prescriber has the decision-making power

1 over what drug is to be used, but in general, the
2 prescribers permit the substitution of a generic. And
3 I believe in all 52 jurisdictions, if a substitution is
4 permissible, then the pharmacist is required to
5 substitute the generic.

6 Q. And that substitution of the generic for the
7 brand is the primary way that generics make their
8 sales; right?

9 A. Yes.

10 Q. Now, are you also familiar with the term
11 "180-day exclusivity"?

12 A. Yes.

13 Q. Can you tell me what 180-day exclusivity is?

14 A. So the 180-day exclusivity refers to the period
15 conferred to -- the period of exclusivity conferred to
16 the filer, the first filer, of a patent challenge of an
17 ANDA.

18 Q. And am I right that during that 180-day
19 exclusivity period, the FDA is not permitted to approve
20 any other generic product? Is that right?

21 A. Well, they wouldn't be allowed to launch. I
22 don't know how the FDA deals with it. I guess they
23 could grant tentative approvals or other approvals that
24 didn't allow the people to launch, but generally
25 speaking, the way I understand it, the 180 days

1 exclusivity is for the first filer who's successful.

2 Q. Meaning that during that exclusivity period,
3 other generics cannot launch their generic version of
4 whatever branded product we're talking about; right?

5 A. That's my understanding. Yes.

6 Q. Okay. Now, are you familiar with the term
7 "authorized generic"?

8 A. Yes.

9 Q. What is an authorized generic?

10 A. An authorized generic is a generic that is made
11 available for sale using the NDA label, their approval,
12 just as an authorized product under the NDA, so hence
13 authorized generic.

14 Q. And an authorized generic is generally launched
15 by the branded company or another company licensed by
16 the branded company; correct?

17 A. Yes.

18 Q. And the 180-day exclusivity period doesn't
19 prevent the launching of an authorized generic;
20 correct?

21 A. That's correct.

22 Q. In other words, the brand, if it chooses, can
23 launch an authorized generic during the 180-day
24 exclusivity period and compete with the first-filing
25 generic during that period; right?

1 A. Yes.

2 Q. And if it does that, the authorized generic
3 generally takes some of the sales of the first-filing
4 generic; correct?

5 A. Well, I mean, I -- it's hard to know what would
6 happen in an individual market, so speaking --
7 generally speaking, if there are two products available
8 for sale, one would expect that they would each gain
9 some market share.

10 Q. And you would expect that competition from an
11 authorized generic would result in lower prices of the
12 generics; right?

13 A. Again, it's difficult to predict in an
14 individual market. Generally speaking, when there's
15 competition, prices may go lower.

16 Q. That's your expectation, is that there would be
17 price erosion in a market with more than one generic;
18 right?

19 A. I would say yes.

20 Q. Now, Mr. Mengler, you were involved in Impax'
21 settlement of patent litigation with
22 Endo Pharmaceuticals concerning Opana ER; correct?

23 A. Yes.

24 Q. In fact, you were the primary negotiator for
25 Impax; right?

1 A. Yes.

2 Q. And when you went into the negotiations with
3 Endo, your primary goal was to get the earliest entry
4 date you could; is that right?

5 A. Yes.

6 Q. But Endo offered a date, an entry date, in
7 2013; correct?

8 A. That's my recollection. Yes.

9 Q. Now, at the time of the negotiations, Impax was
10 the first to file with respect to the five most popular
11 dosages of Opana ER. Do you recall that?

12 A. Yes.

13 Q. And that meant that Impax was expecting to get
14 180-day exclusivity on those five dosages of Opana ER;
15 right?

16 A. Yes.

17 Q. Now, during the settlement discussions with
18 Endo, you discussed a provision in which Endo would not
19 launch an authorized generic during Impax' 180-day
20 exclusivity period. Do you recall that?

21 A. I know there were talks about a no-AG. Yes.

22 Q. And in the settlement Endo did in fact agree
23 not to launch an authorized generic during Impax'
24 180-day exclusivity period; right?

25 A. Yes.

1 Q. And as you mentioned, that's sometimes referred
2 to as a no-AG provision.

3 A. Yes.

4 Q. And getting a no-AG provision was important to
5 Impax; right?

6 A. Well, I mean, most important is, you know,
7 early entry. Then, you know, there's a few -- what's
8 important is the best possible deal that gets the
9 product on the market as quickly as possible and
10 maximizes the value to Impax shareholders, so early
11 entry and no AG are certainly among the more important
12 things, yes.

13 Q. You believe that getting a no-AG would be
14 beneficial to Impax; right?

15 A. Yes.

16 Q. Now, during the settlement discussions with
17 Endo, you became concerned that Endo was planning to
18 launch a reformulated version of Opana ER; right?

19 A. Yes.

20 Q. And you were concerned that reformulation was
21 part of a lifecycle management strategy by Endo to
22 extend the Opana franchise; right?

23 A. I felt it was more an effort to subvert the
24 value of the deal that I was trying to put together to
25 get my product on the market to -- because the only

1 way I'm in business is selling generic drugs, and so
2 call it whatever you want. I thought it was
3 subversion.

4 Q. Subversion of the benefits to Impax of the
5 settlement agreement that you were negotiating; is that
6 what you mean?

7 A. Well, the benefits to the American consumer for
8 getting a generic version of what would have been an
9 important drug and also I benefit, too, in the way I
10 make money is by selling generic drugs, so...

11 Q. So in addition to the benefits to consumers,
12 you felt that this reformulation strategy was
13 potentially damaging to Impax' business; is that
14 right?

15 A. That luckily for us in the generic industry
16 those are the same thing, but yes.

17 Q. And to be more specific, your concern was that
18 Endo would try to shift sales away from original
19 Opana ER to reformulated Opana ER; correct?

20 A. The biggest concern was that -- yes, and the
21 biggest concern that Opana ER somehow in its original
22 form disappears or becomes so insignificant, because,
23 as you correctly described earlier, the way generic
24 drugs are sold is by having a substitute, and if
25 there's no substitute, I get nothing.

1 Q. And you were worried that they were going to
2 launch this strategy of switching patients from
3 original Opana ER to reformulated Opana ER and pull the
4 original off the market before Impax could launch its
5 generic version of original Opana ER; correct?

6 A. Yes.

7 Q. And your concern was that would destroy the
8 market for original Opana ER before Impax could launch
9 its generic; right?

10 A. Yes.

11 Q. And if they did that, that would reduce the
12 value of Impax' generic product; right?

13 A. And increase cost to consumers. Yes.

14 Q. And that's because you were concerned that
15 Impax' generic wouldn't be AB-rated to the reformulated
16 product; right?

17 A. Yes.

18 Q. And so this -- you were concerned that this
19 would reduce the value of the 180-day exclusivity;
20 right?

21 A. Well, or reduce the value entirely, including
22 the 180-day, sure.

23 Q. And it would also reduce the value of the
24 no-AG agreement that you were negotiating with Endo;
25 correct?

1 A. I don't think those have anything to do with
2 each other. I mean, the value is the value. The value
3 we get is by selling the drug, so with or without an
4 AG, there's no -- I'm not really following the
5 question.

6 Q. Well, if Endo reduced the market for Opana ER,
7 that would reduce the value of Impax' generic, it
8 would reduce the value of Impax' 180-day exclusivity
9 period, and it would reduce whatever value you expected
10 to get from a no-AG provision under the settlement;
11 correct?

12 A. I'm -- I don't want to go around in circles,
13 but that -- what you're saying just doesn't really make
14 any sense. I mean, no AG has nothing to do with if
15 there's -- if there's no Opana ER and I can't sell the
16 product, then an AG is not relevant to -- it's sort
17 of -- I'm not understanding where you -- what you want
18 me to answer.

19 Q. I just want to understand that.

20 If there was no Opana ER or no Opana ER market,
21 that no-AG was not going to be worth anything to you;
22 right?

23 A. Again, at the risk of being -- I'm not trying
24 to be difficult, but it doesn't -- what you're asking
25 doesn't make any sense because if there's no Opana,

1 then there's no AG, so there never was any -- there's
2 no implied value to me of no AG necessarily.

3 The value that I get is selling my drug with
4 whatever market conditions exist, so if there's no
5 market, then an AG is not a relevant issue, so I --
6 the -- what you're asking just doesn't make any sense.
7 I'm sorry.

8 Q. So if there's no market for the Opana ER, the
9 original Opana ER, then there's no AG anymore; is that
10 right?

11 A. I -- I -- you're asking me to predict what
12 Endo would do. I think they would be -- personally,
13 if I were them, I wouldn't remove the brand and launch
14 an AG, but I -- you're asking a question again that's
15 kind of sort of nonsensical. It's almost -- I don't
16 know how to answer.

17 Q. Okay. Well, let me ask you a different
18 question. Okay?

19 In your experience, it takes about six months
20 to a year for a branded company to shift the market
21 from an original branded product to a reformulated
22 product; correct?

23 A. I guess it would depend on the product. Six to
24 nine months I guess is a little fast but not
25 unreasonable. And it would depend also what your

1 definition is of "shift the market," you know, half the
2 market or the -- it's -- it's a difficult question to
3 answer.

4 Q. So you think it might take longer than six to
5 nine months to shift from a branded product -- from one
6 branded product to a reformulated version of that
7 product; is that right?

8 A. Well, I guess it would depend on the type of
9 product, on the other, you know, circumstances. In
10 some cases it could occur very rapidly I suspect if it
11 was an acute drug, and in other circumstances, if it's
12 a more chronic therapy, it might take -- take longer.
13 But six to nine months in general doesn't seem
14 unreasonable.

15 Q. In any event, the more time that a brand
16 company has to make that switch, the better -- the
17 better off it is in terms of making that switch;
18 correct?

19 A. Yes. I would say so.

20 Q. Now, during the settlement negotiations with
21 Endo, you told Endo that you believed they were
22 planning to launch a reformulated version of Opana ER
23 before Impax could launch its generic; right?

24 A. Yes.

25 Q. And Endo denied it.

1 A. Yes.

2 Q. But you didn't believe them; isn't that right?

3 A. I certainly did not.

4 Q. And one of the things you tried to negotiate
5 was an acceleration trigger. Do you recall that?

6 A. Yes.

7 Q. In other words, you tried to negotiate a
8 provision in the settlement such that if sales of
9 branded Opana ER declined to some level, Impax would
10 be able to launch its generic sooner than
11 January 1, 2013; right?

12 A. I know something along those lines was one of
13 the things that was contemplated as an acceleration
14 trigger. There may have been other, other specific
15 things that were discussed, but certainly among the
16 acceleration triggers commonly discussed is declining
17 sales.

18 Q. And that was -- that acceleration trigger was
19 discussed in connection with your settlement
20 discussions with Endo; correct?

21 A. Yes.

22 Q. But those discussions regarding an acceleration
23 trigger turned instead to a term called the Endo
24 credit. Do you recall that?

25 A. Yes.

1 Q. And the Endo credit was a mathematical
2 calculation that was designed to give Impax an
3 approximation of the profits that Impax would have
4 earned during its 180-day exclusivity period if Endo
5 had not reformulated; right?

6 A. Well, in the absence of an acceleration
7 trigger, so I wouldn't necessarily say it didn't
8 become, but I felt that Impax -- we needed an
9 alternative mechanism to, one, try to incentivize the
10 product to stay on the market; and then, two, in the
11 worst-case scenario, where the market was in fact
12 destroyed, I at least wanted to be made whole for the
13 profits that we would have otherwise achieved.

14 Q. In other words, if Endo was true to its word
15 and did not reformulate and in fact grew the market,
16 then Impax would launch its generic, and it would get
17 value from its 180-day exclusivity period and the no-AG
18 provision; correct?

19 A. Well, in fact, if other certain sales goals
20 were achieved, we would have even paid Endo a royalty
21 in that scenario and sold the product and lowered
22 cost.

23 Q. And you would have paid a royalty only so long
24 as sales of Opana ER, of branded Opana ER, at the time
25 of launch in January 1, 2013 were at a sufficiently

1 high level; correct?

2 A. Yes.

3 Q. And in that instance, Endo would be better off
4 because of its 180-day exclusivity period and the no-AG
5 provision; right?

6 JUDGE CHAPPELL: Hold it. Did you misstate?
7 You said Endo's exclusivity period.

8 MR. LOUGHLIN: Yes, Your Honor. Thank you.

9 BY MR. LOUGHLIN:

10 Q. In that circumstance, Impax would be benefited
11 because -- by making sales during the 180-day
12 exclusivity period without competition from an
13 authorized generic; right?

14 A. The goal was always to sell as much as you can
15 as soon as you can. Yes.

16 Q. And the benefit, if you were in that context of
17 paying a royalty, would be that you'd be making
18 substantial sales through generic sales during the
19 180-day exclusivity period without competition from an
20 authorized generic; right?

21 A. Yeah. The more sales we have, yeah, the more
22 benefit we could have gotten, yes.

23 Q. And if Endo did reformulate and destroy the
24 market, as you were concerned they would, then Impax
25 would at least make money through the Endo credit

1 payment; right?

2 A. Yes. Some compensation for all the money and
3 risk that we had invested and taken up until that
4 point. Yes.

5 Q. And getting a term that provided that kind of
6 protection was important to you as you continued in the
7 negotiations; right?

8 A. Yeah. Anything that gets me on the market
9 sooner or, in the alternative scenario, provides some
10 value would have been, you know, equal. I don't know
11 what the weights would be, but certainly all things
12 were important.

13 Q. In fact, not getting protection was a
14 deal-breaker for you, wasn't it?

15 A. Well, it's hard to -- it's hard to recall
16 because this is, you know, seven -- seven years ago
17 what the exact other alternative scenarios there were.
18 In any negotiation there's always I guess other
19 possible things. But certainly, absent the
20 acceleration trigger and combined with the concern for
21 this potential adverse effect on the market, certainly
22 it would have been important to have some protection
23 for Impax, yes.

24 Q. It was important that it was a deal-breaker;
25 right?

1 A. Well, it's hard to -- I can't recall that far
2 back if there were anything else that we might have
3 contemplated, so, you know, it sounds like it was
4 pretty important. I don't know -- "deal-breaker" is
5 kind of -- you know, that's a -- that's a high-level
6 thing, but that was very, very important to me, yes.

7 Q. Do you recall testifying earlier in this case
8 that it was a deal-breaker?

9 A. I don't recall, but certainly I could have
10 described it as a deal-breaker. I'm just making sure
11 that, you know, the way you're phrasing your question,
12 I just want to make sure that there's nothing else, I
13 mean. But to me, it was super, super important and was
14 it really truly a deal-breaker, probably, yes. But I
15 mean, I don't recall if anything else would have
16 possibly come up.

17 Q. Okay. And you -- by the end of the
18 negotiations, you believed you were successful in
19 negotiating terms that protected Impax; right?

20 A. I think we ended up with the earliest possible
21 entry date and with a protection in the event that the
22 market conditions became adverse to Impax. Yes.

23 Q. Now, do you recall, Mr. Mengler, that as part
24 of the settlement discussions with Endo you also
25 discussed co-development and co-promotion deal?

1 A. Yes.

2 Q. And that was initially for a product called
3 IPX-066; right?

4 A. Yes.

5 Q. And IPX-066 was a -- was intended to be a
6 Parkinson's disease drug; right?

7 A. Yes.

8 Q. It was in late-stage development?

9 A. Yes.

10 Q. In fact, it was in Phase III development. Do
11 you recall that?

12 A. I think it was, yes.

13 Q. And Phase III is the final stage before filing
14 an NDA with the FDA; correct?

15 A. Yes.

16 Q. And then at some point during the
17 negotiations, IPX-066 was taken off the table. Do you
18 recall that?

19 A. Yes.

20 Q. It was taken off the table by Impax; right?

21 A. Yes.

22 Q. And it was replaced in the discussions with a
23 follow-on product; right?

24 A. Yes.

25 Q. And that was sometimes referred to as 066a --

1 A. Yes.

2 Q. -- correct?

3 Now, there was also a point during the
4 settlement discussions when you stopped being involved
5 for a short period of time. Do you recall that?

6 A. Yes.

7 Q. And during that period of time -- I think it
8 was about a day and a half or so?

9 A. Yes.

10 Q. And during that period of time, Mr. Koch and
11 Ms. Snowden took over direct communications with Endo
12 in terms of settlement negotiations; right?

13 A. I think so. Yes.

14 Q. And that was close to the end of the
15 negotiations; correct?

16 A. Yes.

17 Q. Mr. Mengler, can I ask you to turn in your
18 binder to a document that's marked CX 0321.

19 And Your Honor, I'll note for the record that
20 CX 321 has been admitted and it is not in camera.

21 JUDGE CHAPPELL: All right.

22 BY MR. LOUGHLIN:

23 Q. Do you have it, Mr. Mengler?

24 A. Yes.

25 Q. Okay. Do you see down at the bottom of the

1 first page of CX 321 there's an e-mail from
2 Chris Mengler, dated Thursday, May 27, 2010?

3 A. Yes.

4 Q. Do you see it?

5 And that's you; correct?

6 A. That's me.

7 Q. And you're sending this e-mail to Alan Levin.

8 Do you see that?

9 A. Yes.

10 Q. And Mr. Levin was your point of contact at
11 Endo. Do you recall that?

12 A. Yes.

13 Q. And if you turn the page, you'll see the rest
14 of that e-mail.

15 And this is an e-mail that you sent to Endo as
16 part of your settlement negotiations; correct?

17 A. Yes.

18 Q. And underneath the very first paragraph,
19 you're setting forth proposed terms for a settlement;
20 right?

21 A. Yes.

22 Q. And you say, in the first line of the second
23 paragraph, "Launch date: 1/1/13 with no authorized
24 generic and certain acceleration triggers, including
25 market degradation to any alternate product."

1 Do you see that?

2 A. Yes.

3 Q. And 1-1-13 is January 1, 2013; correct?

4 A. Yes.

5 Q. And the language saying "with no authorized
6 generic," that's a reference to the no-AG provision we
7 discussed earlier; correct?

8 A. Yes.

9 Q. And when you say "certain acceleration
10 triggers, including market degradation to any
11 alternate product," that's referring to the
12 acceleration provision we've discussed earlier whereby
13 Impax would be able to launch before January 1, 2013 if
14 Impax reformulated -- or excuse me -- if Endo did
15 something to harm the size of the Opana ER market;
16 correct?

17 A. Well, that could be among the things. What
18 this says is any market degradation for any reason or
19 other, other triggers that may accelerate our launch.

20 Q. Right. For any reason, including market
21 degradation to an alternate product.

22 A. Yes.

23 Q. Let me ask you to turn in your binder to
24 CX 506. Or you can look -- it will be on the screen as
25 well, Mr. Mengler, if you prefer.

1 A. I like the magic.

2 MR. LOUGHLIN: And Your Honor, I'll note for
3 the record that this document has also been admitted as
4 part of JX 2, and it is not in camera.

5 JUDGE CHAPPELL: Thank you.

6 Can you put the last document back up.

7 Mr. Mengler, it appears to me there you're
8 dealing with -- is it Mr. "Levin" or "Levin"?

9 THE WITNESS: "Levin."

10 JUDGE CHAPPELL: Who appears to be the CFO of
11 Endo?

12 THE WITNESS: That's my recollection. Yes.

13 JUDGE CHAPPELL: Were you ever dealing with the
14 CEO of Endo?

15 THE WITNESS: No.

16 JUDGE CHAPPELL: Was he involved in any of
17 this, as far as you know?

18 THE WITNESS: Not with me.

19 JUDGE CHAPPELL: As far as you know.

20 THE WITNESS: No. Never.

21 JUDGE CHAPPELL: Thank you.

22 BY MR. LOUGHLIN:

23 Q. Okay. Mr. Mengler, can I direct your attention
24 to the middle of the page 506-001 and in the e-mail
25 that you're sending on -- dated Tuesday, June 1, 2010.

1 Do you see that?

2 A. Yes.

3 Q. And you're sending this e-mail to Larry Hsu,
4 Michael Nestor, Meg Snowden and Ted Smolenski.

5 Do you see that?

6 A. Yes.

7 Q. And the recipients are all or were all Impax
8 employees at that time; correct?

9 A. Yes.

10 Q. And you say -- the very first line says, "Here
11 is the current proposal and then my take."

12 Do you see that?

13 A. Yes.

14 Q. And you're reporting to Impax employees on the
15 current settlement proposal in your discussions with
16 Endo; is that right?

17 A. Yes.

18 Q. And if you jump down to the section that says
19 "Generic launch," it says, "We launch
20 February 1, 2013 (with the usual bells and whistles
21 relating to acceleration). If the product grows beyond
22 certain levels, we pay them a profit split during the
23 six-month exclusivity as follows," and then it lays out
24 the terms of a royalty; correct?

25 A. Yes.

1 Q. And that's the royalty we discussed earlier
2 this afternoon; right?

3 A. If the -- if the brand grew above a certain
4 level, then we would pay a royalty on that amount.

5 Q. Right.

6 And then the next paragraph says, "Also, if the
7 product declines by more than 50 percent, we would be
8 entitled to a 'make good' payment such that our
9 potential profits would equal to 50 percent."

10 Do you see that?

11 A. Yes.

12 Q. And the idea of a make-good payment is what
13 became the Endo credit; right?

14 A. Yes.

15 Q. Can I ask you to turn to CX 407.

16 Now -- and I'll again note for the record,
17 Your Honor, that this document is admitted into
18 evidence as part of JX 2, and it is not in camera.

19 JUDGE CHAPPELL: All right.

20 BY MR. LOUGHLIN:

21 Q. Now, if you look down at the bottom of the
22 first page of CX 407, Mr. Mengler, do you see the
23 e-mail from you, dated Thursday, June 3, 2010?

24 A. Yes.

25 Q. And again, this is directed to Larry Hsu,

1 Art Koch, Chuck Hildenbrand, Michael Nestor,
2 Meg Snowden and with a copy to Ted Smolenski.

3 Do you see that?

4 A. Yes.

5 Q. And again, this is you reporting internally on
6 the status of negotiations, settlement negotiations
7 with Endo; right?

8 A. Yes.

9 Q. And Mr. Koch, who's listed there, he was the
10 CFO of Impax at the time.

11 A. Yes.

12 Q. And you say, "Here's where we are - I think
13 this proposal balances the interests of the business
14 with our FTF status."

15 Do you see that?

16 A. Yes.

17 Q. And "FTF" refers to first to file?

18 A. Yes.

19 Q. And that's the 180-day exclusivity that Impax
20 was expecting on the five dosages for which it was the
21 first to file an ANDA with Paragraph IV certification;
22 correct?

23 A. Yes.

24 Q. And if you look down -- a little further down
25 the e-mail under the phrase "Generic," do you see that

1 word?

2 A. Yes.

3 Q. It says, "We enter on January 1, 2013."

4 Do you see that?

5 A. Yes.

6 Q. And that's the ultimate entry date in the final
7 settlement that was signed between Impax and Endo;
8 correct?

9 A. Yes.

10 Q. And down at the bottom you say, "If the units
11 decline by more than 50 percent from peak at launch,
12 make whole provisions kick in that protect the
13 downside."

14 Do you see that?

15 A. Yes.

16 Q. "Make-whole provision" is another phrase for
17 what became the Endo credit; right?

18 A. Yes.

19 Q. Now, Mr. Mengler, when you were at Impax, the
20 company held regular board meetings; correct?

21 A. Yes.

22 Q. And it held them quarterly?

23 A. Yes.

24 Q. And you sometimes presented at those meetings;
25 correct?

1 A. Yes.

2 Q. Can I ask you to turn in your binder or, if you
3 prefer, look at the screen at CX 008.

4 And Your Honor, I'll note for the record that
5 this has also been admitted as part of JX 2.

6 Mr. Mengler, do you see this is a series of
7 e-mails between yourself and Larry Hsu? Do you see
8 that?

9 A. And others. Yes.

10 Q. And others.

11 It starts out at the bottom -- if you turn to
12 the very bottom, it starts out with an e-mail from you
13 to Larry Hsu.

14 Do you see that?

15 A. Yes.

16 Q. And it's dated Thursday, May 13, 2010 --

17 A. Yes.

18 Q. -- correct?

19 And the subject is Mengler Board Slides;
20 correct?

21 A. Yes.

22 Q. And you're sending your slides to Dr. Hsu;
23 correct?

24 A. Yes.

25 Q. And Dr. Hsu is the CEO.

1 A. Yes.

2 Q. And if you look about three e-mails up,
3 Dr. Hsu responds to you on Friday, May 14, 2010, at
4 12:55 p.m.

5 Do you see that e-mail?

6 A. Yes.

7 Q. And he says, "BT-" -- in the second paragraph,
8 he says, "BTW, I think we should alert BOD with
9 potential oxymorphone launch in this meeting even
10 though we will have a special Board conference call
11 when we do decide to launch at risk on a later date."

12 Do you see that?

13 A. Yes.

14 Q. "BOD" is board of directors; right?

15 A. Yes.

16 Q. And "oxymorphone," you understood that to mean
17 oxymorphone ER?

18 A. Yes.

19 Q. And that's the generic version of Opana ER;
20 correct?

21 A. Yes.

22 Q. Is it fair -- is it fair for me to understand
23 from this that at this point, on May 14, 2010, Impax
24 hadn't yet decided whether or not to launch a generic
25 version of Opana ER?

1 A. Well, just repeat what you said.

2 Q. At this point in time, Impax had not decided
3 whether or not to launch a generic version of Opana ER;
4 correct?

5 A. That's correct, we had not.

6 Q. And that was because the patent litigation
7 that Impax was in with Endo was not concluded yet;
8 correct?

9 A. I believe this was after we had received
10 tentative approval and prior to completion of the
11 litigation. Yes.

12 Q. And Dr. Hsu is telling you or he -- let me
13 start that over.

14 Dr. Hsu is asking you to tell the board about
15 the potential for an oxymorphone launch to put it on
16 the board's radar screen in case Impax did decide to
17 launch at risk; correct?

18 A. Well, yeah, there would have been a board
19 meeting anyway to make that final call, but certainly
20 this was an opportunity to -- I think you described it
21 correctly -- put it on the radar.

22 Q. In other words, he didn't want the board to be
23 hearing about a launch of oxymorphone ER for the first
24 time at a special board meeting; correct?

25 A. That would be my interpretation. Yes.

1 Q. Now, can we put up CX 2662.

2 And Your Honor, I'll mention for the record
3 that CX 2662 has been admitted as part of the JX 2. It
4 is partially in camera. We have redacted the in camera
5 portions. I don't intend to ask about those.

6 JUDGE CHAPPELL: All right.

7 BY MR. LOUGHLIN:

8 Q. Mr. Mengler, looking at the first page of 2662,
9 you see it's an e-mail from you, dated Monday, May 17,
10 2010?

11 A. Yes.

12 Q. To someone named Laura Bisbing.

13 Do you see that?

14 A. Yes.

15 Q. Do you recall who Ms. Bisbing was or what her
16 position was in 2010?

17 A. I think she was Art Koch's admin.

18 Q. And you're sending her copies of your board
19 presentation slides; correct?

20 A. Yes.

21 Q. For a board of directors meeting; correct?

22 A. Yes.

23 Q. And if you turn the page of CX 2662, this is
24 the first page of the slides that you were intending to
25 present to the board of directors at a meeting in

1 May 2010; correct?

2 A. Yes.

3 Q. And if I could ask you to turn to page

4 CX 2662-008.

5 Do you see at the top it says

6 "2010 Plan - Assumptions (as presented in Feb)"?

7 Do you see that?

8 A. Yes, I see that.

9 Q. Now, this is showing the assumptions that you
10 laid out for the 2010 sales budget at the
11 February 2010 board meeting; correct?

12 A. Yes.

13 Q. And at the time, the assumption for oxymorphone
14 was "No Launch."

15 Do you see that?

16 A. Yes.

17 Q. And so in February, the sales budget was
18 assuming no launch of generic oxymorphone ER; right?

19 A. The base -- it's a -- yeah. It's important to
20 keep this sort of in a context with our budgeting
21 process and planning process, so what this says is that
22 the base plan, as presented to the board, that
23 triggered a lot of other things in the company, like
24 bonus calculations and things of that nature, did not
25 include an oxymorphone launch.

1 Just from this, it's impossible to know for
2 sure what we were thinking about a potential launch or
3 launch timing, but what we can say with certainty is
4 that this plan as presented in February didn't have any
5 numbers in it, any dollar sales in it.

6 Q. Any dollar sales of generic oxymorphone ER.

7 A. That's correct.

8 Q. Now, if we can put up 266-012 (sic).

9 And now, this is a slide under which you're
10 going to present to the board the current assumptions
11 as of the date of the board meeting; correct?

12 A. Yes.

13 Q. And at this point, if you look down --

14 JUDGE CHAPPELL: Can we get a date for this?

15 MR. LOUGHLIN: Yeah. The date --

16 JUDGE CHAPPELL: From the witness?

17 MR. LOUGHLIN: Yes, I believe so, Your Honor.

18 BY MR. LOUGHLIN:

19 Q. Mr. Mengler, if we turn back to the first page
20 of this document, you're sending these board slides on
21 May 17, 2010; correct?

22 A. Yes.

23 Q. And the board meeting was also in 2010, May of
24 2010; correct?

25 A. Yes.

1 JUDGE CHAPPELL: The last document had at the
2 top somewhere "February" and "Assumptions." Why is
3 there no date and the word "Assumptions" on this
4 document?

5 THE WITNESS: So that's why it's important
6 to -- the -- really the best way to --

7 JUDGE CHAPPELL: I don't mean the one now. I
8 mean the one that was on the screen before this one.

9 THE WITNESS: Yeah, I understand. The best way
10 to appreciate this is actually to see the whole context
11 of the presentation.

12 So what I would do at each board meeting, my
13 first slide would be to show what I promised for the
14 year. Then I would have another slide or two that
15 would explain any changes to that plan. And then I
16 would have a slide that would explain to the board, now
17 when I show you numbers, these are the assumptions that
18 lead to those numbers.

19 So I didn't want to try to hide what I
20 promised in the beginning of the year, but I also
21 wanted to explain, good or bad, how we got to a
22 difference.

23 JUDGE CHAPPELL: Were these agenda items?

24 THE WITNESS: The agenda item generally for
25 the board meeting probably was just generic

1 presentation, generic division presentation. I don't
2 know if my slides had an agenda page.

3 BY MR. LOUGHLIN:

4 Q. Okay. If we could put back up CX 2662-012.

5 And so in terms of the current assumptions as
6 of the May 2010 board meeting, what you're -- what
7 you're explaining to the board in terms of assumptions
8 for the numbers that you're going to present is that
9 now the numbers are assuming an at-risk launch of
10 oxymorphone ER; correct?

11 A. Yes.

12 It's just correct to keep in mind that that's
13 just the numbers, that it doesn't imply or mean that
14 any legal decision has been made to clear the way for a
15 launch. It just says, when you see the slide with
16 numbers -- I don't know how many slides past that it
17 is -- there's going to -- probably there's a line in
18 there that says "oxymorphone" with dollars. That's all
19 that this is saying.

20 Q. Right.

21 And we already talked about the fact that at
22 this point Impax hadn't yet made a decision about
23 whether to launch oxymorphone ER; correct?

24 A. Yes.

25 Q. Hadn't ruled it out either, though, had it?

1 A. I don't know the stage of discussions, but I
2 don't think anything at this point was ruled out or
3 ruled in.

4 Q. Now, Mr. Mengler, when you were at Impax and
5 serving as the president of the generics division, you
6 would have quarterly launch planning meetings;
7 correct?

8 A. It was something that was initiated after I
9 joined, so the answer is yes, but no. How many we had
10 in the two years I was there, I don't think we had
11 eight of them, so we definitely did that, but I don't
12 know how many we had.

13 Q. In any event, regardless of the number, the
14 launch planning meeting was intended to be an
15 operational meeting; correct?

16 A. I mean, it's a -- the intention I think was to
17 be multidisciplinary with the goal of being
18 operationally ready. Yes.

19 So it wasn't run by operations; it was run by
20 me.

21 Q. Right.

22 But the idea was to bring together operations
23 people, manufacturing people, purchasing people, so
24 that they could figure out how to be ready for a
25 launch at a -- of whatever product at the time the

1 company determined to launch it; is that right?

2 A. I don't remember the exact lineup, but
3 certainly the groups that you've mentioned would at a
4 minimum have been there.

5 Q. And am I also right about the -- the purpose
6 was to bring those people together so that they could
7 figure out how to be ready to launch a product when the
8 company decided to launch the product?

9 Is that right?

10 A. Well, I would -- if -- if -- if I --

11 JUDGE CHAPPELL: Hold on, hold on.

12 The purpose of what?

13 MR. LOUGHLIN: The launch planning meetings.

14 THE WITNESS: I mean, if I was -- I mean, I
15 would just phrase it slightly differently. If I was
16 doing a good job, it would not be to have somebody
17 ready when I say it's ready to go, it would be to
18 jointly understand where we're trying to drive the
19 business so that when the time comes we execute
20 smoothly.

21 So it's more of a joint effort as opposed to,
22 you know, operations being ready by a date that may and
23 may not come, so it was a little bit more collaborative
24 than that, but generally speaking, that's correct.

25 BY MR. LOUGHLIN:

1 Q. Generally speaking, it's correct that the
2 idea -- the purpose of the launch planning meeting was
3 to make sure that the company was ready to launch from
4 an operational perspective at the time that the company
5 decided to do that; right?

6 A. Right. Like readiness, exactly.

7 Q. Okay. Can I ask you -- well, let me ask
8 Ms. Clark to put up CX 3348.

9 And I will point out for the record that this
10 document has also been admitted as part of JX 2 and
11 that it is not in camera.

12 Do you see up at the top of this document,
13 CX 3348, there's an e-mail from Todd Engle to you and
14 others?

15 A. Yes.

16 Q. And it's dated Thursday, May 20, 2010?

17 A. Yes.

18 Q. What was Mr. Engle's role in the company as of
19 May 2010? Do you recall?

20 A. Sales operations.

21 Q. And do you see the subject line says "Quarterly
22 Launch Planning Meeting May 20, 2010 Agenda Materials"?
23 Do you see that?

24 A. Yes.

25 Q. So these are materials that Mr. Engle is

1 sending out in connection with the launch planning
2 meeting that was going to occur on May 20, 2010;
3 correct?

4 A. Yes.

5 Q. And if you turn to the first page or to the
6 very next page, CX 3348-002, do you see that?

7 A. Not yet.

8 Q. I'm sorry.

9 There's a number of products listed.

10 Do you see that?

11 A. Yes.

12 Q. And the first one is oxymorphone ER tablets.

13 And it says "June of 2010."

14 Do you see that?

15 A. Yes.

16 Q. And oxymorphone ER tablets, that's the generic
17 version of Opana ER.

18 A. Yes.

19 Q. And if I could ask Ms. Clark to turn to page --
20 turn the page to CX 3348-003.

21 And this is the page -- or this page and the
22 next page are the portion of the launch planning
23 meeting agenda materials related to oxymorphone ER
24 tablets; correct?

25 A. Yes.

1 Q. And if you turn the page to the second -- look
2 down at the bottom of the second page, which is marked
3 CX 3348-004.

4 Do you see the box that says "Recommendation"?

5 It says, "Prepare to launch June 14, 2010;
6 Consider obtaining board approval for an at-risk
7 launch."

8 Do you see that?

9 A. Yes.

10 Q. And what this is telling the attendees at the
11 quarterly launch planning meeting is that they need to
12 make sure that from an operations perspective they are
13 ready to launch on June 14, 2010 if in fact that's what
14 Impax decides to do; is that right?

15 A. Yes. I'm guessing that was the 30-month stay
16 expiry date, so -- since it's a date certain like
17 that.

18 Q. And your expectation was that the operations
19 people would take the steps necessary to be able to
20 launch if that's what Impax chose to do; correct?

21 A. Well, whatever -- yes. Whatever would be
22 necessary to prepare, yes.

23 Q. To prepare to be ready to launch on June 14,
24 2010; correct?

25 A. Yes.

1 MR. LOUGHLIN: I have no further questions,
2 Your Honor.

3 JUDGE CHAPPELL: Any questions?

4 MR. HASSI: Yes, Your Honor.

5 Your Honor, may I approach the witness to give
6 him a binder?

7 JUDGE CHAPPELL: Go ahead.

8 - - - - -

9 CROSS-EXAMINATION

10 BY MR. HASSI:

11 Q. Good afternoon, Mr. Mengler.

12 I want to back up for a second and just ask you
13 a quick couple questions about your education.

14 Can you walk us through your education?

15 A. So --

16 MR. LOUGHLIN: Your Honor, could I ask for a
17 binder?

18 JUDGE CHAPPELL: Yes.

19 MR. LOUGHLIN: I'm not pointing to any
20 documents yet, but I'll make sure you get one. His CV
21 is not in there.

22 BY MR. HASSI:

23 Q. Go ahead.

24 A. So I graduated from Johns Hopkins with an
25 engineering degree in mathematical science.

1 JUDGE CHAPPELL: The Bluejays?

2 THE WITNESS: Yes, the Bluejays, right.

3 Go Blue. We used to be really good at lacrosse, at
4 least when I was there.

5 So Johns Hopkins, engineering degree in math
6 science/operations research.

7 Then after that, I started working in retail
8 pharmacy in the -- in the late '80s and then from there
9 started going to pharmacy school, where I got a
10 bachelor of pharmacy degree from St. John's in
11 New York. And I'm still a licensed and registered to
12 practice and pharmacist in New York state.

13 Then when I finished pharmacy school, after
14 doing one internship at Pfizer and another internship
15 at Lederle that would today be Pfizer, I joined the
16 pharmaceutical industry in regulatory affairs at a
17 company called Sanofi Winthrop that today would be
18 known as Sanofi Aventis.

19 Then while I was working there -- or I should
20 say, after a few years of working there, I switched
21 jobs and joined Barr Laboratories in the early '90s,
22 '94, something like that.

23 And to put it in perspective, when I joined
24 the generic drug industry, when I joined Barr, we had
25 fewer than 200 employees. When Teva bought us in

1 2008, we had 9,000, so explosive growth in the
2 industry.

3 In 2000 -- in 1998, I left Barr and went to
4 Pfizer, where I worked as a project manager managing
5 Phase III-B and Phase IV clinical trials in -- for
6 marketed products in the New York office.

7 And while at Pfizer, I enrolled at
8 Baruch College, where I earned an M.B.A. in finance.

9 And then in 2002, I returned to Barr as head of
10 the corporate development, which I did until 2008, when
11 Teva bought us.

12 And then that's when I joined Impax, in 2009.

13 BY MR. HASSI:

14 Q. And can you describe the kind of work you did
15 at Barr?

16 A. Well, my final position was as the executive
17 vice president of global strategic planning.

18 About two years earlier, we had purchased an
19 international company, so we became an
20 international -- a global firm after previously only
21 being in the U.S., so my role ultimately was for all
22 global product selection. Any product we were going
23 to sell anywhere in the world went through my group.
24 Whether we did it internally, bought it, licensed it,
25 partnered it, negotiated, anything, everything went

1 through my team for the global -- for the global
2 organization.

3 Q. And in that position, did you negotiate deals
4 with other pharmaceutical companies, like co-promotion
5 deals?

6 A. We were very aggressive in that regard and had
7 a very robust business development team, so we would
8 literally sort through, you know, dozens and dozens
9 and dozens of opportunities on a monthly basis,
10 culling them down to products that we would pursue, so
11 we were probably aggressively pursuing between I'll
12 say five or ten deals at any given time, so we've
13 negotiated partnering deals on generics, we bought
14 in -- as a matter of fact, I was just chatting with
15 somebody this morning -- we purchased several key
16 women's healthcare branded products that we just
17 recently resold for huge sums of money in the women's
18 health area.

19 So we had a lot of activity in generics and a
20 lot of activity in brands.

21 Q. And you mentioned being a licensed pharmacist.

22 Did I hear you correctly, you practice as a
23 pharmacist today?

24 A. I've been a little bit lazy lately, so it's
25 probably been about six months. But when I'm in

1 New York, I try to be in the pharmacy anywhere from
2 20 to 30 hours a month.

3 JUDGE CHAPPELL: So like the practice of law,
4 that's state-specific?

5 THE WITNESS: Yes. There are federal
6 licenses, for example, in the VA you can be licensed
7 anywhere, but in New York you have to have a New York
8 license.

9 JUDGE CHAPPELL: "Anywhere" meaning any state.

10 THE WITNESS: Yeah. In any VA, for example, no
11 matter where it's located.

12 JUDGE CHAPPELL: Since you've worked or were
13 acquired by the company, is it pronounced "Teva" or
14 "Teva"?

15 THE WITNESS: "Teva."

16 JUDGE CHAPPELL: "Teva."

17 BY MR. HASSI:

18 Q. Now, you answered some questions about the
19 negotiations with Endo, and I want to start with the
20 basics.

21 Why was Impax willing to negotiate a settlement
22 with Endo?

23 A. Patent challenges are inherently risky because
24 they involve uncertain outcomes with court decisions,
25 so -- and I would say this about any, any business

1 situation -- if I can make a settlement that solves a
2 risky legal problem, I'd do it a hundred percent or try
3 to do it a hundred percent of the time.

4 Q. And for Impax as the generic, what's the
5 downside risk of that risky legal problem of the patent
6 challenge?

7 A. Well, if you lose, then your ANDA is converted
8 to a P-III -- well, I shouldn't say if you lose. If
9 the patents are upheld, then the application is
10 converted to a normal application, and then you have to
11 wait for the patents to expire.

12 Q. You were the lead negotiator in the
13 negotiations with Endo?

14 A. Yes.

15 Q. And what were your main objectives?

16 A. The main objective was to get the best
17 possible settlement, which is the earliest possible
18 entry date.

19 Q. Why?

20 A. The only way we make money is selling
21 products, so the sooner we can get in, the better off
22 we are.

23 Q. Did you have any particular concerns when
24 negotiating with Endo?

25 A. I mean, at least initially, not -- nothing out

1 of the ordinary. We -- you know, at some point we
2 were getting close to our -- you know, gaining a
3 tentative approval and we had 90 percent of the
4 volumes in our ANDAs, so I think we always go in
5 open-minded, so nothing initially was particularly
6 troublesome.

7 Q. And in terms of your principal goal of an
8 entry date, how did the negotiation of that term
9 begin?

10 A. Generally speaking, we always looked for as
11 early as possible. We have some, you know, rules of
12 thumb about what's a reasonable entry date. Sort of
13 kind of half the distance to the goal is sometimes what
14 we look at, how much time is left on the patent, can we
15 split the difference.

16 So -- but in this case, it was Endo who
17 proposed some 2013 dates either first or more
18 adamantly -- I would think first but adamantly was
19 interested in 2013 dates.

20 Q. What do you recall was the first date that they
21 proposed?

22 A. March of '13.

23 Q. And that was in a term sheet that you received
24 from Endo?

25 A. I don't recall the first time we saw it if it

1 was in a term sheet or they were an e-mail, but I
2 think the -- I do think the first term sheet had
3 March of '13.

4 Q. Was Impax satisfied with that as a licensed
5 entry date?

6 A. Well, no. You know, it wasn't early enough
7 as -- as far as I was concerned. Endo was certainly
8 digging in their heels with that date, so we kept
9 trying to improve on that.

10 Q. Did there come a time where they offered a
11 February 1 date?

12 A. I don't know -- yes. I don't recall how many
13 iterations it took to get the extra month, but we did
14 get it to February and then continued to try to improve
15 on that.

16 Q. Did you continue to try to improve beyond that
17 February 1 date?

18 A. Yes.

19 Q. And what date did you ultimately get?

20 A. January 1 of '13.

21 Q. Why not an earlier date, say a date in 2012?

22 A. They were adamant about 2013 and not getting
23 anything into 2012, which of course started to make me
24 suspicious, what was the problem with 2012. I mean,
25 you know, it might have been something as simple as

1 other things good happening in 2013 to the P&L, I
2 didn't know, but certainly it was -- it was a little
3 unusual I thought, troubling I guess, that we couldn't
4 get -- really could not get them to budge from '13.

5 Q. Did they give you a reason as to why they
6 wouldn't give you a date in 2012?

7 A. Not that I remember.

8 Q. Was there ever a point in time where Endo
9 offered to agree to a date earlier than January 2013?

10 A. Not that I remember.

11 Q. Had they offered an earlier date, what would
12 your response have been?

13 A. Absolutely yes.

14 Q. Was there ever any discussion with Endo about
15 Impax accepting a later date in exchange for some value
16 from Endo?

17 A. No.

18 Q. Did you exchange a later date in exchange for a
19 no-authorized-generic provision?

20 A. No.

21 Q. Did you exchange a later date in exchange for
22 the Endo credit?

23 A. No.

24 Q. Did you exchange a later date in exchange for a
25 development and co-promotion agreement?

1 A. No.

2 Q. Why were you concerned -- strike that.

3 You -- I -- you were concerned I take it that
4 Endo was going to switch the market away from
5 Opana ER?

6 A. Yes.

7 Q. And why did you have that concern?

8 A. A couple of things started to trouble me.

9 Number one, we knew of the introduction of
10 crush-resistant formulation especially for long-acting
11 opioids, and this is a long-acting opioid, so that was
12 definitely something on our radar as a general rule.

13 Secondly, the dismissal of acceleration
14 triggers was certainly troubling. It was concerning
15 why that -- that was becoming something that was more
16 commonly seen in settlements.

17 And this insistence of hanging onto 2013 was --
18 started to convince me that there was a good likelihood
19 of something going on that would adversely affect the
20 marketplace.

21 JUDGE CHAPPELL: Hold on. Let's go back to
22 what you called number one.

23 You said, "We knew of the introduction of
24 crush-resistant formulation."

25 How did you know that?

1 THE WITNESS: So this is -- was a big problem
2 happening in the United States before we coined the
3 term "opioid crisis," so it was -- the FDA was
4 pressing companies that sold long-acting opioids to
5 figure out a way to make them tamper-resistant. And
6 the primary manner in which companies were doing that
7 was to make the tablet in such a manner that they
8 couldn't be crushed.

9 And that was -- that was widely known,
10 especially because the big product at the time was
11 OxyContin, and I think Purdue or the company who makes
12 it, it was pretty well-known that they were trying to
13 do a crush-resistant, so it was just something that was
14 expected and anticipated.

15 And in addition, at some point -- I don't
16 remember where that -- we learned of this in the
17 negotiation, but one of my -- one of my guys actually
18 came up with -- I don't know if it was a news release
19 or an analyst report describing the fact that Endo had
20 licensed in or was partnering with somebody on
21 crush-resistant technology, so we felt it was a pretty
22 safe bet that this was an effort on their part.

23 JUDGE CHAPPELL: So you knew Endo was working
24 on such a product.

25 THE WITNESS: Yes.

1 JUDGE CHAPPELL: Did you have any idea of when
2 they planned to introduce it or how far along they were
3 in the process?

4 THE WITNESS: We might have had some
5 discussions or thoughts. I don't recall if we had any
6 specific dates in mind. But I -- we probably had some
7 guesses.

8 JUDGE CHAPPELL: When you said we had
9 discussions or we had guesses, do you mean with Endo or
10 just Impax people?

11 THE WITNESS: With myself and my team.

12 I mean, in fact, I specifically asked Endo was
13 this their plan, and they categorically denied it to
14 me, so...

15 BY MR. HASSI:

16 Q. Let's bring up CX 2540. It's tab 14 in your
17 binder, but we'll bring it up on the screen.

18 And Your Honor, this is in evidence, and it is
19 not in camera.

20 And if you could highlight first the top part.
21 Yeah.

22 So this is an e-mail from Ted Smolenski, dated
23 December 4, 2009.

24 Can you tell us who Ted Smolenski was at that
25 time?

1 A. He was one of my business development team
2 members.

3 Q. So when you just referred to a member of your
4 team, was Mr. Smolenski a member of your team?

5 A. Yes.

6 Q. If we could go down and blow up the section for
7 Opana ER.

8 First, what was Mr. Smolenski sending you here,
9 you and others?

10 A. This is some excerpts from a report either I
11 guess that an analyst had put together or that we had
12 acquired from a service, summarizing a meeting that
13 Endo had.

14 Q. Did Mr. Smolenski track companies like Endo
15 where you had ANDAs filed against a branded company?

16 A. Among the more important responsibilities, Ted
17 had -- Mr. Smolenski had was to pay attention to the
18 marketplace from the market intelligence perspective,
19 whether it's products we had on file or were
20 contemplating producing.

21 Q. And in this paragraph it says "Opana ER.
22 ENDP" -- do you know what "ENDP" stands for?

23 A. That's the stock ticker symbol for Endo.

24 Q. "ENDP expressed confidence in the patent
25 protection for Opana ER. In addition to the 9-2013 and

1 7-2022 patents, the company has additional patent
2 applications pending."

3 Why was Mr. Smolenski sending you that
4 information?

5 A. Well, that's interesting from the perspective
6 that if these new, additional patent applications
7 pending had the potential to be Orange Book-listed and
8 potentially block approvals, that would be very
9 troubling for us.

10 Q. Did that information come into play in your
11 negotiations with Endo?

12 A. No. Well, not with me.

13 Q. Did it come into play with a member of the --
14 with members of the negotiating team in the settlement
15 agreement negotiations with Endo?

16 A. Yes.

17 MR. LOUGHLIN: Objection. Lack of foundation,
18 Your Honor.

19 MR. HASSI: Sir, he's the lead negotiator, but
20 I'm happy to connect it up.

21 MR. LOUGHLIN: He just testified that it didn't
22 come into play for him.

23 JUDGE CHAPPELL: Foundation is the objection.
24 Withdraw and restate or move along.

25 Because, I mean, I'm hearing it maybe not have

1 come into play with him, but it may have come into
2 play with people to his left or right. I don't know.
3 But you're correct, we don't have a foundation right
4 now.

5 BY MR. HASSI:

6 Q. Sir, when you said it didn't come into play for
7 you, can you explain what you meant by that?

8 A. Yeah. My primary concern in negotiating with
9 Endo was the earliest possible entry date for Impax.
10 There was -- I was certainly not doing this in a vacuum
11 and other key members of the team, including Ted, would
12 be legal, who were responsible for looking into other
13 legal aspects of the transaction, including
14 patent-related issues, so it was very important. It's
15 just not -- I never had a discussion with Endo about
16 patents personally.

17 JUDGE CHAPPELL: When you refer to your team,
18 are you talking about a negotiating team regarding the
19 settlement or are you talking about a generic drug team
20 in general or are you talking about an Opana team?
21 What do you mean?

22 THE WITNESS: So in this context when I say
23 "my team" it would be the people working most closely
24 with me negotiating this, so that would be the rest of
25 the management team and Mr. Smolenski and legal.

1 JUDGE CHAPPELL: You said "negotiating." Are
2 you -- do you mean a team negotiating the settlement of
3 the patent case?

4 THE WITNESS: Well, since I was the primary
5 person, but yes, I would consult with people as we went
6 along to make sure that the approach we were taking and
7 things that we were doing made sense, made business
8 sense.

9 JUDGE CHAPPELL: Did you understand my
10 question? I think that's a yes or no.

11 Are you -- do you mean a team negotiating --
12 that this team was negotiating the settlement of the
13 patent case, yes or no?

14 THE WITNESS: I would say no then.

15 JUDGE CHAPPELL: Thank you.

16 BY MR. HASSI:

17 Q. When it came time -- strike that.

18 As drafts --

19 JUDGE CHAPPELL: And I'm leaving it to you. I
20 have no idea what team he's talking about.

21 MR. HASSI: Understood. I'll try to clarify
22 it.

23 BY MR. HASSI:

24 Q. When you began exchanging drafts of settlement
25 agreements with Endo, did others review those drafts?

1 A. Yes.

2 Q. Did those include members of the legal team?

3 A. Yes.

4 Q. People like Huong Nguyen?

5 A. Yes.

6 Q. Margaret Snowden?

7 A. Yes.

8 Q. Were either of those individuals concerned
9 with the patent license that you were seeking from
10 Endo?

11 MR. LOUGHLIN: Objection. Lack of foundation.

12 BY MR. HASSI:

13 Q. Did either of those people communicate to you
14 that they were concerned about the patent license --

15 A. Yes.

16 Q. -- that was being sought from Endo?

17 MR. LOUGHLIN: Objection. Your Honor, those
18 are lawyers, so if Mr. Hassi is trying to waive
19 privilege, that's one thing, but otherwise, I'm not
20 sure why he's eliciting testimony that legal counsel
21 communicated with their client.

22 MR. HASSI: Your Honor, I'm not waiving
23 privilege. But someone has to communicate deal points
24 to the other side. And there were communications and
25 the record reflects communications, and the record

1 reflects changes to an agreement related to the patent
2 license. I'm trying to get at the fact as to who did
3 that and why it was done.

4 JUDGE CHAPPELL: I'll allow that, but you need
5 to make it clear to the witness that he's not to tell
6 you or reveal legal advice he was given. You're not
7 asking him to repeat any legal opinion, but --

8 MR. HASSI: I know.

9 JUDGE CHAPPELL: If someone had concerns,
10 that's fine, but if you're claiming privilege, you
11 can't have him tell us about legal advice.

12 MR. HASSI: I got it.

13 BY MR. HASSI:

14 Q. And sir, do you understand I'm not asking you
15 to waive the privilege or to share any privileged
16 conversations that you may have had with Impax' legal
17 team?

18 A. Yes, I understand that.

19 Q. Okay. With that in mind, are you aware of
20 whether there were communications between Impax and
21 Endo related to the patents to be covered under the
22 settlement agreement?

23 A. Yes, there were discussions.

24 Q. And were those discussions in part informed by
25 this information about Endo having additional patents

1 pending?

2 MR. LOUGHLIN: Objection. Lack of foundation,
3 Your Honor. Also potentially calling for privileged
4 information. He's asking --

5 JUDGE CHAPPELL: Haven't we heard that he was
6 the lead negotiator?

7 MR. LOUGHLIN: We have, Your Honor, but
8 he's --

9 JUDGE CHAPPELL: Then he would certainly know
10 the answer to this question in that capacity.

11 MR. LOUGHLIN: I think he's talking about
12 discussions that other people had, not that -- he's
13 already said that he didn't have these discussions.

14 JUDGE CHAPPELL: Well, I'll sustain it until
15 you lay a better foundation.

16 BY MR. HASSI:

17 Q. As the lead negotiator, were you kept apprised
18 to the extent that other people were discussing issues
19 with Endo in those negotiations?

20 A. Yes.

21 Q. And were you made aware that the lawyers were
22 discussing with -- that Impax' lawyers and Endo's
23 lawyers were discussing the breadth of the patent
24 license to be included in the settlement?

25 A. Yes.

1 Q. Thank you.

2 If we could move further down the page, there's
3 a section under "Tamper-resistant opioids," and it
4 says, "Tamper-resistant opioids. ENDP" -- again,
5 that's Endo; right?

6 A. Yes.

7 Q. -- "is working on tamper-resistant opioids, as
8 the company believes that such features could
9 eventually be necessary for FDA to approve new
10 opioids."

11 Do you see that?

12 A. Yes.

13 Q. Did that information inform your concern about
14 Endo reformulating Opana ER?

15 MR. LOUGHLIN: Your Honor, I need to object to
16 this. This document has been admitted but not for the
17 truth because it's a series of statements from
18 management consultants or something.

19 JUDGE CHAPPELL: First of all, take the
20 document off the screen.

21 Go ahead.

22 MR. LOUGHLIN: And I believe Mr. Hassi is
23 asking Mr. Mengler to assume the truth of the matter
24 stated in those -- in those excerpts from management
25 presentations for purposes of his question.

1 JUDGE CHAPPELL: Well, I'm sustaining the
2 objection. And in addition, I find the question to be
3 too much -- too many -- too leading for a person who's
4 your witness indirectly, so you need to rephrase. I'm
5 sustaining the objection.

6 MR. HASSI: Your Honor, as to the hearsay
7 objection, this is for the effect on the listener.
8 You asked him about his suspicions about
9 reformulation, and he mentioned an analyst report or
10 more -- more than one analyst report that had to --
11 that raised --

12 JUDGE CHAPPELL: So you're telling me you're
13 asking for his state of mind?

14 MR. HASSI: I'm asking for information that
15 informed his state of mind in the negotiations, yes,
16 Your Honor.

17 JUDGE CHAPPELL: Then that's allowed.

18 But you still need to watch the leading.

19 MR. HASSI: Understood.

20 JUDGE CHAPPELL: I know it gets confusing
21 because you didn't call the witness, but he's in effect
22 your witness.

23 MR. HASSI: I'll try, Your Honor.

24 BY MR. HASSI:

25 Q. Sir, if you could read the paragraph

1 Tamper-resistant -- under "Tamper-resistant opioids,"
2 if we could bring that back up again.

3 And just tell me whether that had -- what
4 effect, if any, that had on your negotiations with
5 Endo.

6 A. Well, it certainly would have confirmed our
7 suspicions that they, among others, would have been
8 working on some tamper-resistant, crush-resistant
9 formulation for Opana ER.

10 Q. Okay. And you mentioned you raised your
11 concern about Endo switching the market with Endo; is
12 that right?

13 A. Yes.

14 Q. Who did you raise that with?

15 A. Alan Levin.

16 Q. Did you raise it with him more than once?

17 A. Yes.

18 Q. And what did Mr. Levin say to you about your
19 concerns that Endo would switch the market?

20 A. Reiterated over and over that there was no
21 intention or plan to switch the market. In fact,
22 that's what led to the royalty calculation, because he
23 said, We're going to grow this market, and you should
24 pay us a royalty. And I said, Fine, I'll pay you a
25 royalty, but I don't believe you.

1 JUDGE CHAPPELL: You told him you didn't
2 believe him?

3 THE WITNESS: Yes, I did.

4 BY MR. HASSI:

5 Q. And did you ask for market -- a market
6 acceleration trigger to address this concern?

7 A. Yes. The market acceleration to address a
8 variety of concerns that -- anything that would lead to
9 market degradation, yes.

10 Q. And what was Endo's response to your request
11 for a market acceleration trigger?

12 A. They didn't want to do it.

13 Q. Did you ask more than once?

14 A. Yes. I'm sure I did.

15 Q. So how did -- how did Endo address Impax'
16 concern about the future of the Opana ER --

17 JUDGE CHAPPELL: Are you finished with this
18 document?

19 MR. HASSI: I'm sorry, Your Honor?

20 JUDGE CHAPPELL: Are you finished with this
21 document?

22 MR. HASSI: I am, yes.

23 You can take that down. Thanks.

24 BY MR. HASSI:

25 Q. In your negotiations with Endo, how did they

1 respond to your concern after they told you you
2 couldn't have a market acceleration trigger?

3 A. Well, that's when I came up with the idea of
4 the make-good provision in the event that I was right
5 and this did happen, that at least Impax would have
6 some protection.

7 Q. And that was in connection with the
8 conversation where Mr. Levin said he was going to grow
9 the market and told you you should pay them a royalty?

10 A. Yes. I don't know if it was the same exact
11 conversation or close. Things were happening fairly
12 fast, but right around then, yes.

13 Q. And what this ultimately led to was the -- what
14 was called the Endo credit?

15 A. Yes.

16 Q. With respect to the Endo credit formula, did
17 you do any analyses or forecasting as to what Impax
18 might be paid under the Endo credit formula?

19 A. No.

20 Q. Why not?

21 A. Well, because the Endo credit, make good, was
22 not an attempt to, you know, generate income. It was
23 intended to make us whole for what we would have
24 otherwise achieved, so I didn't really care what the
25 size of the market was. It was going to get in there

1 no matter what.

2 Q. Did anyone on your team -- and I'm not asking
3 for anyone on the -- any lawyers, but did any of the
4 businesspeople on your team express concerns about
5 whether the Endo credit would in fact protect Impax?

6 A. Yes. I mean, the -- the existence of the -- of
7 this credit doesn't necessarily ensure that it's going
8 to be paid. Obviously, we would prefer to be selling
9 product.

10 Also, there are other scenarios in which
11 certain market conditions, degradations, could occur at
12 certain times that could lead to -- could have led to a
13 situation where we would have gotten nothing in essence
14 and still had no market in which to compete.

15 Q. And do you recall who on your team raised those
16 concerns with you?

17 A. Ted Smolenski.

18 Q. I asked you a some questions a minute ago about
19 the patent license.

20 Why did you defer that conversation to your
21 lawyers?

22 A. I -- I never go down the path of having any
23 opinions about anything that's that type of legal
24 thing, including patents. I just listen to what the
25 lawyers tell me.

1 Q. Did you in essence delegate that provision to
2 them?

3 A. Absolutely.

4 Q. We looked at your board slides from the
5 May 2010 board meeting, CX 2929.

6 Do I understand correctly you were not making
7 a recommendation to the board regarding a launch at
8 risk?

9 A. That's correct. No recommendation was made.

10 Q. What were you -- why were you providing that
11 information to the board?

12 A. Larry Hsu, the CEO, requested that we begin to
13 alert the board as to the product being out there that
14 might get to the point of an at-risk launch, so that
15 was it.

16 Q. Do you recall any discussion at that board
17 meeting about an at-risk launch?

18 A. I do not.

19 Q. And do you recall telling the board that
20 oxymorphone was a good candidate for an at-risk
21 launch?

22 A. I would not have said that. No.

23 Q. What would you have said about oxymorphone to
24 the board in the context that you were presenting in
25 May of 2010?

1 A. I forget the exact number, but what I would
2 have said is, if we sell this product, we can make
3 whatever that was, 30 million bucks in 2013 -- 2010.

4 Q. You were shown that the forecast changed from
5 the February board meeting to the May board meeting.

6 What changed between February and May 25 with
7 regard to oxymorphone ER that led you to include it in
8 the forecast?

9 A. Well, it was at Larry's, Larry Hsu's, the CEO's
10 request, and I don't remember exactly, but it's likely
11 related to the fact that we got a tentative approval
12 and it was timely for that board meeting.

13 Q. Was there -- do you recall there ever being a
14 recommendation made to the board to launch Opana ER at
15 risk?

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

17 Q. During your time at Impax as president of the
18 global division, did you launch any products at risk?

19 A. No.

20 Q. You were involved in the negotiation of the
21 development and co-promotion agreement?

22 A. I was more of a point of contact, is how I
23 would describe it.

24 Q. And why were you the point of contact?

25 A. I was there talking with them already about

1 the settlement of the Opana case, so it just became
2 easy to begin the communication of higher-level terms
3 with them instead of somebody else from our company
4 getting involved, but certainly all the details were
5 not -- not from me.

6 Q. Who reviewed the details of that agreement?

7 A. Michael Nestor.

8 Q. What was his position at the time?

9 A. He was my counterpart as president of the
10 branded division.

11 Q. Had you negotiated deals like this before?

12 A. Many.

13 Q. You were asked earlier about 066 being on the
14 table and taking it off the table.

15 Did Impax ever put 066 on the table, so to
16 speak?

17 A. Not really. It was probably more likely me
18 throwing out an idea. I think Michael eventually
19 concluded, probably correctly, it was just, you know,
20 too far along that we could get more benefit from a
21 co-development agreement on a future product, which is
22 correct I think.

23 MR. HASSI: If I could confer with counsel for
24 a second, Your Honor?

25 (Pause in the proceedings.)

1 Your Honor, I have nothing further at this
2 time.

3 JUDGE CHAPPELL: Anything further?

4 MR. LOUGHLIN: Just a few, Your Honor.

5 JUDGE CHAPPELL: Go ahead.

6 - - - - -

7 REDIRECT EXAMINATION

8 BY MR. LOUGHLIN:

9 Q. Mr. Mengler, you just mentioned, in response to
10 a question from Mr. Hassi, that you put out the idea of
11 066; is that right?

12 A. It was probably more of a discussion of the
13 good partnership that could exist between us and them,
14 and for example, we are developing this neuro- --
15 neurology product right now, 066, that could be a great
16 opportunity to partner.

17 Q. But you were the one who raised 066 in the
18 discussions, not Endo; correct?

19 A. Well, I don't know if I mentioned the value of
20 a potential partnership because of all the synergies we
21 would achieve and they mentioned 066 or if I mentioned
22 it right away. I don't know. But certainly it was an
23 early candidate that was discussed.

24 Q. It was the subject of the discussions initially
25 regarding the development and co-promotion agreement;

1 correct?

2 A. Yes. I just don't recall if I said it first or
3 they said it first.

4 JUDGE CHAPPELL: It looks like you should have
5 your next witness standing by. It looks like we'll get
6 started today with that next witness.

7 MR. LOUGHLIN: Your Honor, we don't have
8 another witness here today.

9 Who's our next witness?

10 Our next witness is someone from -- it's an
11 Endo employee, and he is not here yet. We are relying
12 on Endo's counsel to bring those witnesses,
13 Your Honor, here, and Mr. Cuca is not ready until
14 tomorrow.

15 JUDGE CHAPPELL: Is this person going to be
16 here in the morning?

17 MR. LOUGHLIN: He will be here in the morning.

18 JUDGE CHAPPELL: If not this person, have
19 somebody here in the morning.

20 MR. LOUGHLIN: We will do that, Your Honor.

21 JUDGE CHAPPELL: Go ahead.

22 You'd be surprised how much time we can make
23 going half an hour with a witness at the end of the
24 day, so we're losing time.

25 MR. LOUGHLIN: I understand, Your Honor, and I

1 apologize for that. We are reliant on counsel for the
2 witnesses because none of them are our witnesses.

3 BY MR. LOUGHLIN:

4 Q. Now, Mr. Mengler, you mentioned, in response to
5 some questioning from Mr. Hassi, some concerns that
6 someone named Ted Smolenski raised regarding the Endo
7 credit. Do you recall that?

8 A. I'm sorry. State it again, please.

9 Q. I think it was Ted Smolenski? Is that right?

10 A. Yes, that's the name.

11 Q. That Mr. Smolenski had some concerns regarding
12 whether or not there was a possibility that the Endo
13 credit might not be worth anything?

14 A. Yes.

15 Q. Under various -- under certain circumstances,
16 it might not -- you might not end up getting a payment
17 under the Endo credit; correct?

18 A. Yes.

19 Q. Those concerns did not prevent you from
20 finalizing the settlement, did it?

21 A. That's correct.

22 Q. You didn't think it was likely that Impax would
23 get no value from the settlement, did you?

24 A. Well, Ted was right. And there are a set of
25 circumstances that are entirely plausible that could

1 lead to this condition where the market share doesn't
2 fall below 50 percent in a certain period of time but
3 falls to zero by January 1st of 2013. Based on its
4 likelihood of occurrence and the cultural nature of
5 the organization, I decided to not raise that issue at
6 all beyond the conversations between Ted and myself.

7 Q. Because you didn't think it was sufficiently
8 likely to raise it with anyone else; correct?

9 A. I thought that the problems it would cause
10 internally from a debate perspective about its
11 likelihood would not be worth the energy to do so,
12 because while it was a real potential, I didn't --
13 there was no probability ascribed to it. I didn't
14 think it was -- rose to the threshold enough nor, by
15 the way, did I think we could necessarily easily
16 correct for it in the agreement, so it was -- I took
17 the chance.

18 Q. But you negotiated this deal to get value for
19 Impax; correct?

20 A. Yes.

21 Q. And you believe you got it, value for Impax
22 under this deal; correct?

23 A. Yes.

24 Q. And the settlement discussions had a no-AG
25 provision in them from the beginning of the

1 discussions; correct?

2 A. I believe Endo even proposed it initially.

3 Yes.

4 MR. LOUGHLIN: Thank you.

5 I have no further questions, Your Honor.

6 JUDGE CHAPPELL: Anything else?

7 MR. HASSI: Nothing further, Your Honor.

8 JUDGE CHAPPELL: Thank you, sir. You may stand
9 down.

10 THE WITNESS: Thank you.

11 (Pause in the proceedings.)

12 JUDGE CHAPPELL: Anything further from either
13 side?

14 MR. LOUGHLIN: Not from complaint counsel,
15 Your Honor.

16 MR. HASSI: Not from respondents, Your Honor.

17 JUDGE CHAPPELL: Well, we'll reconvene at
18 9:45 a.m. tomorrow.

19 We're in recess.

20 (Whereupon, the foregoing hearing was adjourned
21 at 5:09 p.m.)

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CERTIFICATE OF REPORTER

I, JOSETT F. WHALEN, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

s/Josett F. Whalen
JOSETT F. WHALEN
Court Reporter