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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.)
-----)

November 3, 2017
9:48 a.m.

TRIAL VOLUME 7
PART 1, 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:

2

3 ON BEHALF OF THE FEDERAL TRADE COMMISSION:

4 CHARLES A. LOUGHLIN, ESQ.

5 MARKUS H. MEIER, ESQ.

6 ERIC M. SPRAGUE, ESQ.

7 Federal Trade Commission

8 Bureau of Competition

9 Constitution Center

10 400 7th Street, S.W.

11 Washington, D.C. 20024

12 (202) 326-3759

13 cloughlin@ftc.gov

14

15

16 ON BEHALF OF IMPAX LABORATORIES:

17 EDWARD D. HASSI, ESQ.

18 EILEEN M. BROGAN, ESQ.

19 O'Melveny & Myers LLP

20 1625 Eye Street, N.W.

21 Washington, D.C. 20006-4061

22 (202) 383-5300

23 ehassi@omm.com

24

25

1	FEDERAL TRADE COMMISSION				
2	I N D E X				
3	IN THE MATTER OF IMPAX LABORATORIES, INC.				
4	TRIAL VOLUME 7				
5	PART 1, PUBLIC RECORD				
6	NOVEMBER 3, 2017				
7					
8	WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS VOIR
9	NOLL		1536	1686	
10	ENGLE	1698	1763	1786	1796
11					
12					
13	EXHIBITS	FOR ID IN EVID IN CAMERA STRICKEN/REJECTED			
14	CX				
15	(none)				
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17	RX				
18	(none)				
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20	JX				
21	(none)				
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1 P R O C E E D I N G S

2 - - - - -

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

4 Next question.

5 - - - - -

6 Whereupon --

7 ROGER GORDON NOLL

8 a witness, called for examination, having been
9 previously duly sworn, was examined and testified as
10 follows:

11 CROSS-EXAMINATION (continued)

12 BY MR. HASSI:

13 Q. Good morning, Professor Noll.

14 A. Good morning.

15 Q. Professor Noll, yesterday I asked you some
16 questions about a chart in your report. I
17 misdescribed it as Appendix F. It's Appendix C, the
18 one with the three -- the larger orange ball. Do you
19 recall that?

20 A. Right.

21 Q. Could we put up Appendix C to Professor Noll's
22 report.

23 And Professor Noll, you testified yesterday
24 that the concept behind Appendix C to your report was
25 yours; is that right?

1 A. This is described verbally in my first report.

2 Yes.

3 Q. And the idea of this chart you described to
4 someone at the FTC, who then drew it for you; is that
5 right?

6 A. Yes.

7 Q. Okay. And I asked you some questions about
8 whether you borrowed it from Schering-Plough. Do you
9 recall that?

10 A. You did. And I was not aware of the fact that
11 it was used in Schering-Plough.

12 Q. Could we bring up RX D-3.

13 And Professor Noll, RX D-3 is your Appendix C
14 along with a page from complaint counsel's appeal brief
15 to the commission in Schering-Plough.

16 Do you see that?

17 A. I do.

18 Q. Okay. And do you see that the charts look
19 quite familiar?

20 A. They look -- they look very similar, I agree.
21 I mean, there's differences, but they're similar,
22 certainly similar.

23 Q. So the concept of this chart was used in
24 Schering-Plough; is that fair?

25 A. That's correct.

1 Q. And could we bring up RX D-4.

2 And sir, this is a comparison of your
3 Appendix C compared with -- this is congressional
4 testimony by the Federal Trade Commission in
5 2009 relating to pay-for-delay.

6 Do you see that?

7 A. Yes, I do.

8 Q. And again, the charts are similar?

9 A. They're similar.

10 Q. And the legends are similar?

11 A. Yes. Well, they're not identical because, as I
12 said before, the mathematical symbols are in the other
13 and the size is not the same, but it's -- conceptually
14 they're identical.

15 Q. Thank you.

16 You can take that down now.

17 Dr. Noll, we talked a little bit yesterday
18 about formularies. Do you recall that?

19 A. No. But that's okay.

20 Q. You refer to formularies in your report; is
21 that correct?

22 A. Yes.

23 Q. And for example, in your expert report you talk
24 about the formulary for UnitedHealthcare; is that
25 right?

1 A. I believe so. Yes.

2 MR. HASSI: And Your Honor, I apologize. May I
3 approach and provide the witness with a binder of
4 exhibits?

5 JUDGE CHAPPELL: Go ahead.

6 BY MR. HASSI:

7 Q. Sir, if you can turn to tab 14 --

8 A. I see it.

9 Q. -- in your binder.

10 Does this appear to be the formulary from
11 UnitedHealthcare that you relied upon in your expert
12 report?

13 A. Well, it certainly is a formulary from
14 UnitedHealthcare, but I don't know whether it's the one
15 that actually -- the one that I actually used I -- I
16 did it off the Internet, and I don't know whether this
17 is the same one or not.

18 MR. MEIER: Your Honor, I object to this
19 document is not in evidence.

20 MR. HASSI: It's referred to -- Your Honor,
21 this is cross-examination, and it's a document that, as
22 the witness just said, he referred to in his report and
23 pulled it off the Internet.

24 JUDGE CHAPPELL: He was asked the foundational
25 question about whether he relied upon it. He demurred

1 and basically said, I don't know for sure. I think
2 that's foundational. I think this is an expert witness
3 paid by the hour on cross-exam. He can handle it.
4 Overruled.

5 BY MR. HASSI:

6 Q. Sir, would you turn to page 4 of this
7 formulary.

8 A. Okay.

9 Q. Do you see at the top of the page of this
10 formulary it reads, "Tiers are the different cost
11 levels you pay for a medication. Each tier is assigned
12 a cost, which is determined by your employer or health
13 plan. This is how much you will pay when you fill a
14 prescription"?

15 Do you see that?

16 A. Yes.

17 Q. And that's an explanation UnitedHealthcare
18 provides to its members about how a formulary works; is
19 that right?

20 A. It's a vague and incomplete explanation. Yes.

21 Q. Well, there's more to the explanation; right?

22 It goes on to say, "Tier 1 medications are your
23 lowest-cost options. If your medication is placed in
24 Tier 2, 3 or 4, look to see if there's a Tier 1 option
25 available."

1 You see that; right?

2 A. I do.

3 Q. And that's consistent with your understanding
4 of how formularies work; right?

5 A. Yes.

6 Q. UnitedHealthcare wants to encourage its members
7 to move to a lower-cost drug where one is available;
8 right?

9 A. To the degree that the patient has a choice,
10 yes.

11 Q. If you would turn to page 19 of that formulary,
12 there's a section entitled Musculoskeletal Pain Relief.

13 JUDGE CHAPPELL: Do the documents the experts
14 refer to -- are they identified as attachments like A,
15 B and C? Are they identified as attachments to a
16 report or just mentioned in a footnote?

17 MR. HASSI: This one is mentioned in a
18 footnote with a World Wide Web address, Your Honor,
19 and that's where we pulled it from. The document
20 wasn't exactly -- wasn't attached to his report, but
21 it's referenced in the report in a footnote.

22 JUDGE CHAPPELL: So it wasn't something that
23 was provided to you you could make a copy of, you had a
24 link.

25 MR. HASSI: Your Honor, we agreed with the

1 other side that if it was a publicly available document
2 we didn't need to provide each other copies, so we just
3 pulled it off the web. We could have requested
4 complaint counsel provide us a copy under the rules.
5 We chose not to for documents that were publicly
6 available.

7 JUDGE CHAPPELL: No. That's fine. But just so
8 the record is clear, I don't think he's agreed with you
9 that this is something he relied on.

10 MR. HASSI: I'll try to establish that.

11 JUDGE CHAPPELL: His original response was not
12 clear, as I go back and read it on realtime.

13 BY MR. HASSI:

14 Q. Sir, did you rely in your report on a review of
15 formularies?

16 A. I did rely on reviews of formularies, yes.

17 Q. And one of the --

18 A. The problem is I don't know that this
19 particular one is the one that I looked at.

20 Q. Okay. Did you rely on a formulary from
21 UnitedHealthcare?

22 A. One of the many formularies from
23 UnitedHealthcare. The problem is each insurance
24 company has multiple formularies for different
25 categories of patients.

1 Q. Do you believe this formulary to be
2 substantially different than the formulary you relied
3 upon?

4 A. I don't know. I would have to look at the one
5 I used and see if this is the same one or if it's
6 similar. I just don't know.

7 JUDGE CHAPPELL: Okay. Do you want us to wait
8 while he looks at the one he used?

9 MR. HASSI: He would have to go to the
10 World Wide Web for that, Your Honor.

11 JUDGE CHAPPELL: He's the expert. You decide.

12 BY MR. HASSI:

13 Q. Sir, would you like to look at the one you
14 used?

15 A. I don't know. Since I don't know what
16 questions you're going to ask me, I can't possibly
17 know whether it even matters, because formularies are
18 all very similar. They -- it's just that the placement
19 of a specific drug can be different on different
20 formularies and the rule --

21 JUDGE CHAPPELL: Let's start with the questions
22 you've been asked so far. You said you don't know what
23 he's going to ask. You've been asked questions
24 already.

25 Do you need to go online and verify that this

1 is something you relied on?

2 THE WITNESS: Well, all the questions he's
3 asked me would be -- I would answer the same
4 regardless of which one, whether this is the right one
5 or the wrong one. Thus far, he hasn't asked a
6 question where whether this is the right one or not
7 matters, and maybe he won't, so -- because if -- if
8 the questions are about the general structure of
9 formularies and -- then it -- and the role -- and
10 where Opana gets placed and things like that, then I
11 can answer them. But if it's about why do you think
12 they're in this position on this formulary, I wouldn't
13 know whether that was -- I could answer that or not
14 until I heard the question, unless I knew for sure that
15 it was the one that I looked at.

16 JUDGE CHAPPELL: All right. If you need to
17 refer to a document, let us know.

18 THE WITNESS: Okay.

19 BY MR. HASSI:

20 Q. Sir, on the list on page 19, for
21 musculoskeletal pain relief, do you see Opana listed?

22 A. Yes.

23 Q. Opana ER?

24 A. Yes.

25 Q. And what tier is it on, sir?

- 1 A. It says 2.
- 2 Q. Okay. And do you see that it's bolded?
- 3 A. I'm sorry. What?
- 4 Q. Do you see that the text is bolded for
5 Opana ER?
- 6 A. Yes, I see the text is bolded.
- 7 Q. And if you look on page 18, you'll agree with
8 me that bolded drug names are branded drugs; is that
9 right?
- 10 A. That's correct.
- 11 Q. And nonbolded, those are generics?
- 12 A. That's correct.
- 13 Q. Now, do you see OxyContin -- stepping back for
14 a second, you're familiar with OxyContin; right?
- 15 A. I know what OxyContin is. I'm not familiar
16 with it.
- 17 Q. Fair point.
- 18 You're aware, sir, that OxyContin is another
19 long-acting opioid; right?
- 20 A. Yes.
- 21 Q. And do you see it on this list?
- 22 A. Yes. It's in Tier 4.
- 23 Q. It's in Tier 4; right?
- 24 A. Yes.
- 25 Q. And that's also a branded drug; right?

1 A. Yes, it is.

2 Q. Is it fair to say that Endo did not get
3 Opana ER on UnitedHealthcare's Tier 2 of its formulary
4 by accident?

5 A. Of course not.

6 Q. They would have offered a discount, for
7 example, over OxyContin to get favorable formulary
8 placement from UnitedHealthcare; correct?

9 A. That's one way, but it's not the only way.

10 Q. They could have offered rebates or coupons as
11 well; right?

12 A. But that -- also that's true, but it's not the
13 only way. Where the brand name drug is depends on
14 whether there's generics available as well. You get --
15 the brand name drug tends to get put in a lower tier if
16 there's a generic.

17 Q. Do you see a generic version of Opana ER or
18 oxymorphone ER on this formulary?

19 A. No, I do not.

20 Q. And you're aware that, as of September 1,
21 branded Opana ER is no longer available; correct?

22 A. That's correct.

23 Q. Does that mean that patients with insurance to
24 UnitedHealthcare who would have been prescribed
25 Opana ER up till September 1 are no longer able to use

1 Opana ER?

2 A. Well, you're saying UnitedHealthcare. Those
3 patients whose insurance was covered by this
4 particular version of the formulary may not have
5 access to it.

6 One of the features is that physicians can
7 recommend that drugs be prescribed and covered even if
8 they're not in the formulary, so it would be too harsh
9 to say, you know, it would be over the top to say you
10 can't get access.

11 We don't know how UnitedHealthcare has
12 responded to the removal of Opana ER from the market,
13 so I can't testify to that. I actually looked it up in
14 September to try to figure it out, and I couldn't.

15 Q. Okay. You can set that to the side.

16 A. I'm sorry?

17 Q. You can set that binder to the side for now.

18 A. Okay.

19 Q. Sir, yesterday I asked you -- sorry.

20 Yesterday I asked you about the duration of
21 long-acting opioid therapy, and you said you didn't
22 know, but you agreed there's a reasonably high turnover
23 rate in the use of long-acting opioids. Do you recall
24 that testimony?

25 A. Yes, I do.

1 Q. And a reasonably high turnover rate would
2 suggest that there are new patients starting on
3 long-acting opioids on a reasonably regular basis;
4 correct?

5 A. Yes.

6 Q. And absent --

7 JUDGE CHAPPELL: Hold it, hold it, hold it.
8 One at a time.

9 BY MR. HASSI:

10 Q. I'm sorry. The answer was yes? Was there
11 more?

12 A. Well, I said the number is declining, but yes,
13 there is some number of new patients every month.

14 Q. And for those new patients, absent some prior
15 experience with a particular opioid, the prescribing
16 physician can give them -- prescribe them any one of a
17 number of long-acting opioids; correct?

18 A. Or they can also prescribe other ways of
19 managing pain besides opioids, but yes, they can do it.
20 Whatever the physician wants the physician can do
21 subject to professional ethics and rules of the
22 insurer.

23 Q. And you referred yesterday to a lock-in effect
24 for patients that need to switch from one opioid to
25 another.

1 That effect and the switching effect does not
2 apply to new patients; correct?

3 A. Yes and no.

4 Q. Sir, are new patients locked into a particular
5 opioid before they start?

6 A. Yeah -- they can be. They're usually not.

7 Q. And what's the basis for your statement that
8 they can be locked into a particular opioid?

9 A. Recall you asked me a bunch of questions about
10 being treated in a hospital with an opioid, and so if
11 you're being treated through intravenous and/or you're
12 using an immediate-release opioid, then it's much less
13 costly to -- if you're switching to an ER version of an
14 opioid, to do the same one than it is to switch.

15 JUDGE CHAPPELL: It sounds like you and the
16 witness differ on what "new patient" means. You need
17 to clarify that.

18 BY MR. HASSI:

19 Q. When you used "inpatient" in that last example,
20 can you tell us what you meant by that?

21 A. Yeah. I mean that a patient who goes into a
22 hospital or a clinic may be treated with some sort of
23 pain medication while they're there. Usually that's an
24 immediate-release version, and it can be either a pill
25 or it can be intravenous.

1 And then when the patient is released, they
2 may continue to need some sort of pain treatment. And
3 what I was referring to is, in that circumstance,
4 it's -- it requires less physician intervention to keep
5 them on the same drug than it does to switch them to a
6 new drug.

7 JUDGE CHAPPELL: So when you refer to what is
8 called a new patient, you include those that are being
9 discharged from a hospital.

10 THE WITNESS: "A new patient" I interpreted as
11 being new to extended-release opioids as contrasted to
12 the -- new to opioids in general, that one of the
13 switches that happens is to go from immediate-release
14 opioids to extended-release opioids. That, in the way
15 the data are collected and presented and analyzed by
16 everybody in the case, that is a -- that is a new
17 patient, and it shows up as a new prescription for the
18 extended-release version of the drug.

19 But it doesn't mean they weren't taking any
20 opioid before. It just means that this is the first
21 time they've had an extended-release version.

22 JUDGE CHAPPELL: All right. And I might have
23 misunderstood, but I thought his question said
24 "long-acting opioids," so wouldn't that exclude what
25 you're talking about on immediate-release opioids,

1 those people?

2 THE WITNESS: I thought his question was new
3 patients for long-acting opioids. And a new patient
4 for a long-acting opioid may have had other opioids
5 before, and so -- and they would still be a new patient
6 for a long-acting opioid.

7 JUDGE CHAPPELL: All right.

8 BY MR. HASSI:

9 Q. Now, Professor Noll, with respect to those
10 inpatients who are leaving the clinic and are new to a
11 long-acting opioid but may have had some -- an
12 immediate-release opioid in the clinic, you're aware
13 the FTC's expert Dr. Savage testified that it is common
14 at that point for the prescribing physician to switch
15 opioids; correct?

16 A. Sometime they do and sometimes they don't.
17 Yes. I mean, they --

18 JUDGE CHAPPELL: Hold it, hold it.

19 That's a compound question. Are you asking him
20 if something is correct or if he's aware of what the
21 witness testified to, Dr. Savage? There were two
22 questions in there.

23 BY MR. HASSI:

24 Q. I meant to ask whether you're aware that
25 Dr. Savage --

1 JUDGE CHAPPELL: Ask him.

2 THE WITNESS: You did say "Dr. Savage."

3 BY MR. HASSI:

4 Q. I did.

5 A. I am aware of that testimony.

6 Q. Thank you.

7 Now, yesterday you testified that customers
8 get locked into one drug because of switching drug
9 costs, and they wouldn't really be induced to change
10 unless there was some therapeutic reason that they had
11 to change.

12 Do you recall giving that testimony?

13 A. Yes.

14 Q. And as we've just established, you agree
15 formularies encourage patients to switch prescriptions
16 from one drug to another; correct?

17 A. Of course -- well, yes and no. I mean, they
18 would encourage them if it were to a less costly drug.
19 You know, it's not that they in general encourage
20 people to switch, but they're -- formularies do have
21 the property that they would -- they try to give you an
22 incentive to produce -- switch to a cheaper drug.

23 Q. And you agree that you've not done any
24 empirical analysis of switching costs; correct?

25 A. I have not estimated precisely what the

1 switching costs are. I've identified what the
2 switching costs are.

3 Q. You've identified -- you've described them as
4 high; correct?

5 A. I'm sorry. I didn't hear -- I described what?

6 Q. You described switching costs among long-acting
7 opioids as high; correct, sir?

8 A. Yes. And I explained what they were.

9 Q. Now, we talked a minute ago about OxyContin.
10 OxyContin has the same indication as Opana ER;
11 correct?

12 A. It's a long-acting opioid. Yes.

13 Q. And you mentioned yesterday you reviewed the
14 materials cited by Dr. Addanki in his report; is that
15 right?

16 A. I have seen Dr. Addanki's report, yes.

17 Q. And you reviewed the materials cited by
18 Dr. Addanki in his report?

19 A. Yes.

20 Q. So you're aware that the UPMC Health Plan did a
21 retrospective analysis of pharmacy and medical claims
22 pre and post formulary change; is that right?

23 A. Yes.

24 Q. And they tested the effect of their health
25 insurance's formulary change to disfavor OxyContin over

1 other long-acting opioids; right?

2 A. Yes, they did that.

3 Q. Okay. If we could bring up RX 87.

4 And if you want to look at the paper copy, it's
5 in your binder at tab 11. The print is kind of small.
6 The screen may be easier.

7 And for the record, we received from Endo a
8 color copy. The original was produced in
9 black-and-white. This is a slightly more legible, but
10 still on the screen hard to read.

11 And so if I could ask -- if, Robert, if you
12 could pull up just sort of the first column on the
13 left.

14 Now, sir, do you recognize this as the study
15 that UPMC Health Plan did of a formulary change away
16 from OxyContin and long-acting opioids?

17 A. Well, yeah, I believe it is. Obviously, I
18 can't tell from the snippet, but yes, I accept that it
19 is.

20 JUDGE CHAPPELL: He referred to the snippet.
21 Give him a full copy if you're going to ask him about
22 it.

23 BY MR. HASSI:

24 Q. Sir, if you'd turn in your binder, if you need
25 to see a full copy --

1 A. The one that you --

2 Q. -- tab 11.

3 Yes, the big binder. Thank you.

4 (Document review.)

5 A. Okay.

6 Q. You would agree that this is the
7 UPMC Health Plan's study of the impact of an OxyContin
8 formulary change on member opioid utilization and
9 prescriber practice?

10 A. Yes. This is a summary of the study, yes.

11 Q. Yes.

12 And this was done in the 2008 to 2009 time
13 frame; is that right?

14 A. I don't remember, but if you say so. I mean,
15 I -- I don't -- I don't recall when it was done, but
16 that's roughly right.

17 Q. If you could take that down, Robert, and just
18 bring up the method, yeah, from there down through
19 Methods.

20 Do you see, sir, under Methods on the left-hand
21 side it says Stuffed Design retrospective analysis of
22 pharmacy and medical claims pre and post formulary
23 change?

24 A. Yes, I see that.

25 Q. And it refers to the time frames that they did

1 that starting from April 1, 2008 --

2 A. Well, the Medicaid one is January 1, 2008.

3 Q. Fair point.

4 A. So that some of it was in 2008 and some of it
5 was 2009.

6 Q. Thank you.

7 You can take that down. Now, if you can blow
8 up the middle column.

9 JUDGE CHAPPELL: Just so the witness knows, he
10 has the full version, but what you're asking him about
11 you're blowing up so it's easier for him to see on the
12 screen; correct?

13 MR. HASSI: Yes, sir.

14 JUDGE CHAPPELL: That might help.

15 BY MR. HASSI:

16 Q. So do you see here under Figure 2 they tallied
17 the patients in their study?

18 A. Yes.

19 Q. Okay. And they studied a total of
20 1639 patients; is that right?

21 A. Again, I -- yeah, I assume so. I -- that's
22 what the number says, yes.

23 Q. Those were the total members with a paid claim
24 for OxyContin pre formulary change; right?

25 A. Well, that's what it says, yes.

1 Q. And if you go directly below that to the
2 left -- no, that same figure, Robert.

3 Directly below that to the left you see that
4 after the formulary change, 329 or roughly 20 percent
5 of the patients stayed on OxyContin?

6 A. Yes.

7 Q. And 1310 patients or merely 80 percent switched
8 away from OxyContin as a result of the formulary
9 change?

10 A. Hold on just a second. Let me -- let me --
11 this is so impossible to read. Just give me a second.

12 Q. Professor Noll, it may be easier -- we've got
13 it blown up on the screen. It may be easier if --

14 A. No. But it's all fuzzy, and so I want to look
15 at the whole thing. I'm trying to remember precisely
16 what they did.

17 (Document review.)

18 Okay. You're using the word "switch," and
19 that's not accurate. It's -- it's the -- it's the
20 number of people who get an OxyContin prescription.
21 All right. It's not following a patient through time
22 and seeing if the patient switched.

23 So the numbers refer to the number of patients
24 in the plan before and after the event that were
25 prescribed OxyContin. That's what the -- that's what

1 that number is.

2 Q. Sir, if we look at the two boxes in the bottom
3 right-hand corner of figure 2, do you see that the way
4 UPMC Health Plan --

5 A. Yeah.

6 Q. -- describes this --

7 A. That one box there at the left at the bottom,
8 yeah.

9 Q. So the two boxes on the bottom --

10 A. Yeah.

11 Q. -- one says "Members that switched to an opioid
12 alternative," number 1142.

13 Do you see that?

14 A. Yes.

15 Q. And that reflects that 87 percent of the
16 patients who stopped using OxyContin switched to an
17 opioid alternative; correct?

18 A. No. That's not what it says.

19 What it says, of those who continued using an
20 opioid through the study period, it's the fraction who
21 started with OxyContin and switched to something else.
22 The people who just stopped taking opioids are not in
23 the study.

24 Q. Sir, the box right next to that, that doesn't
25 include the people who did not --

1 JUDGE CHAPPELL: No. Hang on a second.

2 Sir, I think you misunderstood his question.

3 He didn't say people who stopped. He said people who
4 stopped using OxyContin.

5 Did you misunderstand his question?

6 THE WITNESS: No. I understood.

7 The two boxes at the bottom -- I'm sorry this
8 is so difficult. It says "Members that switched to an
9 opioid alternative"; "Members that did not switch to an
10 opioid alternative." All right?

11 And so there's -- there's three categories of
12 people. There's people who stopped using OxyContin,
13 there's people who continued to use OxyContin, and
14 there's people who switched to some other opioid. And
15 it's only the last two categories that are in this
16 table.

17 But it doesn't matter. They're --

18 JUDGE CHAPPELL: Isn't there a fourth group
19 possible? People that stopped altogether using any
20 opioid?

21 THE WITNESS: Oh, that's the third -- that --
22 yeah, there's three groups.

23 JUDGE CHAPPELL: Because you said people who
24 stopped using OxyContin as your first group.

25 THE WITNESS: There's three groups, yeah.

1 There's three groups.

2 It's all that -- at the beginning of the
3 period, there's a bunch of people using OxyContin, and
4 then three things can happen. They can stop using
5 OxyContin altogether, they can continue to use
6 OxyContin, or they can switch to another opioid.

7 JUDGE CHAPPELL: Can't they also stop using all
8 opioids?

9 THE WITNESS: Yeah. That's what I -- that is
10 the first group.

11 JUDGE CHAPPELL: Well, to me, stopped using
12 OxyContin doesn't mean you stopped every opioid.

13 THE WITNESS: There's people who stop OxyContin
14 and don't switch, people who stop OxyContin and switch,
15 and people who stay with OxyContin. Those are the
16 three groups.

17 And you're right, the first group is people who
18 stop and don't do anything else.

19 JUDGE CHAPPELL: All right. Did you ask the
20 witness what the formulary change was that he's talking
21 about now?

22 BY MR. HASSI:

23 Q. Do you understand that the formulary change is
24 a formulary to take OxyContin off the formulary, to
25 disfavor it and move it to Tier 4?

1 A. This -- what I understand happened was they
2 gave it -- they put it on a lower-ranking tier at this
3 moment in time and -- but the -- but it -- we haven't
4 gotten into why, which is not about price.

5 Q. And we will.

6 But sticking with this chart for a second and
7 the numbers, so they started with 1639 patients who
8 were using OxyContin on the formulary; right?

9 A. Yes.

10 Q. And after the formulary change, 168 of those
11 patients stopped using an opioid altogether; right?

12 A. Yes.

13 Q. And that's 12.83 percent; right?

14 A. Yes.

15 Q. Was that yes?

16 A. Yes. I'm sorry. I wasn't at the mike. I did
17 say yes, but I wasn't at the mike. I was trying to
18 read the silly document.

19 Q. And 329 patients or 20.07 percent continued
20 using OxyContin notwithstanding the formulary change;
21 right?

22 A. That's correct.

23 Q. And the majority, 1142 patients, switched to an
24 opioid alternative; right?

25 A. That's right.

1 Q. And if we could go down one to figure 3 I think
2 it is, the pie charts below that.

3 And this figure shows where people switched to;
4 is that right?

5 A. Yes.

6 Q. And of the 1142 who switched, 29.23 after the
7 switch were taking Opana ER; right?

8 A. I cannot actually read the number, but I assume
9 you're reading the number correctly.

10 Q. Okay. If we could go up to the figure in the
11 upper right-hand corner, the next column, figure 4.

12 And UPMC Health Plan studied the effect on
13 costs; right?

14 And they found -- is that right?

15 A. Yes.

16 Q. And they found that they reduced both the
17 prescription drug cost on the left. That's the opioid
18 Rx cost went down; right?

19 A. Yes.

20 Q. And they also found that they reduced medical
21 costs after the formulary change; is that right?

22 A. Yes.

23 Q. And if you could now go down to the conclusions
24 in the bottom right.

25 JUDGE CHAPPELL: Let's go back to the previous

1 screen.

2 MR. HASSI: Yes, Your Honor.

3 JUDGE CHAPPELL: Is that cost to the patient or
4 cost to the insurance company?

5 MR. HASSI: I believe it's cost to the
6 insurance company, Your Honor.

7 JUDGE CHAPPELL: I say insurance company. It's
8 the health plan, which is an insurance company.

9 MR. HASSI: Yes. One of the largest in the
10 Pennsylvania area. Actually a frequent antitrust
11 defendant, so...

12 JUDGE CHAPPELL: All right.

13 BY MR. HASSI:

14 Q. Okay. Robert, if you could bring up that
15 Conclusions paragraph.

16 And you see that the conclusion of this study
17 by the UPMC Health Plan was that "The OxyContin
18 formulary change did not result in an adverse cost
19 increase while helping to shape prescribing and
20 utilization of opioids to preferred formulary
21 alternatives"; is that right, sir?

22 A. That's what it says.

23 Q. And you've not done any empiric work that would
24 help you refute the UPMC Health Plan study that
25 Dr. Addanki refers to; is that right?

1 A. I don't disagree with it. I wouldn't try to
2 refute it. There's nothing -- there's nothing to
3 refute.

4 Q. Okay. You can take that down, Robert.
5 Thank you.

6 I want to talk for a second about the product
7 market.

8 Sir, did you look to see whether the
9 Federal Trade Commission or Department of Justice had
10 ever considered product market definition in the
11 long-acting opioid space?

12 A. I -- I haven't done a systematic study of what
13 they have defined as relevant markets in other cases.
14 I only know in some of the cases, but I haven't
15 systematically studied it. No.

16 Q. In looking at other cases, did you review the
17 Federal Trade Commission's agreement containing consent
18 order to aid public comment in the King Pharmaceuticals
19 and Alpharma merger?

20 A. I'm aware of that, and I think that they
21 defined the market there as all opioids.

22 Q. Okay. Let's take a look at that. If you want
23 to look at a paper copy, it's tab 13 in your binder.

24 A. I don't know yet. We'll see what it looks like
25 on the screen. If it's as bad as the last one, I'll

1 look at the paper copy.

2 Q. And sir, you see that this is the
3 Federal Register publication of the
4 Federal Trade Commission's agreement containing consent
5 order to aid public comment in King Pharmaceuticals and
6 Alpharma?

7 A. I -- I can read what it says, and yes, I
8 understand what it says.

9 JUDGE CHAPPELL: Can you tell us the date of
10 this?

11 MR. HASSI: The date, Your Honor?

12 It was published January 5, 2009, Your Honor,
13 in the Federal Register.

14 JUDGE CHAPPELL: This is a page out of the
15 Federal Register?

16 MR. HASSI: Yes, Your Honor.

17 JUDGE CHAPPELL: All right.

18 BY MR. HASSI:

19 Q. And if we could go to the next page, in the
20 middle column under Roman II, if you can go about
21 two-thirds of the way down the page, all of column II
22 about two-thirds of the way down the page.

23 And I'm sorry. Did you say you're familiar
24 with this?

25 A. I'm aware of it, but "familiar" would be

1 overstating it.

2 Q. Well, sir, do you agree with the
3 Federal Trade Commission that oral long-acting opioids
4 have become the standard of care for the management of
5 moderate to severe chronic pain?

6 A. I believe in -- at the time this was written
7 that was closer to being true than it is now, but yes,
8 it's --

9 Q. And among the reasons for that are, number one,
10 ease of titration; is that right?

11 A. I do not recall having seen the phrase "ease of
12 titration" in the clinical guidelines for long-acting
13 opioids. It may be there, but I do not recall it, so I
14 can't say that's true or false.

15 Q. Okay. You would agree that all long-acting
16 opioids -- you would agree with the
17 Federal Trade Commission that all long-acting opioids
18 have the same mechanism of action; right?

19 A. Yes.

20 Q. And they have similar indications?

21 A. They have similar indications, and they have
22 some -- to some degree dissimilar contraindications.

23 Q. They have similar dosage forms?

24 A. That to me doesn't have a whole lot of content
25 because they have different dosage forms, but there's a

1 well-known formula for converting them from one to
2 another, and so if that's what it means, yes.

3 Q. And they have similar dosage frequency?

4 A. Yeah -- yes and no. They do have -- I don't
5 know what "similar" means. Some of them are once
6 every eight hours and some are once every twelve
7 hours.

8 Q. And would you agree with the
9 Federal Trade Commission that, as of this time, the
10 most significant of the oral long-acting opioids is
11 Purdue Pharma's OxyContin?

12 A. Where are we?

13 Q. Toward the bottom of the page, bottom quarter
14 of the blown-up part.

15 A. Oh, they're saying that OxyContin was the most
16 important. At the time this was written, that was
17 true, yes.

18 Q. And it goes on to say it's four times -- in
19 referring to OxyContin, it's four times larger than
20 Avinza and Kadian combined?

21 A. I -- I mean, I don't know whether that's true
22 or not in -- at the beginning of 2009. You could
23 actually see if it was true from looking at my report
24 because the data are all in my report, but I don't have
25 them memorized.

1 Q. Do you agree with the Federal Trade Commission
2 that a fourth product, Endo Pharmaceuticals' Opana ER,
3 also competes in this market?

4 A. I believe that it competes with those drugs. I
5 do not believe they're all in the same relevant
6 market.

7 Q. So you disagree with the
8 Federal Trade Commission's relevant market conclusion
9 in this case?

10 MR. MEIER: Your Honor, I'm going to object.
11 It doesn't say "relevant market" in this document. I
12 don't know why Mr. Hassi's interpreting the FTC's
13 statement. It says "the market," not "the relevant
14 market."

15 JUDGE CHAPPELL: Response?

16 BY MR. HASSI: I'll drop the word "relevant."

17 BY MR. HASSI:

18 Q. Do you disagree with the
19 Federal Trade Commission's conclusion about what the
20 market -- that there is a market for long-acting
21 opioids?

22 A. I do not believe there is a relevant antitrust
23 market for long-acting opioids. I believe that the
24 common parlance use of the word "market" in the
25 industry is used to apply to all long-acting opioids,

1 but it's not a relevant antitrust market.

2 Q. Do you believe that the
3 Federal Trade Commission in weighing in on this merger
4 was doing something other than determining a relevant
5 antitrust market?

6 A. I don't think the relevant market at issue
7 here was opioids. I think that they were concerned
8 about the pharmacies.

9 So I don't know what the relevant market in
10 this case was just from reading this, and I don't
11 remember what it was.

12 Q. I'm sorry. You think they were concerned about
13 pharmacies in this review of a merger of two drug
14 companies?

15 A. I said I don't know what they were concerned
16 about. All right?

17 So I don't know what relevant market they --
18 and if they did define the relevant market as all
19 long-acting opioids, then I would disagree with it.

20 Q. Okay. You can take that down, please.

21 Sir, you acknowledge that the settlement
22 agreement between Endo and Impax was only
23 anticompetitive if Endo had monopoly power?

24 JUDGE CHAPPELL: Hold on a second.

25 Are you finished asking him about product

1 market?

2 MR. HASSI: Yes, Your Honor.

3 JUDGE CHAPPELL: I have a question -- two
4 questions.

5 Yesterday you told us you had determined the
6 product market to be basically this one drug,
7 Opana ER?

8 THE WITNESS: Oxymorphone ER.

9 JUDGE CHAPPELL: All right. Was that
10 suggested to you or was that your determination
11 independently?

12 THE WITNESS: That was completely me.

13 JUDGE CHAPPELL: And do you have a point in
14 time in which you say that is the product market? For
15 example, is it today? Was it 2010? What date was or
16 is that the product market?

17 THE WITNESS: Actually, it's the whole period.
18 I do say that in my report. It's from soon after the
19 introduction of Opana ER to the present that's been the
20 relevant market.

21 JUDGE CHAPPELL: Okay. And based on some
22 answers you gave about the previous screen, you said at
23 the time the LAO market would be defined that way.

24 You understand, based on what I heard here in
25 this courtroom, Opana ER was on the market at the time

1 this was published.

2 THE WITNESS: Yes. No. I agree with you, that
3 the -- the -- the -- of interest in this case of course
4 is what was the relevant market in June of 2010 going
5 forward, but it was -- not only was it on the market in
6 January of 2009, it was -- it had already achieved
7 considerable commercial success. It was in the middle
8 of a big growth spurt, so two thousand and -- the
9 circumstances wouldn't be any different in January of
10 2009 than they were in June of 2010.

11 JUDGE CHAPPELL: And just so we're clear,
12 you're saying that no one on FTC staff suggested to you
13 what the product market should be in this case.

14 THE WITNESS: I'm the one who determines what
15 the product market is.

16 JUDGE CHAPPELL: Because I heard you yesterday
17 say that certain exhibits were provided or
18 calculations were provided to you by FTC staff;
19 correct?

20 THE WITNESS: I instruct the FTC economists,
21 not the lawyers, the economists, what kinds of data
22 collection I want them to do. I -- the -- in my -- the
23 exhibits in my expert report were actually prepared by
24 the economists at the FTC, but I was the one who told
25 them what to do.

1 JUDGE CHAPPELL: Are you familiar with any
2 antitrust case where a relevant product market has been
3 defined as one drug?

4 THE WITNESS: Oh, yes. It's common.

5 I mean, it's not always true. In fact, if we
6 were going to -- if this case were about
7 extended-release morphine, it would probably contain
8 several branded drugs. I don't know that for sure
9 because I haven't done the analysis.

10 But it depends -- the degree to which there's
11 competition across brand name drugs depends on the
12 facts. It has to do with what's actually happening on
13 the ground. It's not theoretical.

14 So, for example, in the GlaxoSmithKline case,
15 the three protease inhibitors that were at issue in
16 that case were all part of the same relevant market.
17 They actually engaged in price competition against each
18 other.

19 So it's all about the facts, do they actually
20 engage in sufficient price competition to produce
21 competitive pricing. That's the -- that is the
22 empirical fact that determines whether things are in
23 the same market. And sometimes there's price
24 competition across different kinds of drugs and --
25 brand name drugs, and sometimes there isn't.

1 JUDGE CHAPPELL: All right. And I just heard
2 you say it's all about the facts, and this is why I
3 asked you if you had made a determination of a point in
4 time that you define the market, the product market.

5 Have you factored into your analysis the facts
6 as we've heard them in this case, for example, that
7 Opana ER is no longer available, for example, that the
8 crushproof alternative has been ordered off or
9 recalled from the market? Have you considered these
10 things in your definition of the product market, these
11 facts?

12 THE WITNESS: Yeah. The --

13 JUDGE CHAPPELL: Well, let me ask you some --
14 you said yes. You said yes. That's what I wanted to
15 hear.

16 I'd like to know how those changed or did not
17 change your analysis, those facts I just mentioned.

18 THE WITNESS: They don't change the market
19 definition. They will change the degree of market
20 power of --

21 JUDGE CHAPPELL: The drug that's available to
22 patients being available or not available, you're
23 telling me that does not change your analysis as you
24 defined the product market.

25 I want to make sure. Is that correct?

1 THE WITNESS: Yeah. Market definition --

2 JUDGE CHAPPELL: You said yes?

3 THE WITNESS: Market definition --

4 JUDGE CHAPPELL: Hold on, hold on.

5 The fact that a drug is available or not
6 available, you're telling me that does not change your
7 analysis of the product market.

8 THE WITNESS: The fact that one member of the
9 market no longer is in it doesn't change the
10 definition of the market. It changes the degree of
11 competition in the market, but it doesn't change the
12 definition of it.

13 The market is oxymorphone ER, and there's still
14 a drug on the market that's oxymorphone ER, and that's
15 Impax, so it's gone from two drugs to one drug, but the
16 market is still oxymorphone ER.

17 JUDGE CHAPPELL: All right. Go ahead.

18 BY MR. HASSI:

19 Q. Sir, with respect to market power, you would
20 acknowledge that the settlement between Endo and Impax
21 was only anticompetitive if Endo had market power;
22 correct?

23 A. Substantial market power.

24 Q. I want to talk now about the development and
25 co-promotion agreement.

1 You agree that Endo received a series of rights
2 related to a drug called IPX --

3 JUDGE CHAPPELL: Hold it. Before you ask that,
4 I -- sorry -- I have one follow-up. I was pondering
5 what he had just told me.

6 Did you factor in the fact that, as we've heard
7 in this trial -- and there's been no determination
8 whether right or wrong -- the only reason that a
9 patient can even get a prescription of this drug is
10 because of the agreement the parties formed in this
11 case, when you defined the market?

12 Does it matter to you that the product is
13 available only because of the agreement?

14 THE WITNESS: I don't agree that it's
15 necessarily only available because of the agreement,
16 no.

17 JUDGE CHAPPELL: Are you aware of the current
18 state of the market for this drug?

19 THE WITNESS: Yes, I am.

20 JUDGE CHAPPELL: And so you disagree with that,
21 what I just said?

22 THE WITNESS: No. If Impax had never come on
23 the market, then Endo would have had an incentive to
24 introduce a version of original formulation of
25 Opana ER when they knew that the FDA was considering

1 withdrawing Opana ER reformulation, and that -- they'd
2 known that -- they knew that for a long time before it
3 was withdrawn.

4 So Endo's strategy about whether they want to
5 stay -- they want to bring original oxymorphone ER
6 back is affected by whether Impax is in the market.
7 They've chosen not to come back because they don't want
8 to compete with a generic, but if no generic had
9 existed, they would have had an incentive to stay in
10 the market with the original formulation.

11 JUDGE CHAPPELL: Okay. You're giving me I
12 guess economic theory talking about incentives, but you
13 don't know for a fact that Endo would have come on with
14 a generic, do you?

15 THE WITNESS: We haven't had any -- we have no
16 discovery at all about Endo's plans in the last year,
17 so we just don't have any information about that. But
18 I'm saying that the proposition that we know for
19 certain that the product wouldn't exist now, that's not
20 correct. We just don't know the answer to that
21 question.

22 JUDGE CHAPPELL: But on the other hand, you
23 don't know, for example, to use your words, that the
24 product would exist now, do you?

25 THE WITNESS: No. I said we just don't know.

1 It's uncertain. We simply -- we can't say for a
2 certainty that anything would have happened.

3 JUDGE CHAPPELL: Well, we can say for certain
4 what is existing at the moment; correct?

5 THE WITNESS: Pardon?

6 JUDGE CHAPPELL: We can say for certain what's
7 happening right now, what we do know.

8 THE WITNESS: What we do know now is Impax is
9 the only drug on the market. What we don't know is, if
10 Impax had never entered, what would Endo have done when
11 it realized there was a problem with the reformulation
12 of Opana ER. They -- that their decision about what to
13 do about that, we just don't know why they did what
14 they did, and we don't know what they would have done
15 had there been no Impax on the market.

16 JUDGE CHAPPELL: Well, you agree with me what
17 we do know, but I think you just told me there's a
18 heckuva lot more we don't know than what you just said.
19 There is so much we don't know, we don't have a clue,
20 do we?

21 THE WITNESS: Well, no. I think we have a
22 clue, but you're right, there's a lot we don't know. I
23 mean, I'm not -- I'm not at all trying to convey the
24 information I know what would have happened. I'm just
25 saying that anybody who asserts that they know for

1 certain what would have happened, I don't think they
2 know what they're talking about. All right.

3 Nobody really knows what the world would look
4 like today if a year ago Endo had realized it was -- it
5 was in trouble with reformulated Opana ER and there was
6 nobody else in the market.

7 JUDGE CHAPPELL: Exactly.

8 But what we do know is what the world does look
9 like today; correct?

10 THE WITNESS: That's the only thing we know,
11 which is a world in which Impax is there. And we don't
12 know what the world would look like if Impax wasn't
13 there.

14 JUDGE CHAPPELL: All right.

15 BY MR. HASSI:

16 Q. I want to ask a couple of follow-up questions
17 about that.

18 First of all, you would agree that the reason
19 Impax is able to be on the market today is because they
20 settled with Endo back in 2010; correct?

21 A. I don't know that, and you don't know that.
22 You have arguments why you think that's true, but it's
23 certainly not a certainty that Impax would not be on
24 the market without the settlement agreement.

25 Q. I'm saying with the settlement agreement.

1 A. Yes.

2 Q. Impax settled and in that settlement got a
3 broad patent license; correct?

4 A. The settlement agreement said they could come
5 on the market in January of 2013. If there had been no
6 settlement agreement, we do not know -- it is
7 incorrect to assert they would never have been on the
8 market.

9 Q. You're not listening to my question, sir.

10 My question was, Impax is on the market today
11 as a direct result of the settlement it entered into
12 with Endo. Do you disagree with that?

13 A. I disagree with that.

14 Q. Okay. And with respect to whether Endo would
15 have come back on the market after introducing
16 reformulated, you are aware, sir, that Endo told the
17 Food and Drug Administration that Opana ER was unsafe;
18 correct?

19 A. They did tell them that, and the FDA rejected
20 that.

21 Q. And you believe that Endo would have started
22 marketing a drug again that it had publicly said in
23 court filings was unsafe; is that your testimony?

24 A. They -- their claim that it was unsafe we now
25 know retrospectively was false in the sense that

1 however unsafe it is, it's less unsafe than the
2 reformulated version.

3 Q. Do you know whether Endo is facing significant,
4 bet-the-company products liability litigation over
5 Opana ER today, sir?

6 A. No. I know the existence of this, but I don't
7 know anything about it.

8 Q. And do you think that a company beset by that
9 kind of litigation would introduce a drug that it had
10 previously said publicly was unsafe?

11 A. I do not know. We don't have information
12 about that. There are benefits and costs. There's a
13 bunch of considerations. We don't know what the
14 outcome of that would be. And I'm not going to -- I'm
15 not going to try to reach a judgment or forecast or
16 prediction about that because I don't have enough
17 information to do it.

18 Q. Okay. Let's talk about the development and
19 co-promotion agreement.

20 You agree that Endo received a series of rights
21 related to IPX-203 under the development and
22 co-promotion agreement; right?

23 A. I agree.

24 Q. And you include the \$10 million that Endo paid
25 Impax as part of that agreement in your calculation of

1 whether Impax received a large payment; correct?

2 A. Yes. On the -- on the dimension of was it
3 large, yes.

4 JUDGE CHAPPELL: I thought I heard him say that
5 he didn't have an opinion regarding that agreement,
6 that part of the agreement.

7 MR. HASSI: I think he's going to say it again,
8 Your Honor.

9 BY MR. HASSI:

10 Q. Sir, you testified you do not have an opinion
11 on the value of the development and co-promotion
12 agreement to Impax; right?

13 A. I have not done an analysis of whether -- on
14 the dimension of whether it was justified. I have not
15 done that analysis, and so that involves trying to
16 evaluate how -- what it's worth.

17 Q. You offer no opinions in this case related to
18 the value of the development and co-promotion agreement
19 to Impax; correct, sir?

20 A. That's correct.

21 Q. And you're not offering any opinions in this
22 case about the value of the development and
23 co-promotion agreement to Endo; correct?

24 A. I have not addressed the issue of its value.

25 Q. And so you're not offering any opinion as to

1 whether Endo overpaid for the bundle of rights it got
2 in the development and co-promotion agreement; right?

3 A. I'm not offering any opinion about whether the
4 payment was justified or not, whether there was
5 overpayment or not.

6 Q. You relied on Dr. Geltosky for a detailed
7 analysis of the degree to which the \$10 million payment
8 and co-development deal represented the acquisition of
9 an asset that was approximately valued at a \$10 million
10 price?

11 A. Yes, in the sense that was his responsibility.
12 His responsibility was to analyze that part of the
13 transaction.

14 Q. And you agree that if Dr. Geltosky did not
15 offer any opinion as to what the market price for the
16 profit-sharing rights that Endo acquired under the
17 development and co-promotion agreement would be, then
18 we can pull the \$10 million out of this case; correct?

19 A. No. I wouldn't say that.

20 I mean, you know, you're trying to say that he
21 has to estimate a price in order to know whether it was
22 justified, and I don't think that's true. But,
23 you know, if he didn't -- if he didn't provide a
24 sufficiently well-documented rationale for the
25 conclusion that the payment was unjustified, then you

1 would pull it out of the case.

2 Q. Isn't justification tied to value; sir?

3 A. Yes. But you don't have to estimate the price
4 in order to reach a conclusion about that.

5 Q. Well, you understood Dr. Geltosky to say the
6 development and co-promotion agreement was valueless;
7 right?

8 A. I don't remember whether that's the conclusion
9 I reached from his report. His report would have to
10 speak for itself. I just -- I -- I have not -- I
11 haven't thought about it for two months, so I don't
12 remember what his specific conclusion was.

13 Q. Do you recall testifying that you understood
14 him to say that the agreement was valueless?

15 A. I -- I -- at the time I took my deposition, I
16 had just read the report, so I probably had it more
17 fixed in my mind than I do now. I don't recall whether
18 he had that conclusion, but if I said it then, it
19 probably reflected my view of what was in the report at
20 the time.

21 Q. Okay. Well, if Dr. Geltosky testified in this
22 courtroom earlier -- was it earlier this week or last
23 week? -- testified in this courtroom that he didn't
24 have any opinion at all as to the actual value of the
25 DCA, would that change your reading of his report?

1 A. I -- I -- I would have to see what he actually
2 said. Conceivably, yes.

3 JUDGE CHAPPELL: Wait a minute.

4 Why don't you just answer based on the facts
5 you were given. Can you not do that?

6 THE WITNESS: Because I'm not sure that the
7 characterization of it is complete. I don't know what
8 he said in his testimony, so I don't know whether his
9 testimony supports that statement or not.

10 JUDGE CHAPPELL: Just listen to the question
11 you're asked. He's not asking you to admit or deny any
12 factual matter. He's asking you for an answer based on
13 the information he's giving you, so listen to the
14 question and see if you can answer it.

15 MR. MEIER: Your Honor, if I -- may I make an
16 objection for a moment because --

17 JUDGE CHAPPELL: You're objecting to what I
18 just said?

19 MR. MEIER: No.

20 JUDGE CHAPPELL: I'm overruling that.

21 Go ahead.

22 MR. MEIER: No. To Mr. Hassi's question. Not
23 at all. But to Mr. Hassi's question because what
24 Mr. Hassi is doing is he's taking selective portions of
25 what --

1 JUDGE CHAPPELL: All right. I don't want you
2 to be coaching your witness. Hold on right there,
3 Counselor. Before you say anything else, do not coach
4 this witness, because he's sitting right there
5 listening to you.

6 MR. MEIER: I'm not coaching the witness,
7 Your Honor. I'm making a rule -- federal rule of
8 evidence 106 objection, the rule of completeness.

9 JUDGE CHAPPELL: That's why we have redirect.
10 This is an expert witness, well-paid. He can handle
11 this. That's overruled.

12 MR. MEIER: Okay. Thank you, Your Honor.

13 BY MR. HASSI:

14 Q. Sir, let me -- I'm going to read you what --

15 JUDGE CHAPPELL: This is not a lay witness
16 who's never been in trial before. We don't need to
17 protect this witness. He knows what he's doing.

18 MR. MEIER: That's right, Your Honor. But I
19 want to make my objection for the record on federal
20 rule of evidence 106.

21 JUDGE CHAPPELL: Thank you.

22 BY MR. HASSI:

23 Q. Sir, let me read you what Dr. Geltosky said in
24 this case.

25 The question was: "So you don't have any

1 opinion at all as to the actual value of the DCA to
2 Endo at the time it was executed; correct?"

3 His answer was: "That's correct."

4 With that foundation, does that change your
5 reading of his report?

6 A. No. I mean, that -- that statement, if that's
7 all he said, would say that he didn't have an opinion
8 about whether it was unjustified. And if he doesn't
9 have an opinion about whether it's unjustified, then I
10 would not include the \$10 million as part of the large
11 payment that was unjustified.

12 Q. So based on that statement, would you agree you
13 don't have an opinion as to whether or not the
14 \$10 million is unjustified?

15 A. I said, if that's all he said, then you can --
16 it would be pulled out.

17 JUDGE CHAPPELL: All right. He's answered your
18 hypothetical or whatever it was. Move along.

19 BY MR. HASSI:

20 Q. I want to talk now about the authorized generic
21 provision.

22 Sir, you believe that if Impax would have
23 launched at risk, Endo would have launched an
24 authorized generic; is that right?

25 A. I'm sorry. You said it as a certainty?

1 Did you say they would have?

2 Q. I did say "would have."

3 A. Yeah. Okay. I -- I do not have an answer to
4 the question whether for certain they would have
5 authored -- launched an authorized generic. That
6 wasn't my -- the conclusion of my analysis of that
7 issue.

8 Q. You reviewed some Endo forecasts where Endo
9 considered launching an authorized generic; is that
10 right?

11 A. Among other things, yes.

12 Q. And those forecasts were assuming a generic
13 launch at risk; is that right?

14 A. Those -- some of them were assuming a generic
15 launch at risk, yes. Some of them were analyses that
16 were later in the game where the launch might not have
17 been at risk. It might have been after the court
18 decision, appeals court decision.

19 So yes, in some cases it's at risk.

20 Q. But in all cases, the assumption by Endo that
21 it would launch an authorized generic was in response
22 to entry by another generic; right?

23 A. The launching of an authorized generic would
24 only happen if Impax or some other firm had launched a
25 generic version, yes. You don't launch an authorized

1 generic unless the first filer has launched and then
2 this is a strategy for minimizing the damage from the
3 first filer's launch.

4 Q. And those assumptions about the need to launch
5 an authorized generic go away in the event of an Impax
6 settlement with a licensed entry date; is that right?

7 A. That's -- that's precisely right. That's what
8 the -- what they negotiated was a promise not to enter
9 with an authorized generic if Impax agreed to the
10 January 2013 launch date.

11 Q. Well, setting aside the no-authorized-generic
12 provision in the settlement, you'd agree that Endo did
13 not plan on launching an authorized generic if Impax
14 didn't enter; right?

15 A. Of course. If Impax doesn't enter, then
16 there's no generic competition and there's no reason to
17 launch an authorized generic.

18 Q. Endo's plan was to reformulate the drug and
19 launch a new version of Opana; right?

20 A. That was their plan.

21 Q. And you read the testimony of Endo's executives
22 who testified that Endo had no intention of launching
23 an authorized generic; is that right?

24 A. They had no intention of launching an
25 authorized generic if their reformulated product was on

1 the market.

2 Q. And you agree that Endo would not have both
3 moved the market to a reformulated and launched an
4 authorized generic; correct?

5 A. I'm sorry. I couldn't follow you.

6 Q. You agree that Endo would not have both
7 launched a reformulated and moved the market to
8 reformulated Opana ER and launched an authorized
9 generic; correct?

10 A. I think that's just exactly what I said in
11 answer to your last question.

12 Q. And you're aware that Endo never did launch an
13 authorized generic; correct?

14 A. Well, of course. They agreed not to.

15 Q. Well, they didn't launch an authorized generic
16 ever, even after the end of the agreement; right?

17 A. That's true.

18 And that's not when you do it. You do it
19 during the first filer 180-day period. You don't --
20 there's no point to having an authorized generic later
21 because the price is so low, it's not worth it.

22 Q. You're not offering any opinion as to whether
23 Endo would have actually launched an authorized
24 generic; correct?

25 A. No.

1 Q. Sir, in your report, in footnote 276 on
2 page 105, you give a formula for expected value;
3 right?

4 A. That's correct.

5 Q. And expected value is the probability-weighted
6 sum of the values of all possible outcomes; is that
7 right?

8 A. That's correct.

9 Q. And you didn't calculate an expected value to
10 Impax of the authorized generic at the time of
11 settlement; correct?

12 A. Well, yes and no. I mean, I did -- I didn't
13 calculate an expected value of all the branches on the
14 decision tree as of the signing of the agreement. I
15 did have a calculation in there about what the --
16 putting boundaries on the probabilities that would
17 cause this -- the -- the settlement agreement terms to
18 be large.

19 Q. Sir, you didn't calculate probabilities;
20 right?

21 A. I didn't calculate probabilities of events in
22 the -- in the -- in the decision tree in all the -- all
23 the contingent outcomes.

24 Q. So, for example --

25 A. I did calculate boundaries on probabilities for

1 various purposes.

2 Q. So, for example, you didn't calculate the
3 probability that Endo would launch an authorized
4 generic; right?

5 A. Of course not.

6 Q. And so using your --

7 A. That's impossible.

8 JUDGE CHAPPELL: Hold it, hold it. Let him
9 finish. I know there was a pause, but he wasn't
10 finished.

11 MR. HASSI: Understood, Your Honor.

12 BY MR. HASSI:

13 Q. Did you finish, sir?

14 A. Yeah. I just said it's impossible. I didn't
15 do anything that's impossible.

16 Q. And so you did not calculate an expected value
17 to Impax of an authorized generic at the time of
18 settlement; correct?

19 A. I did not multiply the outcome by a
20 probability. I know what the outcome -- what they
21 thought the outcome was going to be, but I didn't
22 multiply it by the probability they'd do it because I
23 have no way of estimating that probability.

24 Q. When you say they thought they knew what the
25 outcome is going to be, who are you referring to?

1 Who's the "they"?

2 A. Endo.

3 Endo had an estimate of what it believed would
4 happen to them if Impax launched and then another
5 estimate of how the loss to Endo could be reduced by
6 launching an authorized generic, so they have those
7 calculations.

8 And then in order to get the expected value of
9 the authorized generic, you'd have to multiply the
10 benefits of the authorized generic times the
11 probability that they would actually launch. And that
12 last step, which is to estimate the probability, as far
13 as I know, no one has done, and I certainly haven't
14 done it.

15 Q. And those were Endo calculations you're
16 referring to; right? Not Impax calculations; right?

17 A. I just said -- I thought I said Endo. If I
18 didn't, I meant Endo.

19 Q. You did.

20 My point is, you didn't calculate the values to
21 Impax of the no-authorized-generic based on Impax
22 calculations, did you?

23 A. Actually, they do have similar financial
24 studies of the difference to Impax if an authorized
25 generic is launched and if one is not. They have

1 similar calculations to Endo's. And again -- but I
2 didn't multiply those estimates by probabilities.

3 Q. And to be fair, none of those documents you're
4 referring to are estimates in the context of
5 settlement; right? Those are just normal forecasts
6 you're looking at and extrapolating from?

7 A. That's right. Because in the context of
8 settlement you wouldn't be bothered estimating the
9 value of your product under the circumstance of an
10 authorized generic because it had already been ruled
11 out.

12 Q. So you'd agree that Impax never calculated, in
13 connection with the settlement, the value to Impax of
14 the no-authorized-generic term; correct?

15 A. Well, they -- they had -- they knew what the
16 value of an authorized generic -- what the impact of an
17 authorized generic on them would be at the time they
18 were negotiating the settlement.

19 Q. Sir, my question was, at the time they were
20 negotiating the settlement, you didn't see Impax making
21 any calculations of the value of the
22 no-authorized-generic term in the settlement to Impax;
23 correct?

24 A. There's no -- there's no number that they
25 assigned to that provision in the settlement agreement,

1 but there's numbers that directly relate to it that
2 they have.

3 Q. There's no calculation, sir -- can you point to
4 any calculation performed by Impax, at the time it was
5 negotiating the settlement, in which Impax valued the
6 no-authorized-generic to it in connection with the
7 settlement?

8 A. Oh, I don't know how to answer it other than
9 the way I did.

10 They knew what the effect on them of a
11 no-authorized-generic -- of an -- excuse me. They knew
12 what the impact on them would have been had an
13 authorized generic been launched. There is no document
14 that then translates that estimate into a valuation of
15 the settlement, but they already have the number that
16 would go into such a document.

17 Q. So your testimony is, if I understand it
18 correctly, you didn't see any documents, but you know
19 that they knew the value of a no-authorized-generic?
20 Do I have that right?

21 A. They have documents that estimate the effect
22 on their sales and profits of entry by an authorized
23 generic. That's all -- and I -- I'm not saying
24 anything about what's in their head because I don't
25 know what's in their head, but they -- that's -- that's

1 the information they had, was that it was the result of
2 that forecast.

3 Q. And none of those forecasts were in connection
4 with the settlement; correct?

5 A. I don't know whether any of those forecasts
6 were done to inform the settlement negotiations or not.
7 They're just there.

8 Q. They're just there, meaning they're among the
9 hundreds of thousands of documents that Impax produced;
10 right?

11 A. Well, there's not hundreds of thousands that
12 are contemporaneous to the negotiations of the
13 settlement. If we talk about what information that
14 they produced in, you know, 2010, the first half of
15 2010, it's not hundreds of thousands. It's less than
16 that.

17 But yeah, it's among -- it's among the --
18 it's -- this -- these forecasts are part of the
19 information that is being produced by the financial
20 analysts inside Impax. And whether those people were
21 talking to the -- whether the settlement negotiation
22 people were paying any attention to that I can't
23 possibly answer.

24 Q. Let's talk about the entry date.

25 A. I'm sorry. The what?

1 Q. The entry date.

2 A. Okay.

3 Q. You would agree that if Impax could not reach a
4 settlement with Endo, its options were to continue the
5 litigation or withdraw; correct?

6 A. Yes.

7 Q. And you're not offering any opinion about
8 whether a hypothetical alternative settlement with an
9 earlier entry date would have been feasible for Impax;
10 correct?

11 A. Well, feasibility -- there are other
12 settlement agreements that in principle could have
13 been feasible, but they weren't considered, as far as I
14 know.

15 I mean, the feasibility is sort of something
16 about what's in the set of things that both parties
17 would have found in their interests to negotiate and
18 that they didn't actually actively consider -- well, it
19 wasn't obvious they -- they were anywhere near close to
20 agreeing on anything other than what came out.

21 Q. Sir, you're not offering an opinion in this
22 case as to whether a hypothetical alternative
23 settlement with an earlier entry date would have been
24 feasible between Impax and Endo, are you?

25 A. No. I mean, I -- what I'm saying is,

1 feasibility as an economic concept is the range of
2 possible bargaining outcomes. But as I said, I'm not
3 aware that they actually came anywhere near agreeing on
4 anything other than what they agreed to.

5 Q. And you didn't delve into that range of
6 possible bargaining outcomes; correct?

7 A. I don't have -- I don't have it characterized,
8 no.

9 Q. Now, you would agree that it doesn't matter to
10 your opinions as to whether it was actually feasible
11 for the parties to agree to a settlement without a
12 payment; correct?

13 A. No, it doesn't. The nonexistence of a feasible
14 procompetitive settlement agreement does not justify an
15 anticompetitive settlement agreement, so it just
16 doesn't matter.

17 JUDGE CHAPPELL: Was that a statement of law
18 right there?

19 THE WITNESS: No. That's from the -- from my
20 perspective as an economist, that -- that -- whether a
21 settlement agreement is anticompetitive does not
22 depend upon the feasibility of a procompetitive
23 agreement.

24 That whether -- whether an agreement is
25 anticompetitive is whether it causes anticompetitive

1 harm, and that has nothing to do with whether they
2 could have agreed to a settlement without a reverse
3 payment.

4 JUDGE CHAPPELL: Can we get back onto the main
5 road here?

6 MR. HASSI: I'm happy to, Your Honor.

7 BY MR. HASSI:

8 Q. Sir, you've not seen any direct evidence that
9 Endo was willing to offer Impax an earlier entry date
10 than January 1, 2013; correct?

11 A. I'm not aware of any serious consideration of
12 anything before then, no. I think Endo had decided it
13 wanted something quite near the beginning of the
14 tolling of the 180-day period and the issue -- what
15 they were really negotiating over was the price as
16 opposed to when the date would be.

17 Q. And you believe that based on your review of
18 the Impax and Endo documents; is that your testimony?

19 A. Well, yes. And the fact that, you know,
20 that -- remember when they tried for the trigger for an
21 earlier entry and there was a debate about whether it
22 would be March or January. It -- you know, what I
23 inferred -- I don't know what Endo would have been
24 willing to accept as the worst possible agreement for
25 them that they would have been willing to accept. I

1 don't know. There's no evidence about that, and I --
2 you know, so I don't know what that is.

3 But the -- the record of the negotiations
4 that's in -- that's in the discovery documents is that
5 there wasn't really any serious negotiation, other than
6 whether it's going to be January or March, about what
7 the entry date was going to be. That wasn't the main
8 focus of the negotiations.

9 Q. You base what you thought the main focus of
10 the negotiation was based on your reading of some
11 documents that were produced in this litigation; is
12 that right?

13 A. The documents plus the depositions of the
14 parties.

15 Q. And in the depositions of the parties, you
16 understand that the Impax witnesses all testified that
17 their primary goal was an early entry date; right?

18 A. Yes. They wanted -- they wanted to get in --
19 of course. A generic always want to get in as soon as
20 possible. The brand name always wants the generic to
21 come in as late as possible. And then the issue is,
22 okay, associated with every one of these entry dates is
23 how much it's going to cost, right, what are the other
24 terms going to be.

25 And Impax' attempt to get an earlier date met

1 with complete resistance, so my -- my expectation was
2 that, you know, based -- my inference that I draw from
3 reading this material is that the main thing to be
4 negotiated was -- were the other terms, not the -- the
5 entry date was pretty much just fixed within a couple
6 of months.

7 Q. So you're not offering any opinion as to
8 whether Impax would have launched at risk; correct?

9 A. I do not know whether they would have launched
10 at risk. I have -- I can't estimate that probability.
11 I don't know how to estimate it.

12 Q. You believe that's irrelevant to your
13 analysis?

14 A. Actually, no, I do not believe that knowing
15 whether they would have launched at risk is relevant to
16 my analysis. No, all of these probabilities are
17 irrelevant to whether the settlement agreement is
18 anticompetitive.

19 JUDGE CHAPPELL: So you were asked if it's
20 irrelevant and you said no. Did you mean yes?

21 THE WITNESS: I'm not sure. Did I -- did I
22 misinterpret the sentence, the question?

23 BY MR. HASSI:

24 Q. My question, sir, was, it's irrelevant to your
25 analysis; correct?

1 A. The probabilities are irrelevant to my
2 analysis, yes.

3 Q. And so you've not attempted to estimate those
4 probabilities.

5 A. That's false. If I could estimate them, I
6 would. But it's not possible to do anything other than
7 put bounds on them.

8 Q. So you haven't estimated them; correct?

9 A. It's -- you can't estimate them. It's -- yes.

10 Q. And --

11 A. I haven't estimated anything that's impossible
12 to estimate.

13 Q. You're not offering any opinion as to when
14 Impax would have launched at risk; correct?

15 A. I'm not offering any opinion that they would
16 have launched at risk for sure, and I've not tried to
17 come up with a date for sure when they would have done
18 that because I don't know.

19 Q. And you've not done any economic analysis to
20 determine whether, from Impax' perspective, launching
21 at risk was a good idea or a bad idea from Impax'
22 perspective; correct?

23 A. I have not attempted to estimate what the
24 profitability of launch at risk for Impax would be.
25 No.

1 Q. You're not offering the opinion that it would
2 have been economically rational for Impax to launch at
3 risk; correct?

4 A. I am not offering the opinion that for certain
5 it would have been in their interest to do anything.

6 Q. Now, yesterday, you offered four possible
7 dates when Impax could have launched as possibilities;
8 right?

9 A. Right.

10 Q. And the first of those was at the end of the
11 30-month stay in June of 2010; correct?

12 A. Yes.

13 Q. And that would be a launch at risk; correct?

14 A. It would be launch at risk.

15 Q. And you're aware that Impax had told the judge
16 who was hearing the case between Impax and Endo that it
17 would not launch at risk during trial; correct?

18 A. During the trial, yes, which -- but that
19 statement was made after the negotiations began, so
20 yes.

21 Q. You believe that statement was made after the
22 negotiations began?

23 A. I believe so. Yes. Negotiations began in --
24 the very first negotiations were in the fall of
25 2009.

1 Q. So while it was possible that Impax would
2 launch at risk, given that it had told the judge it
3 would not launch at risk, it's not a very plausible
4 scenario; correct?

5 A. I don't know whether they would -- well, I
6 don't know what the -- I -- I'm not going to make any
7 guess about how much of a commitment that is because I
8 just don't know.

9 Q. It's not your area of expertise; right?

10 A. Well, it's not an area of expertise. It has to
11 do with how much did Impax believe that that
12 statement -- did the lawyers actually know what they
13 were talking about, did they -- was that really
14 something of a commitment. I just don't know. There's
15 no information available about that.

16 Q. Now, the second date you hypothesized was a
17 potential date for Impax to launch at risk was after a
18 decision by the district court; correct?

19 A. That's correct.

20 Q. And that would have to be a decision in favor
21 of Impax; right?

22 A. Well, it would still be a launch at risk.
23 They could still launch at risk even with an
24 unfavorable decision, depending on the nature of the
25 decision, but I certainly -- it's much more likely they

1 would have launched if the decision were favorable than
2 unfavorable.

3 Q. So you consider it a possibility that they
4 would have launched at risk after losing in the
5 district court and being enjoined by the district
6 court?

7 A. It certainly reduces the likelihood that they
8 would introduce, but it -- they would launch, but it --
9 you know, if the decision had an obvious mistake in it,
10 they still might have done it.

11 So -- but I think that -- I think I testified
12 before already that it's far more likely that they
13 would have launched at risk if they had received a
14 favorable decision.

15 Q. But even if it were a favorable decision, it
16 would be a launch at risk; right?

17 A. It's always a launch at risk until the case is
18 completely terminated.

19 Q. And you're not offering an opinion as to
20 whether or not Impax would have won at the district
21 court level; right?

22 A. No. It doesn't matter what the probability
23 that they would win was.

24 Q. A third date you offered was after a decision
25 in the Federal Circuit; is that right?

1 A. That's right.

2 Q. And that, too, would require Impax winning;
3 correct?

4 A. Well, there's -- there's a remand possibility
5 as well, so -- which is, we don't know who won yet.
6 Instead, we have to redo it.

7 So there is -- there's three outcomes that can
8 happen at the appeal, appeals court, and the most
9 likely one that's going to cause you to launch is you
10 win, the least likely that's going to cause you to
11 launch is you lose, and then there's the one in the
12 middle, which is you don't know yet because it has to
13 be redone.

14 Q. Are you aware of any drug company that has ever
15 launched at risk following a Federal Circuit court
16 decision against them?

17 A. I don't know. I'm -- I doubt -- I said it
18 gets -- it's unlikely, but -- but it's much more
19 likely you launch if you win than if you lose by far,
20 so...

21 Q. Now, you're not offering any opinion that any
22 of those launches would have occurred, just that
23 they're hypothetical possibilities; right?

24 A. I'm -- there's no certainty to anything. All
25 these things are just probabilistic. They may have

1 happened or they may not.

2 Q. And you acknowledge that if Impax had launched
3 at risk, it would be risking the benefits of its
4 180-day exclusivity?

5 A. That's one of the things that goes into the
6 calculation, is the possibility you'd lose part of the
7 180-day exclusivity. Or even all of it.

8 Q. You're aware that Impax' expert, a patent
9 lawyer named Mr. Figg, has suggested that launches at
10 risk are rare?

11 A. Yes.

12 Q. And you disagree with that; right?

13 A. Well, since the term "rare" is vague, I said,
14 you know, I know that a lot of them happened, and I
15 produced a list of them, but I don't think -- I don't
16 think the word "rare" is the word I would use.
17 They're -- they're a low fraction of all cases, but
18 they happen with some frequency, and there's a lot of
19 them. There's several a year.

20 Q. And so you base your criticism on that list
21 that the Federal Trade Commission assisted you in
22 preparing?

23 A. The list that -- the exhibit in my report is
24 the basis for that, yes.

25 Q. And that's Exhibit 4 to your rebuttal report?

1 A. It -- I don't have the numbers memorized. I
2 think -- it sounds like it to me.

3 Q. What instructions did you give the
4 Federal Trade Commission in asking them to prepare that
5 report for you?

6 A. Give me a list of all the launches at risk
7 that you know about. Search the public information for
8 all the launches at risk we can find.

9 Q. And your report identified 48 at-risk launches;
10 is that right?

11 A. I believe that's the number. Yes.

12 Q. And that's 48 at-risk launches over a 15-year
13 period?

14 A. I believe that's correct. Yes. The document
15 speaks for itself.

16 Q. So that's roughly three at-risk launches a
17 year?

18 A. Approximately.

19 Q. And you don't know how many Hatch-Waxman cases
20 were brought in that time period; right?

21 A. I don't know. Most of those cases, I know
22 almost nothing about them because there isn't any
23 publicly available information about them.

24 Q. So you don't know, for example, whether any of
25 those launches at risk involved a company putting its

1 first-to-file exclusivity at risk; right?

2 A. I -- I'm -- there have been some launches by
3 Teva that I just know from the other facts that were at
4 risk and they were first to file. But if the -- if
5 the -- the more general point is right. Most of these,
6 I do not know where they were in the process. And
7 exactly what the circumstances were of the at-risk
8 launch.

9 Q. And in light of the fact that you don't know
10 how many Hatch-Waxman litigations are filed every year,
11 you don't know whether at-risk launches occur in
12 10 percent, 1 percent or even one-tenth of 1 percent of
13 all Hatch-Waxman cases, do you?

14 A. I don't know what the fraction is, but that's
15 not the right denominator.

16 Q. But you don't know what the right -- you don't
17 know the number that is the right denominator; right?

18 A. I know what the right denominator is and I
19 don't know what the number is. And the reason I don't
20 know the right denominator is because it's not all
21 Hatch-Waxman cases, it's a subset of those.

22 Q. But you don't know how many.

23 A. No, I don't know.

24 Q. And you mentioned Teva a minute ago.

25 Of the 48 examples of at-risk launches, you

1 would agree that 21 of 48 involved the company Teva;
2 right?

3 A. Involved what?

4 Q. Teva, T-E-V-A.

5 A. It involved a lot of them. Teva is by far the
6 most likely company to do at-risk launches. It does
7 them frequently.

8 Q. And with respect to small companies -- and I'll
9 define that as companies with less than a billion
10 dollars in revenue, like Impax -- over your 15-year
11 history, you identified four at-risk launches by small
12 companies; right?

13 A. Yes. Although I don't think the size of the
14 company has anything to do with it.

15 Q. The only at-risk launch involving Impax that
16 you located was actually done with Impax and Teva
17 together; right?

18 A. Jointly with Teva, yes.

19 Q. And you don't know, for example, whether Teva
20 shouldered the risk in that --

21 A. I don't know anything about that, the agreement
22 between Teva and Impax, if there was one. I don't even
23 know if there was an agreement.

24 Q. And so you didn't identify a single instance in
25 which Impax launched a product at risk without a

1 partner in 15 years; correct?

2 A. I do not know of any launches by Impax other
3 than the one with Teva.

4 Q. Let's talk now about the Endo credit.

5 You're familiar with that term?

6 A. Yes.

7 Q. Sir, you've not seen any documents indicating
8 that Impax put a dollar value on the Endo credit;
9 correct?

10 A. I -- I'm not aware of anybody attempting to
11 calculate its value, no.

12 Q. And you agree --

13 A. I shouldn't say it that way.

14 There are attempts to calculate its value
15 under certain circumstances, but I assume your
16 question was about the overall value of what's the
17 expected value. No one has attempted to calculate the
18 expected value. They've just -- there are some
19 examples of what it might be in the record and the most
20 obvious being the one that then showed -- ended up in
21 the financial report of Endo.

22 Q. Okay. So it was calculated after it was
23 reasonably probable and estimable and thus ended up in
24 Endo's financial report; right?

25 A. Yeah. Because the -- by the time they -- by

1 the time you get to early 2012, a lot of the
2 contingencies have been resolved, so the expected
3 value -- the range of possible values is much narrower
4 in early 2012 than it would have been in June of 2010,
5 so in order to estimate the value in June of 2010, you
6 would have had to estimate a much larger, longer list
7 of probabilities of outcomes.

8 Q. And as of June 2010, you had not seen -- you'd
9 not seen any Impax documents predating June 2010 in
10 which it estimated a value for the Endo credit;
11 correct?

12 A. That's -- there's no attempt to estimate what
13 the expected liability for Endo is under the Endo
14 credit, no.

15 Q. And likewise, there was no attempt to estimate
16 what the expected liability for Endo was done by Endo
17 prior to the settlement agreement; right?

18 A. That's just -- isn't that just what I said?

19 Q. My question asked you about Impax.

20 A. Oh, I'm sorry. I --

21 Q. So let me just ask --

22 A. Neither company -- neither company calculated
23 the expected value in June of 2010 of the Endo credit.

24 Q. You would agree that there was a possibility
25 that neither the Endo credit nor the no-AG provision

1 would have value to Impax; correct?

2 A. Yes. There's a -- there is a circumstance in
3 which that statement would be true.

4 Q. And the Endo credit was a contingent
5 calculation; right? It was contingent on certain
6 factors?

7 A. Whether the Endo credit would be paid or the
8 amount that would be paid depends on contingent
9 events.

10 Is that -- I'm trying to be responsive. Is
11 that what you meant?

12 Q. That is what I meant.

13 A. Okay.

14 Q. Thank you for that clarification.

15 A. Yeah.

16 Q. And you'd agree that those factors, those
17 contingent factors, several of them were outside of
18 Impax' control; correct?

19 A. That's precisely right.

20 But the most obvious being the date at which
21 the reformulated Opana ER would be approved by the
22 FDA.

23 JUDGE CHAPPELL: Sir, is it possible for you to
24 answer any question yes or no without giving some
25 explanation or remark after your answer?

1 THE WITNESS: Sometimes, yes.

2 JUDGE CHAPPELL: Please try to do that.

3 BY MR. HASSI:

4 Q. Sir, you didn't calculate the expected value of
5 the Endo credit; correct?

6 A. No, I did not.

7 Q. And you didn't calculate an expected value for
8 the Endo credit and the no-AG provision either
9 separately or together; correct?

10 A. No. I just gave examples of what -- what they
11 would be under various circumstances. I didn't attach
12 probabilities to those.

13 JUDGE CHAPPELL: So that's a no?

14 THE WITNESS: Well, it sounds like it's about
15 did I do anything, any calculations, and I wanted to
16 make it clear which calculations I did and didn't do.

17 BY MR. HASSI:

18 Q. Sir, I think you said a moment ago you didn't
19 see any documents where Endo calculated the value of
20 the Endo credit prior to the settlement; right?

21 A. I said both Endo and Impax.

22 Q. Okay. I just -- yesterday, you said -- you
23 testified that you saw documents where the possible
24 payment under the Endo credit was calculated, and I
25 wanted to be sure.

1 You didn't see any documents; correct?

2 A. I didn't see any documents that did what?

3 Q. Under -- where Endo calculated the value of the
4 Endo credit prior to the date of the settlement.

5 A. Okay. There's no explicit estimate of the
6 liability, the expected liability, of the Endo credit
7 prior to early 2012.

8 Is that -- is that what you're asking?

9 Q. I think --

10 A. I don't know.

11 Q. I think so, and I want to clarify the meaning
12 of "explicit."

13 When you say "explicit," there's not only not a
14 single number, there isn't a range calculated by Endo
15 that you saw; correct?

16 A. There's -- no. You're right. That is correct.
17 There's no attempt to evaluate it in any way.

18 Q. I want to talk now about your three-part test.

19 Now, you agree that the rule of reason applies
20 to cases like this one?

21 A. Yes.

22 Q. And the first prong of your three-part test is
23 whether the settlement agreement eliminated a
24 possibility of entry during some period after the date
25 on which the FDA gave final approval to the ANDA; is

1 that right?

2 A. That's half right.

3 Q. Tell me what part I got wrong.

4 A. And before the date of entry in the settlement
5 agreement. It has to be in that range. There has to
6 be some possibility of entry in that time span.

7 Q. And your opinion is that that prong tests
8 whether the settlement eliminates the risk to the
9 brand name firm of entry occurring before the
10 agreed-upon date?

11 A. That's the -- that is what the first prong
12 means, is that you've eliminated the risk of entry
13 during the period between FDA approval and the date in
14 the settlement agreement.

15 Q. And so if Impax and Endo had entered into an
16 entry date-only settlement, no payments, in other
17 words, with an Impax licensed entry date of
18 January 1, 2013, the first prong of your test would be
19 met; right?

20 A. That's correct.

21 Q. And that's because if Impax were to enter into
22 a settlement with an entry date only after
23 June 14, 2010, it would be eliminating the risk that
24 it would compete with Endo after June 14, 2010 and
25 before the licensed entry date; right?

1 A. That's correct.

2 That alone is insufficient for it to be
3 anticompetitive.

4 Q. But it does eliminate the risk of competition;
5 right?

6 A. That's correct.

7 Q. And so settlements with only an entry date and
8 no payment terms can eliminate the risk of competition;
9 right?

10 A. Yeah. A settlement that has no other
11 provisions does eliminate the risk of competition in
12 the early period, and it also eliminates the risk of no
13 competition in the later period, so -- and they
14 balance. They're equivalent because there's no other
15 side payment.

16 Q. Now, you testified yesterday that based on your
17 model, a generic has the incentive to delay as long as
18 possible. Do you recall that?

19 A. It's -- it's brand names that have the
20 incentive to delay generic entry as long as possible.
21 Generics have an incentive to come in as soon as
22 possible.

23 JUDGE CHAPPELL: Did you misstate your
24 question?

25 MR. HASSI: No. I think the record -- I think

1 yesterday maybe the witness misstated in his
2 testimony. I just wanted to make sure I understood
3 it.

4 BY MR. HASSI:

5 Q. Let's talk about "large."

6 The second part of your test is did the generic
7 entrant receive a payment that is large compared to the
8 savings to the brand name firm in ending the
9 infringement litigation before a court renders a
10 verdict; is that right?

11 A. I think -- it sounds like that's what I said.
12 I mean, whether I said it exactly that way I don't
13 know, but it sounds right.

14 Q. I'm trying to read from paragraph 29 of your
15 report.

16 A. But I don't know that. See, that's the
17 problem. I did sound -- that sounds like me.

18 Q. Well, in determining whether a payment is
19 large, it's your opinion that it should be measured
20 against the parties' saved litigation costs?

21 A. That's the conclusion from my analysis. Yes.

22 Q. And you base that on your reading of the
23 Actavis case?

24 A. No. I based that on the economics of reverse
25 payment settlements and then it -- the Actavis decision

1 contains a similar statement.

2 Q. You don't consider any other interpretation of
3 "large," do you?

4 A. Yes. I mean, I -- it's also large relative to
5 the expected profits or revenues of Impax.

6 Q. Is that built into your test for large,
7 comparison to the revenues of the generic company's
8 profits?

9 A. It's not -- it's not the test that's derived
10 from the economic model. The test in the economic
11 model is with respect to litigation costs. But I also
12 calculated the payment relative to the revenues and
13 profits of generic oxymorphone ER by Impax.

14 Q. Do you make any attempt to quantify
15 substantially more than saved litigation costs, as used
16 by Actavis?

17 A. I don't -- no. I don't know what that means.

18 Q. And if the payment from the brand to the
19 generic is more than the sum of the parties' saved
20 litigation costs, you believe that the settlement is
21 100 percent anticompetitive; is that right?

22 A. No. That's -- this is one of three parts to
23 the test. You have to -- you have to pass all three
24 parts. The fact that the payment is large doesn't mean
25 by itself it's anticompetitive. Just like the entry

1 date by itself doesn't mean it's anticompetitive. You
2 have to satisfy all three conditions.

3 Q. So just to understand, on your test, if the
4 saved litigation costs -- excuse me -- if the payment
5 is greater than the combined -- strike that.

6 If the payment received by the generic is
7 greater than the sum of the litigation costs, didn't
8 you testify it's necessarily anticompetitive?

9 A. Not -- you have to do the third part, which is
10 it's unjustified. The -- the size of the payment alone
11 is insufficient.

12 Q. Okay. So let's talk about justification.

13 That's the third prong of your test, is whether
14 the payment is unjustified?

15 A. Yes.

16 Q. And in determining whether a payment is
17 justified you consider two possibilities, one, the
18 payment is less than saved litigation expenses or, two,
19 the payment reflects compensation for other services;
20 is that right?

21 A. The term I used is "goods, services and
22 assets."

23 Q. Your opinion is that "justified" means the
24 brand company is actually purchasing something?

25 A. I'm sorry. I didn't hear that. It went too

1 fast.

2 Q. Your opinion is that "justified" means the
3 brand company actually purchases something; right?

4 A. Well, if it's not saved litigation costs, yes.

5 Q. And that something could be, for example, a
6 bundle of rights as we saw in this case under the
7 development and co-promotion agreement?

8 A. Exactly. If those were purchased at a fair
9 market price, yes.

10 Q. Your test doesn't consider whether there may be
11 other justifications; correct?

12 A. I'm not aware of any other justifications.

13 Q. I want to talk about patents for a few minutes.

14 Your opinion rests on the view that patents are
15 probabilistic?

16 A. That's correct.

17 Q. You believe a patent is a probability of a
18 patent right, not a certainty; right?

19 A. Well, there are rights that come with patents
20 that are certain, which is the right -- the rights
21 inherent in the legal process for challenging them.
22 There are certain burdens and standards of proof about
23 getting around a patent, but -- so there are rights
24 that accrue with having a patent, but whether the
25 patent actually precludes competitive entry is

1 probabilistic.

2 Q. So in your opinion, patents grant the
3 potential of a right to exclude, not a certain right to
4 exclude.

5 A. In the sense that I just described, yes. I
6 mean, it's -- there are rights that are probabilistic
7 and there are rights that are not probabilistic. But
8 the core right about blocking entry is probabilistic.

9 Q. Have you published on this subject of
10 probabilistic patents?

11 A. No. I'm using the existing economics
12 literature. I'm applying that literature.

13 Q. Okay. And yesterday you referenced an article
14 by Farrell and Shapiro.

15 A. That's one of them. Yes.

16 Q. Okay. Do you mean Farrell and Shapiro?

17 A. Well, there's other articles. I'm not sure.
18 One of the articles that I remember is theirs.

19 What would you like -- I'm not sure what you're
20 after here, so...

21 Q. I know of an article by Farrell and Shapiro
22 about the Merger Guidelines.

23 A. No. There's another one. But I -- you know,
24 sitting here, I -- we can look at the report and go
25 through the references I have, and I can tell you from

1 looking at the references how -- what role they play.

2 Q. You'd agree you're not an expert on patents or
3 patent rights; correct?

4 A. I'm -- I'm -- there's an economic field that
5 studies intellectual property rights which I've written
6 about and I have taught, so on the economics of
7 intellectual property, including patents, I am an
8 expert to the sense -- in the sense that I know that
9 and teach it.

10 I am not a patent lawyer, and I'm not a person
11 who is in a scientific or engineering discipline who
12 evaluates elements of patents, such as novelty and all
13 that kind of thing.

14 Q. Sir, under this probabilistic view of patents,
15 a patent with a 50 percent chance of being upheld
16 should be viewed as likely to continue to govern
17 competition for half of its remaining patent life?

18 A. That's -- yeah, that's the -- the expected
19 duration of the patent is what's being referenced
20 there, which is the probability that the patent will be
21 upheld times the remaining life of the patent.

22 Q. And so to determine the expected duration of a
23 patent requires an assessment of whether the patent is
24 likely to be upheld; correct?

25 A. Exactly. The probability is -- of a patent

1 being upheld is a necessary piece of information to
2 estimate the expected date of entry.

3 Q. And you did not conduct any assessment of how
4 likely Endo's patents were to be upheld; correct?

5 A. That's correct. Because you don't -- that
6 probability can't be estimated.

7 Q. So you've not seen any assessment of the
8 probability that Endo's patents would be upheld;
9 correct?

10 A. Well, there's a -- yes. There's assessments,
11 but they're not -- they're not numbers.

12 I mean, your expert Mr. Figg has an
13 assessment, but it's not -- I think he also says what I
14 just said, that you can't possibly assign a
15 probability to it.

16 Q. Your three-part test skips any antitrust
17 analysis of competitive restraints within the patent
18 scope; correct?

19 A. I'm sorry. I didn't hear a couple of those
20 words.

21 Q. Your three-part test skips any antitrust
22 analysis of competitive restraints within the patent
23 scope; correct?

24 A. Yeah. I think that's right, yes.

25 Q. And you didn't do a probabilistic assessment of

1 the competition that would have arisen in the absence
2 of a settlement; correct?

3 A. The competition that would have arisen after
4 what?

5 Q. Absent, without a settlement, in other words.

6 A. I didn't hear the word. I'm sorry.

7 Q. I'll try it again.

8 You didn't do a probabilistic assessment of the
9 competition that would have arisen in the absence of a
10 settlement; correct?

11 A. Well, yeah, it's hard to answer yes or no to
12 that. I mean, I -- I did take into account the
13 possibilities of competition in the absence of a
14 settlement. Did I predict exactly what that would be?
15 No.

16 Q. So you didn't calculate the average period of
17 competition that would have arisen in the absence of
18 the settlement; right?

19 A. No. Of course, these -- I did not figure out
20 among all the condition -- contingent events which one
21 would be the most likely to happen, no.

22 Q. You agree that your test does not consider
23 entry prior to patent expiration to be a factor to be
24 considered in assessing the competitive consequences
25 of the challenged reverse payment agreement; correct?

1 A. You do not need to assess that to determine
2 whether a settlement agreement is anticompetitive or
3 procompetitive. That has nothing to do with whether a
4 particular contingent event occurs.

5 Q. And under your test, the fact that there are
6 two district court rulings upholding Endo's
7 later-acquired patents isn't relevant; correct?

8 A. The outcome of the cases after the
9 settlement -- the date the settlement was reached are
10 irrelevant.

11 Q. Do you agree that the district court's decision
12 on Endo's patents would be binary, either Endo would
13 win or Impax would win?

14 A. I think it's possible they both could lose, but
15 I mean, from Impax' point of view certainly it's
16 binary, they either get to come in or they don't.

17 Q. But the court wasn't going to --

18 JUDGE CHAPPELL: Hold on a second.

19 Did I hear you correctly that you said the
20 outcome of cases after the settlement, after the date
21 the settlement was reached, are irrelevant? Is that
22 what you said?

23 THE WITNESS: Yes.

24 JUDGE CHAPPELL: And why are they irrelevant?

25 THE WITNESS: Because they're uncertain events

1 at the time of the settlement, that what -- what the
2 settlement is about is eliminating the possibility of
3 bad outcomes.

4 So it wouldn't help the plaintiffs if the
5 generics had won those patent cases in the same way it
6 wouldn't -- doesn't help the defendants that Endo won
7 them, because they're uncertain at the time.

8 And what the settlement agreement buys and is
9 about is eliminating some adverse consequences that
10 could happen to you in the future but that are not
11 certain.

12 JUDGE CHAPPELL: Well, in that same regard,
13 what about a Supreme Court case like Actavis that comes
14 year after the settlement was reached? Is that
15 irrelevant?

16 THE WITNESS: The Actavis decision is relevant
17 only because it gives information about how to evaluate
18 these things.

19 JUDGE CHAPPELL: But you would agree that it
20 comes years after the settlement in this case was
21 reached.

22 THE WITNESS: Oh, yeah. But -- so the issue
23 of whether the settlement agreement is anticompetitive
24 is -- is different -- how you evaluate that today is
25 different than how you would have evaluated it in

1 June 2010, yes.

2 JUDGE CHAPPELL: So if I understood you right,
3 because of a case in the Supreme Court that was issued
4 years after the settlement agreement, how that
5 agreement is valued has changed.

6 THE WITNESS: The value they would place on it
7 has changed to the degree that the probability that
8 it's anticompetitive has changed, so --

9 JUDGE CHAPPELL: Did these parties need, in
10 your opinion, to foresee that the Supreme Court would
11 issue a ruling years later that would change the game?

12 THE WITNESS: That's exactly the point, is
13 that you'd -- that you can't possibly have an economic
14 set of criteria for evaluating whether something makes
15 the market more or less competitive that depends on
16 what happens in the future, so you have -- you sort of
17 look back at it with 20/20 hindsight and say, Aah, now
18 that I know that, then this must be anticompetitive or
19 procompetitive.

20 The rule can't be like that. It's got to be
21 objective conditions that people knew at the time. It
22 can't be that you require people perfectly to foresee
23 how some case is going to be decided in the future.

24 JUDGE CHAPPELL: Exactly.

25 So what the people knew at the time didn't

1 include what the Supreme Court said in Actavis, did it,
2 could not have?

3 THE WITNESS: It couldn't have possibly
4 included any court case that was decided after June,
5 whether it's Actavis or a patent infringement case or
6 anything else.

7 JUDGE CHAPPELL: So, and the reason I ask these
8 questions, is it fair then for you to say, well, you
9 can't look at any patent cases that happened after
10 that, yet this Supreme Court case that happened after
11 the settlement changed everything and that's fair to
12 apply that? Is that your opinion?

13 THE WITNESS: No. Because remember I'm not
14 estimating probabilities. I'm -- I -- I'm not
15 evaluating the -- any settlement agreement on the basis
16 of the probabilities, and that's precisely why.
17 All right?

18 I completely agree with you that it's not
19 realistic to say people have to have perfect
20 foresight. You have to have another set of criteria
21 for evaluating these things or it doesn't make sense.
22 It's incoherent.

23 JUDGE CHAPPELL: If you had consulted on this
24 agreement, would you think it's fair to be judged on
25 the law that has changed or on the law that existed at

1 the time you formed the agreement? What do you think
2 is more fair?

3 THE WITNESS: I think that antitrust decisions
4 should be based upon whether there was harm to
5 consumers, and I don't need to know the Actavis
6 decision to know whether the settlement agreement
7 harmed consumers. All right? And --

8 JUDGE CHAPPELL: Okay. So wait a minute.
9 That's what I'm -- hold on, hold on. I'm speaking.
10 I'll let you answer.

11 THE WITNESS: Okay.

12 JUDGE CHAPPELL: But you're not answering my
13 question.

14 THE WITNESS: Well, I'm trying to.

15 JUDGE CHAPPELL: Are you saying that
16 regardless of Actavis, you say this agreement was
17 unlawful?

18 THE WITNESS: I don't know whether it's
19 unlawful. All I know is within a matter of economics
20 that it caused anticompetitive harm to consumers.
21 Maybe there can be --

22 JUDGE CHAPPELL: Okay. Let me use your words.
23 I shouldn't have used "unlawful" because I've kept you
24 from talking about legal terms.

25 THE WITNESS: Yeah.

1 JUDGE CHAPPELL: Then your opinion would be,
2 with or without Actavis, this agreement was
3 anticompetitive?

4 THE WITNESS: Yes. That would -- within
5 economics -- all I can do is economics. I can't do
6 law. All right? And in economics it was
7 anticompetitive in that it caused harm to consumers
8 without a compensating benefit.

9 JUDGE CHAPPELL: Well, would you agree that,
10 based on your reading of Actavis and again as an
11 economist, the rules that apply to define
12 "anticompetitive" and whether the agreement is valid or
13 not or anticompetitive, those rules changed with the
14 Actavis decision?

15 THE WITNESS: Those -- yes -- well, yes and
16 no. I mean, there were -- there were differences in
17 the circuits. All right. That's why we got the
18 Actavis decision. But -- but the reality is, you're
19 right, there was an uncertainty in the law about what
20 the appropriate test of anticompetitiveness was as a
21 legal matter, and that was resolved by Actavis or
22 partially resolved, not completely.

23 JUDGE CHAPPELL: All right. Thank you.

24 BY MR. HASSI:

25 Q. So going back to the court's -- the district

1 court decision that was considering the Impax and Endo
2 patent case, that court wasn't going to split the
3 remaining time on the patent; right? Either --

4 A. Oh, of course not.

5 Q. Now, in your report at paragraph 246 you
6 provide the standard approach to economic analysis of
7 patent litigation; is that right?

8 A. Yes.

9 Q. But your opinion doesn't contain any economic
10 analysis of the patent litigation; right?

11 A. Well, it does, but it doesn't -- it's -- it's
12 not about the outcome of the patent litigation. It's
13 about the how the patent litigation affects it. I'm
14 not -- you know, I'm not sure what you're driving at,
15 so --

16 Q. You have a formula at paragraph 246 of your
17 report in which --

18 A. May I look at it --

19 Q. Absolutely.

20 A. -- so I know what you're talking about? The
21 first report?

22 Q. The first tab, paragraph 246 -- second tab.
23 I'm sorry.

24 (Document review.)

25 A. Okay. I now -- okay.

1 Q. And you refer to that as the standard approach
2 to an economic analysis of patent litigation; right?

3 A. Yeah. This is about the economics of what the
4 expected result of patent litigation is, yes.

5 Q. You didn't apply that formula in this case, did
6 you?

7 A. Yes, I did. This is -- this is baked into the
8 economic theory by setting up the payoffs to
9 consumers, the brand name firm and the generic firm in
10 exactly this format, the probability of an out.

11 Come times its value. But I -- what the -- so
12 then you -- then the criteria for deciding whether
13 something is anticompetitive is derived from setting it
14 up exactly this way.

15 This is the way that Lemley does it, and so --
16 the -- you don't -- when you -- the assumptions that go
17 into the model have the probabilities in them, but the
18 results from the model don't have the probabilities in
19 them. The probabilities disappear, because they become
20 irrelevant to the question of whether it's
21 anticompetitive.

22 JUDGE CHAPPELL: We've been going a couple
23 hours. We're going to take a break.

24 MR. HASSI: Yes, Your Honor.

25 JUDGE CHAPPELL: We'll reconvene at noon.

1 We're in recess.

2 (Recess)

3 JUDGE CHAPPELL: We're back on the record.

4 Do you have a time estimate for the amount of
5 time you need for cross?

6 MR. HASSI: I would say an hour, maybe a little
7 bit less.

8 JUDGE CHAPPELL: All right. Go ahead.

9 BY MR. HASSI:

10 Q. Sir, before the break, we were talking about
11 paragraph 246 of your report and the standard approach
12 to economic analysis of patent litigation; correct?

13 A. Yes.

14 Q. Now, you didn't calculate, for example, the net
15 payoff to a litigant from infringement litigation;
16 right?

17 A. I didn't calculate the numbers in that
18 equation. Those were the starting place for the
19 economic theoretic model.

20 Q. So there isn't anywhere in either of your
21 reports where we'll find numbers applied to this
22 equation; correct?

23 A. No. This is a verbal description of an
24 equation that appears later in the report.

25 Q. But you don't calculate, for example, the net

1 probability of winning the Endo-Impax patent
2 litigation.

3 A. No. I'm entering assumptions in the model.

4 Q. And you didn't calculate, for example, the
5 probability that Endo would have won the patent
6 litigation.

7 A. No. I didn't calculate any probabilities.

8 JUDGE CHAPPELL: Let me ask a couple questions
9 in this regard.

10 You were telling us yesterday about what you
11 called litigation savings?

12 THE WITNESS: Yes.

13 JUDGE CHAPPELL: And we were talking about
14 where you got your information from surveys, what
15 patent attorneys charge by the hour, et cetera. You
16 didn't actually look at the hour, but you've looked at
17 surveys and documents from these parties on litigation
18 savings or the cost of litigation; correct?

19 THE WITNESS: Right.

20 JUDGE CHAPPELL: And I don't know if that's
21 what he was asking or not, but what I'd like to know
22 is, did you factor into that had Impax been in the
23 market at risk and lost and what that would cost and,
24 if that were trebled, what that would cost? Did you
25 include that in your calculation of litigation

1 savings?

2 THE WITNESS: No. We -- there aren't any
3 damages associated with Paragraph IV patent litigation
4 because you don't actually enter. All right.

5 So the --

6 JUDGE CHAPPELL: Well, wait. You think that
7 the parties don't calculate themselves or think about
8 what they might owe, they don't take that into
9 consideration what they might owe if they lose?

10 THE WITNESS: No. They do. But it's zero,
11 because there's no -- entry hadn't actually occurred at
12 the time of that litigation.

13 What Paragraph IV enables you to do is litigate
14 infringement before there's any damages, so the outcome
15 is purely a judgment on the validity and -- of the
16 patent and whether it was infringed. There's no
17 damages associated with it.

18 JUDGE CHAPPELL: But this trial had already
19 started; right? It wasn't before litigation started.

20 THE WITNESS: Yes, the trial had started, but
21 entry hadn't happened, so there wouldn't have been
22 damages.

23 JUDGE CHAPPELL: So because entry hadn't
24 happened in this case, it wasn't a factor to you.

25 THE WITNESS: Right.

1 JUDGE CHAPPELL: But if entry had already
2 occurred in this case, you would have included that or
3 not?

4 THE WITNESS: If entry had occurred, then
5 obviously the firm's decision-making is governed in
6 part by its exposure to damages, yes.

7 JUDGE CHAPPELL: Right. And would that have
8 changed the numbers you determined would apply here for
9 litigation savings?

10 THE WITNESS: No.

11 JUDGE CHAPPELL: Not in this case, but in the
12 scenario where entry has occurred.

13 THE WITNESS: There are other cases where it
14 would, but not in this one.

15 JUDGE CHAPPELL: All right.

16 BY MR. HASSI:

17 Q. One follow-up question on litigation savings.
18 Do you take into account the risk of an
19 attorney fee award?

20 A. With a what?

21 Q. The risk of an attorney fee award.

22 Do you know what that is?

23 A. Yeah, I know what it is. That's basically cost
24 shifting.

25 So it wouldn't -- since I'm using the

1 summation of the saved litigation costs of the two
2 sides, how those -- how that sum is divided among the
3 parties is irrelevant. It's still is it less than the
4 sum.

5 Q. But your saved litigation costs is only future
6 litigation costs, not total litigation costs; right?

7 A. That's right.

8 Q. And an award of costs and attorneys' fees could
9 go back to the filing of the complaint; right?

10 A. Yes. But it's still just a transfer among the
11 parties. The summation of the two parties' costs, if
12 you add -- if you add something to one side, you
13 subtract it from the other.

14 Q. Sir, your estimate of three to five million
15 dollars, those were only future costs. That did not
16 include the costs that had been spent by Impax or Endo
17 to get that case to trial, did it?

18 A. No, of course not. But if there's fee shifting
19 of prior costs, one side gets a plus and the other side
20 gets a minus. The summation is unaffected.

21 Q. But the risk is that -- the risk to Impax is
22 they wind up paying Endo's attorneys' fees; right?

23 A. That's absolutely right. But that has nothing
24 to do with the standard for whether the payment is
25 large.

1 JUDGE CHAPPELL: You mean it has nothing to do
2 with it the way you calculated it; is that what you're
3 saying?

4 THE WITNESS: No. I'm saying the reason we
5 care about saved litigation costs is because it's a
6 use of resources of society's resources to do
7 something, and so it's a benefit to society at large
8 that you don't complete the litigation. That's the
9 benefit of settlement from a societal point of view.

10 My context is not what's in the interest of
11 Endo or what's in the interest of Impax. My con- -- my
12 concern is, is this -- does this have a net cost to
13 society. And how that's allocated among them is only
14 relevant to the extent it affects their incentives, and
15 that was incentives taken into account in modeling.

16 But the standard for whether a settlement of an
17 antitrust case -- or excuse me -- a patent infringement
18 case is pro- or anticompetitive doesn't hinge on any of
19 that. It only hinges on the benefits to society and
20 the costs to society.

21 JUDGE CHAPPELL: All right. So just so we're
22 clear, you're talking about the benefits and costs to
23 society. But what about from the perspective of the
24 settling parties? You don't think the attorneys have
25 to consider, well, if we lose, we may have to pay their

1 legal fees, and a lot of the litigation costs are
2 depositions and preparation for trial before you ever
3 get to trial, so do you think the parties sit around
4 and talk about costs to society when they're deciding
5 whether to settle or not?

6 THE WITNESS: Of course they don't.

7 That's why the model starts off with what is
8 the profit-maximizing decision for the patent holder
9 and what is the profit-maximizing solution for the
10 potential infringer, and it compares that to the
11 welfare of society at large and says when do these
12 things diverge.

13 That's the -- the whole idea about deciding
14 whether there's harm to competition is about whether
15 the private parties pursuing their own self-interests
16 produce a result that is also beneficial to people in
17 general. That's the whole idea of the analysis.

18 So the -- the -- the point you're making is
19 correct. Each side cares about its own private costs
20 and its own private benefits, and the issue is whether
21 the incentives created by that lead to an outcome that
22 makes society in general better off as opposed to just
23 the parties.

24 JUDGE CHAPPELL: So your position would be
25 that it's more fair to determine whether a settlement

1 was large based on an outsider's view of societal
2 costs rather than what the parties themselves would
3 have tried to figure out when they were determining
4 whether to settle or not. Did I understand that
5 correctly?

6 THE WITNESS: I didn't say anything about
7 fairness. All right? Because --

8 JUDGE CHAPPELL: Well, let's just talk about
9 reality. Forget fairness.

10 THE WITNESS: No.

11 JUDGE CHAPPELL: Isn't the reality that the
12 parties that are settling --

13 THE WITNESS: What I was saying is reality,
14 too, because I was taking into account their financial
15 incentives, and so that aspect of it is there. But
16 this is -- this is -- whether a -- whether a conduct is
17 anticompetitive isn't about fairness, it's about the
18 benefits and costs to people in general, not just the
19 parties.

20 JUDGE CHAPPELL: Didn't you say it was about
21 incentives, that that's what you were trying to
22 determine, incentives?

23 THE WITNESS: Yes. The -- the -- the fairness
24 is -- is an issue about is it just, is the -- is the
25 allocation of benefits and costs that emerges from this

1 process just.

2 JUDGE CHAPPELL: You don't see any component of
3 what's just having to do with fairness? Is that what
4 you're telling me?

5 THE WITNESS: No. I said that's exactly --
6 fairness is justice. I'm quoting Rawls; right?

7 I'm saying that fairness is something that is
8 a perfectly valid thing to consider, but it's
9 something you consider. It's not something an
10 economist models. All right.

11 What I'm talking about is the economic impacts
12 of the settlement. And if you think that pursuing a
13 more efficient and a less anticompetitive, more
14 procompetitive outcome produces an unfair result, then
15 that's what you decide.

16 But as an economist, I can't tell you what's
17 fair. You know, you would be extremely displeased with
18 me if I tried to tell you what's fair, because that's
19 your job, not mine.

20 JUDGE CHAPPELL: You're referring to a model.

21 What model are you talking about?

22 THE WITNESS: The economic analysis of the
23 consequences of settlements that's in the expert
24 report.

25 JUDGE CHAPPELL: Is there a name for this

1 model?

2 THE WITNESS: It -- I don't know. That's a
3 good -- I don't have a model -- a name for the model in
4 the expert report. It's the -- it is a model of the
5 consequences of settlements of patent disputes on the
6 efficiency and distribution of income arising from a
7 drug market.

8 JUDGE CHAPPELL: Has this model been accepted
9 or utilized by other courts?

10 THE WITNESS: Yeah -- well, that's hard to
11 answer. My specific thing hasn't, but the -- but the
12 approach to how you think about settlements of drug
13 patent disputes, other experts have written similar
14 things in their articles in journals, and I believe
15 it's -- that's what the Actavis decision says. But
16 that's for you to decide, not me.

17 JUDGE CHAPPELL: All right. Thank you.

18 BY MR. HASSI:

19 Q. To be clear, your model hasn't been
20 peer-reviewed; right?

21 A. The specifics of what's in my paper -- my
22 report have never been peer-reviewed. Elements of it
23 have been published by other people in other articles.

24 Q. And there is a dispute in the academic
25 literature about how to model this; right?

1 A. No.

2 Q. There's no disagreement?

3 A. There's -- there's -- the dispute is not about
4 how you model it. There's a dispute about what it
5 means and -- but the -- I -- the -- the -- the
6 suggestions that are made in some of the papers that I
7 cite are about things to take into account, that can
8 easily be taken into account, and they -- they're --
9 and you don't -- it doesn't -- their conclusions aren't
10 affected and my conclusions aren't affected.

11 Q. In terms of your conclusions, your opinion is
12 that whether or not Impax would have lost the patent
13 litigation and therefore been unable to enter until
14 after September 9, 2013 is irrelevant; right?

15 A. Ask it again because I'm not sure I understood
16 it.

17 Q. Your opinion is that whether or not Impax would
18 have lost the patent litigation and therefore been
19 unable to enter until September of 2013 is irrelevant;
20 correct?

21 A. What's irrelevant is the -- yeah, what the
22 probability -- where that probability is is
23 irrelevant.

24 Q. And likewise, it's irrelevant whether or not
25 Impax would have lost the subsequent litigation. The

1 litigations that Endo brought against other ANDA filers
2 and successfully won against other ANDA filers, that's
3 irrelevant to you; correct?

4 A. The probability of those -- of the outcome of
5 subsequent litigation is irrelevant to the conclusions
6 I reach. It's part of the model, but it's not part of
7 the conclusions.

8 Q. And so you're not providing an opinion as to
9 whether Endo would have won its patent case; correct?

10 A. I do not provide an opinion about who would win
11 anything.

12 Q. You acknowledge the outcome of litigation is
13 always uncertain; correct?

14 A. That's exactly right.

15 Q. And that's true even if the patent was rock
16 solid; correct?

17 A. Yes. Although that gets you very high
18 probabilities, and I don't think we'd have a dispute on
19 what happens if there's -- if the probability that the
20 patent is rock solid is -- if the patent is rock solid,
21 the probability of the patent holder winning is
22 extremely high.

23 Q. But you're not offering an opinion in this case
24 as to whether Endo's patents were or were not rock
25 solid; correct?

1 A. That's correct.

2 Q. So there was uncertainty for both Endo and
3 Impax.

4 A. That's precisely right. That's the entering
5 wedge of the analysis, is there's uncertainty.

6 Q. And you've not attempted to measure that
7 uncertainty.

8 A. There's no -- you don't need to measure it.
9 No. I made no attempt because it doesn't play any role
10 in the model.

11 Q. I want to talk about -- I refer to it as the
12 broad patent license. If I refer to it that way, do
13 you know what I'm referring to?

14 A. Yes.

15 Q. The patent license that was in the settlement
16 between Impax and Endo?

17 A. Yes.

18 Q. And that gave Impax a license not just to the
19 patents that were in suit --

20 A. Yes.

21 Q. -- but to future patents; right?

22 A. That's correct.

23 Q. Now, that broad patent license didn't play any
24 role in your analysis; correct?

25 A. No. It plays no role.

1 Q. But you've also previously testified that it's
2 important to take the agreement as a whole; correct?

3 A. That's correct.

4 JUDGE CHAPPELL: Before you go on, I'm getting
5 back to what you told me. You said that your model
6 had not been tested or peer-reviewed, but you told me
7 there were similar models that had been used by
8 courts?

9 THE WITNESS: There have been similar cases to
10 this where other experts have testified, yes. And I
11 don't -- I don't know -- I haven't read the decisions
12 in those courts, so I can't testify about exactly what
13 role the model played. I don't know, but --

14 JUDGE CHAPPELL: That's not my question,
15 though.

16 THE WITNESS: Yeah.

17 JUDGE CHAPPELL: These other models that have
18 been utilized, are they models that have a name?

19 THE WITNESS: There's -- no. It's --
20 interestingly enough, to my knowledge, no name has ever
21 been attached to this. It's just that there is a --
22 there is a way of modeling the patent litigation in the
23 drug industry that is part -- it's already been
24 published and that's been used by other experts in
25 other cases as well as me.

1 JUDGE CHAPPELL: Okay. And are you aware of
2 other models you could have used in this case to form
3 your opinion in this regard?

4 THE WITNESS: No. This is the only way I'm
5 aware of that you -- the approach that I have taken is
6 the only approach that I'm aware of.

7 JUDGE CHAPPELL: All right.

8 BY MR. HASSI:

9 Q. Sir, you're aware that there were also royalty
10 terms in the settlement?

11 A. Yes.

12 Q. And you didn't consider evaluation of the
13 royalty terms in your evaluation; correct?

14 A. I did not attempt to estimate the value of
15 royalty term again because that requires estimating a
16 probability that that would ever happen.

17 Q. And with respect to the broad patent license,
18 you didn't consider whether that license has had any
19 effect on consumer welfare; correct?

20 A. I did not unpack the effect of each provision
21 on consumer welfare because that's not the appropriate
22 way to do it.

23 Q. Would you agree that the broad patent license
24 made the settlement agreement more valuable to Impax?

25 A. The settlement agreement was made more

1 valuable to Impax by the nature of the patent rights
2 that were granted to it, the license that was granted
3 to it.

4 Q. You didn't include the nature of those patent
5 rights in your large and unjustified payment
6 calculations; right?

7 A. No. Because it wasn't necessary. It's not --
8 I'm evaluating the value of the entire settlement, not
9 each of the components individually.

10 Q. You're not offering -- strike that.

11 You're not offering an opinion as to whether
12 an alternative settlement could have existed; correct?

13 A. No. I -- I'm sure there could have been, but
14 I'm not offering an opinion. I haven't tried to
15 identify any.

16 Q. And you didn't attempt to determine whether a
17 less restrictive agreement was available; correct?

18 A. I have not attempted to see if there was a less
19 restrictive, feasible settlement agreement, no.

20 JUDGE CHAPPELL: Hold on.

21 (Pause in the proceedings.)

22 Go ahead.

23 BY MR. HASSI:

24 Q. Professor Noll, Mr. Meier asked you the
25 following question yesterday, "In forming your opinion

1 that the payment was large, did you review Endo's and
2 Impax' contemporaneous plans and forecasts about the
3 payment?" to which you responded, "I did."

4 Do you recall giving that testimony?

5 A. I remember the question and the answer. I
6 reviewed the documents about it, yes.

7 Q. What contemporaneous plans or forecasts of
8 Impax or Endo did you review that showed a payment
9 being made under the settlement agreement?

10 A. That's not -- I don't -- there weren't any.
11 What I -- what I thought -- I took the question to be
12 more general about did I review forecasts and
13 financial analysis about various outcomes, contingent
14 outcomes that would be affected by the settlement, and
15 I did -- I did review whatever the internal financial
16 analyses and forecasts were that were contemporaneous.

17 Q. So you reviewed ordinary-course business
18 documents and extrapolated from that what you think
19 the settlement payment might result in; is that right?

20 A. Well, the -- the -- the first part is
21 definitely right. The second part is not exactly what
22 I did, but I did make use of those in my analysis,
23 yes.

24 Q. But you didn't see any contemporaneous
25 documents that showed a payment going one way or the

1 other between the parties as a result of the
2 settlement; correct?

3 A. I'm not aware of a document that estimates the
4 expected value of any provision of the settlement
5 agreement or the overall expected value of the
6 settlement agreement to either party.

7 Q. Okay. You testified yesterday regarding
8 Appendix F, which has four scenarios on it. Do you
9 recall that?

10 A. No, I don't, but that's okay.

11 Q. We'll put it up for you.

12 A. Okay.

13 Q. Robert, if you can put up CX 5000.

14 A. Okay. Now I know what you're talking about.

15 Q. This is an appendix that appears at the end of
16 your report, but it's nowhere mentioned in your report;
17 is that right?

18 A. The components of it are all in the report, but
19 the -- the -- there's no reference to the exhibit that
20 summarizes it, no.

21 Q. And this appendix lists four scenarios; is that
22 right?

23 A. Four, yeah. And you're right, there were many
24 more.

25 Q. You didn't calculate the probability of any of

1 these scenarios occurring; right?

2 A. I did not calculate the probability of any of
3 these or any of the others that are in the report.

4 Q. And so the numbers on this slide under
5 Approximate Value, those aren't probability-weighted;
6 right?

7 A. I'm sorry. The -- no. These are the -- these
8 are the numbers without multiplying them -- I think I
9 said that yesterday. These are the numbers prior to
10 multiplying by the probability.

11 Q. And so they're not expected values; right?

12 A. No. This is -- there's no expected value here.
13 These are just examples of outcomes, ranges of
14 outcomes.

15 Q. And these are just examples. You're aware
16 there are other scenarios, including scenarios under
17 which Impax does not receive a payment under either
18 the Endo credit or get any value from the no-AG;
19 correct?

20 A. That's what we talked about, is can you time
21 the entry perfectly so that you don't trigger either
22 one of these provisions.

23 JUDGE CHAPPELL: Did I understand you to say
24 these are not calculated by you, they're just
25 examples?

1 THE WITNESS: The report contains a large
2 number of examples, of which these are four, about
3 potential outcomes under the settlement. It does not
4 contain an expected value because that would require
5 multiplying all the possible outcomes by their
6 probabilities, and that's not possible.

7 JUDGE CHAPPELL: Does this chart represent your
8 opinion of what these outcomes are?

9 THE WITNESS: This represents my estimation of
10 what the -- what either the value of the authorized
11 generic provision or the value of the Endo credit
12 provision would have been under various circumstances
13 about how big the market was and what the state of the
14 market was at -- at the time that reformulated Opana ER
15 was introduced.

16 JUDGE CHAPPELL: And to be clear, when you say
17 "under various circumstances," you mean under various
18 assumptions that you made?

19 THE WITNESS: Well, we have -- we have
20 historical data on how much sales actually were in
21 each quarter for original formulation Opana ER, so we
22 can estimate the effect of the entry of reformulated
23 Opana ER by just changing the date and saying okay,
24 the original formulation's peak sales would have been
25 on this date because that's when reformulated would

1 have entered. And that sets the peak sales for
2 original -- the original formulation, which then plugs
3 into what the Endo credit would be. If entry occurs
4 before the reformulated version has entered, then the
5 no-AG provision is triggered.

6 So the -- all the no-AG examples are when Impax
7 enters before reformulated is launched, and then all
8 the Endo credit examples are when Impax enters after
9 reformulated is launched.

10 JUDGE CHAPPELL: Is an estimation an
11 assumption?

12 THE WITNESS: The -- no. An estimation is a
13 calculation, and it's based upon the actual sales data
14 combined with an assumption about when the reformulated
15 version enters.

16 JUDGE CHAPPELL: Based on that assumption.

17 THE WITNESS: Yeah. The -- and -- so you
18 have -- you have an earliest possible date, which is in
19 the Endo documents, what's their earliest date that
20 they thought reformulated Opana ER might be introduced,
21 and then you have later dates. And you can go all the
22 way to almost the end of 2012. And the example where
23 you get zero of both is one in which you would enter
24 roughly November of 2012.

25 JUDGE CHAPPELL: Go ahead.

1 BY MR. HASSI:

2 Q. And that example where you get zero of both,
3 you didn't include that on your demonstrative of
4 scenarios, did you?

5 A. No, I didn't. Because it was -- I didn't. It
6 was -- it didn't appear -- it was not a scenario that
7 was considered by either party in their analysis.

8 Q. Is it your testimony that neither party
9 considered the possibility that they could wind up with
10 a zero payment?

11 A. No. Not -- the -- the contemporaneous
12 forecasts about what the outcome of what the market was
13 going to look like didn't include any provisions like
14 that. There was nothing -- there's nothing in the
15 document -- the contemporaneous documents that even
16 holds that out as a possibility.

17 Q. And again, those are contemporaneous business
18 documents, not documents evaluating the settlement;
19 correct?

20 A. Well, there are no documents evaluating the
21 settlement. These are documents about expectations
22 about how the market is going to develop in terms of
23 sales of Opana ER and in terms of the date of entry of
24 the reformulated version.

25 Q. Sir, do you understand --

1 A. Consider the situation in which the entry would
2 occur in such a way that the results would have been
3 zero.

4 Q. But you understand that the parties and
5 representatives of the parties that were involved in
6 the negotiations understood that the settlement could
7 result in a zero payment either way; correct?

8 A. I'm not sure that's true. I think that
9 they -- they -- they thought there were circumstances
10 where the Endo credit could be zero, yes, or the AG,
11 but both be zero, I don't recall seeing any of that.
12 Maybe there were. But I don't recall it.

13 Q. Are you aware that Mr. Mengler testified in
14 this courtroom that there were a set of circumstances
15 that are entirely plausible that could lead to this
16 condition where market share doesn't fall below
17 50 percent in a certain period of time but falls to
18 zero by January 1, 2013?

19 A. I said contemporaneous documents. I didn't say
20 ex post, 20/20 hindsight statements. I said at the
21 time and in the first half of 2010 I'm not aware of any
22 statement by anybody that neither provision being
23 triggered was actively considered by anyone. You know,
24 if there are, I didn't see it.

25 Q. So when you say "contemporaneous documents,"

1 you discount the testimony of the witnesses; is that
2 right?

3 A. No. I mean the testimony happened after I
4 wrote my report, so -- I mean, I -- it's -- it's --
5 it's -- it's -- I'm not denying the existence of the
6 possibility. What I'm saying is, at the time the
7 document was signed, it was not something that either
8 party shows any evidence, to my knowledge, of having
9 considered as a likely outcome.

10 Q. Your view is that Mr. Mengler's testimony is a
11 reaction to your report; is that what I'm hearing?

12 A. No. I don't know. I don't know why he
13 testifies. I'm just saying I don't know. He said what
14 he did, and you can take it at whatever value you want,
15 attribute any weight to it you want. What I'm talking
16 about in the answer to the question you asked me about
17 is what I saw in the discovery record.

18 Q. And in the discovery record, you read the
19 testimony of Mr. Smolenski; right?

20 A. Yes, I did.

21 Q. Do you know who he is?

22 A. Not by memory. I did at one point.

23 Q. You relied on him in your report?

24 A. Well, I listed him as one of the things I
25 considered. Yes. I don't recall whether there's

1 anything that relies on him, but I don't remember.

2 Q. I'll represent to you that you did rely on him
3 in your report in a footnote citing to the testimony,
4 including the investigational hearing testimony, of
5 Mr. Smolenski.

6 A. Fine. I just said I don't remember whether I
7 actually relied on it.

8 MR. MEIER: Your Honor, just if I may for the
9 record, could we have the citation, the footnote
10 citation?

11 I'd just like to know which footnote it is.

12 MR. HASSI: Among others, footnote 357 refers
13 to his investigational hearing testimony of
14 September 30, 2014, pages 80 to 81 and 94 to 95, 375 --
15 do you want more?

16 MR. MEIER: No. Got it. Thank you.

17 BY MR. HASSI:

18 Q. I'm going to read to you what Mr. Smolenski
19 testified to.

20 Sir, I'm going to read to you what
21 Mr. Smolenski testified to in his investigational
22 hearing. If you'd prefer to read it along with me, I'm
23 happy to give you a copy.

24 Would you like a copy or --

25 A. I -- I don't know. If it's -- if it's

1 extensive and -- I don't know whether I'm going to
2 need to read it or not because it depends on the
3 question.

4 MR. HASSI: May I approach your, Your Honor,
5 and give --

6 JUDGE CHAPPELL: Go ahead.

7 BY MR. HASSI:

8 Q. So this is from page -- it's in evidence. It's
9 CX 4002.

10 Reading Mr. Smolenski's answer starting on
11 page 129 and carrying over to 130:

12 "So we discussed life cycle management and
13 switch strategies before. So I don't have the
14 contract open in front of me, but my recollection was
15 the Endo credit was based upon a quarterly sales
16 figure.

17 "And in the reality of a life cycle management
18 or a switch strategy, sometimes things don't happen in
19 quarters, they happen in days. So, for example, if
20 Endo performed the switch strategy in the fourth
21 quarter of 2012, it is very possible that the sales of
22 the product, based on IMS data, which, by the way, is
23 sales coming out of a pharmacy, right, that that would
24 show a volume that was greater than 50 percent and,
25 therefore, would not trigger the Endo credit.

1 "But in reality if Endo effected a switch
2 strategy in that quarter, in that time period, it is
3 quite possible that by the time January 1, 2013 rolls
4 around, there's actually no brand product left in the
5 market and they have actually withdrawn it.

6 "And in that scenario, even though the product
7 is completely gone and the market has degraded in a
8 real-time situation to zero percent, there would be no
9 payment received."

10 Do you recall reading that testimony?

11 A. Yes. That was September of 2014. It wasn't a
12 contemporaneous document.

13 Q. It was well before your report, however;
14 right?

15 A. No, it was, but it was not a contemporaneous
16 document. And so my statement was about
17 contemporaneous documents, so yes. And I -- I didn't
18 take into account testimony in September of 2014 in
19 considering the options that they were thinking about
20 in June of 2010.

21 Q. And you didn't take into account the parties'
22 understandings at the time because you didn't see a
23 contemporaneous document that laid out this scenario
24 where they didn't get paid; right?

25 A. They didn't have any plan that I saw on either

1 side where that would have been the outcome. Yes.

2 Q. But you didn't see any contemporaneous
3 documents -- and by that I mean documents referring
4 specifically to the settlement -- under which they
5 calculated that a payment would get made; right?

6 A. No. The -- the -- there's nothing about an
7 attempt to evaluate the settlement.

8 Q. Okay. Let's talk about outcomes under your
9 test.

10 Under your test, am I correct that any payment
11 that is greater than the sum of the parties' litigating
12 costs is automatically anticompetitive?

13 A. It went too fast for me to follow, so can you
14 slow down for me, please.

15 Q. Certainly.

16 Under your test, if the payment is greater than
17 the sum of the parties' litigating costs, it's
18 automatically anticompetitive; right?

19 A. If it's unjustified.

20 Q. And you believe the anticompetitive harm from
21 the settlement agreement arises because the settlement
22 deprives consumers of the possibility that generic
23 entry will occur before the settlement date in the
24 agreement; correct?

25 A. That's correct.

1 Q. And your opinion is that the relevant analysis
2 in a rule of reason case does not require a showing of
3 actual anticompetitive effects; correct?

4 A. I believe those are actual anticompetitive
5 effects, but it doesn't mean you have to actually
6 model what's going to actually happen in the market,
7 no. The -- as I said before, the -- you can put a
8 boundary on what would happen in the market by looking
9 at the value of the settlement.

10 JUDGE CHAPPELL: He asked you a question about
11 what had to be shown, and you responded with something
12 about what you have to model.

13 Can you ask the -- do you want her to ask the
14 question again? I'd like for you to try to answer the
15 question, because it doesn't ask about a model.

16 THE WITNESS: Well, I thought you were talking
17 about my test. That derived from the model.

18 JUDGE CHAPPELL: He was asking about your
19 opinion.

20 Josett, would you ask him the question again.

21 THE WITNESS: Okay.

22 (The record was read as follows:)

23 "QUESTION: And your opinion is that the
24 relevant analysis in a rule of reason case does not
25 require a showing of actual anticompetitive effects;

1 correct?"

2 THE WITNESS: Well, I have to say yes or -- yes
3 and no, I mean. Since I'm only allowed to say that, I
4 can't explain why.

5 JUDGE CHAPPELL: Did you consider actual
6 effects in your analysis?

7 THE WITNESS: I considered them, yes. And the
8 issue is how I considered them.

9 BY MR. HASSI:

10 Q. Sir, as a matter of economic -- strike that.

11 Your opinion is that once the payment is large
12 relative to saved litigation costs and unjustified,
13 you're basically done from the standpoint of economics;
14 right?

15 A. That if it's large and unjustified and there
16 was a -- and precluded the possibility of earlier
17 entry, then it's anticompetitive.

18 Q. And so, in your opinion, you don't need to
19 show actual anticompetitive effect, as a matter of
20 economic theory, because it isn't actually necessary to
21 decide whether something is anticompetitive as an
22 economist; right?

23 A. That's -- that's where you get yes and no,
24 because, you know -- because I -- I'm not allowed to
25 give an explanation.

1 Q. You believe that economic analysis teaches
2 that one can infer whether a settlement is
3 anticompetitive from the terms of the agreement;
4 right?

5 A. That's correct.

6 Q. And you believe -- strike that.

7 You did not determine whether the settlement
8 agreement had actual anticompetitive effects. Instead,
9 you used the purported payments from Endo to Impax as,
10 quote, a reliable index of the welfare loss to
11 consumers; right?

12 A. The answer is yes, that's what I did, but no,
13 it's not true. That has nothing to do with
14 anticompetitive effects.

15 JUDGE CHAPPELL: That question was somewhat
16 compound. You might want to break it up. You asked
17 him whether he determined whether the agreement had
18 actual anticompetitive effects, and then you inserted
19 "instead," and I don't know -- to me, that was a vague
20 question.

21 MR. HASSI: Okay.

22 JUDGE CHAPPELL: His answer is not clear to me,
23 maybe because the question isn't clear.

24 MR. HASSI: It was not a great question,
25 Your Honor, I agree.

1 JUDGE CHAPPELL: I don't want him to
2 misunderstand and give us something that he doesn't
3 intend.

4 MR. HASSI: Understood, Your Honor.

5 BY MR. HASSI:

6 Q. You used the purported payments from Endo to
7 Impax as a reliable index of the welfare loss to
8 consumers; right?

9 A. Yes.

10 Q. You don't measure the actual welfare loss of
11 consumers; right?

12 A. The welfare loss to consumers is greater than
13 the payment. It's a -- there's an inequality. It's
14 not an equality, it's an inequality, so it is -- it's a
15 lower -- a lower bound on the anticompetitive harm.

16 Q. And your opinion is that you don't need to look
17 at or estimate actual effects after the settlement to
18 determine the impact of the agreement on consumer
19 welfare; correct?

20 A. I don't have to measure precisely what the
21 anticompetitive effects are if I can say that I know
22 they're positive.

23 Q. And you did not measure what the actual
24 anticompetitive effects are; correct?

25 A. I only put a lower bound on them.

1 Q. And that lower bound --

2 JUDGE CHAPPELL: Hold it, hold it.

3 Is that a no or is that a yes?

4 THE WITNESS: Well --

5 JUDGE CHAPPELL: And the reason I ask is, you
6 ended the question with "correct?" Why don't you ask
7 it again, or I'll have her read it, because the way the
8 question ended and the way he answered it, it's not
9 clear in the record.

10 MR. HASSI: Understood.

11 BY MR. HASSI:

12 Q. You did not measure what the actual
13 anticompetitive effects are.

14 A. That's correct. I do not measure the actual
15 anticompetitive harm in the market. I do not put a
16 dollar sign on the actual anticompetitive harm.

17 Q. And you didn't make any effort to calculate
18 the savings consumers would have arisen in the
19 hypothetical world where Impax would have entered;
20 correct?

21 A. That's not true there's no effort made to
22 measure any of that. There -- I did undertake effort
23 to produce a measure that's a lower bound.

24 Q. Sir, do you recall I asked you that question in
25 your deposition?

1 A. I don't remember.

2 JUDGE CHAPPELL: Hold on. The judge's realtime
3 is not working. Anyone else?

4 (Pause in the proceedings.)

5 Go ahead.

6 BY MR. HASSI:

7 Q. Sir, do you recall in your deposition I asked
8 you -- and this is at page 88 lines 5 to 8 -- "Did you
9 make any effort to calculate the savings to consumers
10 that would have arisen in this hypothesized world of
11 generic entry?" And you answered, "No"; correct?

12 A. Yes. I did not attempt to measure that
13 particular thing. What I did is put a lower bound on
14 it.

15 JUDGE CHAPPELL: That wasn't the question that
16 was asked, sir.

17 THE WITNESS: Yeah.

18 JUDGE CHAPPELL: The question was whether he
19 asked that and that was your answer at the deposition.

20 BY MR. HASSI:

21 Q. And the answer to that is yes?

22 A. I said, "Yes."

23 Q. Your opinion is that a large reverse payment
24 settlement rules out the possibility that the
25 settlement could benefit consumers; right?

1 A. Yes.

2 Q. I asked you earlier, but you agree that if
3 Impax could not reach a settlement with Endo, its
4 options were to continue the litigation or withdraw;
5 correct?

6 A. That's possible. Yes.

7 Q. And you acknowledge that Impax continuing the
8 litigation could have left -- rather than settling,
9 could have left consumers worse off; correct?

10 A. There are all kinds of -- that -- yes, that's
11 true. If they had decided to withdraw from the patent
12 infringement case, that would have been worse for
13 consumers.

14 Q. Well, I asked you if they considered -- if they
15 continued litigating instead of settled, that could
16 leave consumers worse off; right?

17 A. If they continued litigating and lost, that
18 would make consumers worse off.

19 Q. And likewise, if they abandoned their efforts,
20 that would almost certainly leave consumers worse off;
21 correct?

22 A. I thought that was the question you already
23 asked and I already answered it. I said -- yes, that's
24 what I just said.

25 Q. And your opinion is that the expectations of

1 the parties regarding the agreement's likely outcome
2 doesn't matter here; correct?

3 A. I'm sorry. I didn't follow.

4 Q. Your opinion is that the expectations of the
5 parties, meaning Impax and Endo, regarding the
6 agreement's likely outcome does not matter; correct?

7 A. Yeah. The -- the -- what matters is the value
8 of the settlement, not their expectations of it.

9 Q. So the parties' ex ante expectations about the
10 value of the settlement don't matter; correct?

11 A. That's correct. What matters is what the --
12 what the payment was, what the value -- what the
13 transaction was. The actual transaction was what
14 matters.

15 Q. And you don't make any effort to compare
16 ex ante expectations to ex post events; right?

17 A. I don't think I do compare the actual outcome
18 with any ex ante expectations.

19 Q. And you don't consider any of the ex post
20 events; correct?

21 A. Any of the ex post events?

22 Q. Ex post events, the events after the
23 settlement.

24 A. Well, I consider them, but I don't estimate a
25 probability of them. Remember we just talked about

1 ending of court cases of various kinds, so I consider
2 them, but they're not for the purpose of estimating
3 expected value.

4 Q. And also you don't consider those events for
5 the purpose of estimating consumer welfare; correct?

6 A. Yes. But that's an expected value.

7 Q. In other words, you've not set out to determine
8 whether in the real world consumers are better off as a
9 result of the settlement or not; correct?

10 A. Yes, I do attempt to decide whether in the real
11 world consumers are better off or worse off. I just
12 don't do it the way you're describing.

13 Q. You do it with a payment that you use as a
14 proxy for that; is that right?

15 A. It's not a proxy. It is a number that has
16 certain properties.

17 Q. Is it fair to say you believe consumers are
18 better off today because Impax is selling oxymorphone?

19 A. I think that's an extremely difficult question
20 to answer.

21 From the standpoint of the analysis in my
22 report where you evaluate things premised on my market
23 definition and my analysis of the benefits and costs,
24 then consumers are better off. But that doesn't mean
25 that the answer to the question is whether consumers

1 are better off from the existence of generic
2 oxymorphone ER. That's a -- that's a bigger question.

3 Q. Sir, you're aware that Impax' right to sell
4 oxymorphone ER today --

5 A. I'm sorry. What?

6 Q. You are aware that Impax' right to sell
7 oxymorphone ER today flows from the settlement that
8 Impax and Endo agreed to in 2010.

9 A. Well, it's part of the settlement agreement
10 that they get -- they're not going to be challenged on
11 the patents. That doesn't mean they wouldn't be
12 there.

13 I'm not sure I understand what you're -- what
14 you're asking me. Please clarify what you're asking
15 me, and I'll answer it.

16 Q. The settlement gave them certainty that they
17 could be -- gave Impax certainty that it could be in
18 the market today notwithstanding those patents; right?

19 A. That's exactly right. What a settlement does
20 is take uncertainty and create certainty from it.

21 Q. Going back to before the settlement, did the
22 fact that Impax had filed an ANDA and was first to file
23 have any effect on Endo's Opana ER prices?

24 A. At what point in time?

25 Q. Any point in time prior to June of 2010.

1 A. No. The existence of the Paragraph IV process
2 going on did not have an effect on prices.

3 JUDGE CHAPPELL: Along those lines, as an
4 economist, wouldn't the patent holder anticipating
5 generic entry consider increasing their current prices
6 to make money while they can?

7 THE WITNESS: What they actually do is not
8 that. What -- what -- what the pattern -- the normal
9 pattern of behavior in these markets is that they --
10 they do increase their price, but after entry occurs.

11 And the reason they do it is because the
12 market gets segmented between people who are subject
13 to generic substitution laws and formularies versus
14 people who aren't, and so the people who continue to
15 buy the brand name have a less elastic demand curve, so
16 brand name drugs typically raise their price when
17 generics enter. They don't lower them.

18 JUDGE CHAPPELL: But in this case, which is
19 the one we're concerned with, Opana ER was gone, is
20 gone and was gone.

21 THE WITNESS: Well, the Opana ER price
22 generally declined over the period before there was
23 generic entry. It was slightly declining. It was not
24 changing very much, but to the extent there was a
25 change, it was declining.

1 JUDGE CHAPPELL: Are you aware of when Opana ER
2 was removed from the market?

3 THE WITNESS: Just recently.

4 Well, there's two. Okay. You mean original or
5 reformulated?

6 JUDGE CHAPPELL: Original.

7 THE WITNESS: Okay. Yeah, the original -- the
8 original formulation was withdrawn early 2012.

9 MR. HASSI: May I proceed, Your Honor?

10 JUDGE CHAPPELL: Go ahead.

11 BY MR. HASSI:

12 Q. After -- had Impax and Endo not settled, but
13 after the end of the 30-month stay in June of 2010 --

14 A. Yes.

15 Q. -- would you expect Impax to have any -- Impax'
16 existence to have any effect on Endo's Opana ER
17 pricing?

18 A. Yes.

19 Q. And what effect would they have had on Endo's
20 prices?

21 A. Well, it could have gone several different
22 ways.

23 Had entry occurred then, it would have been
24 against original as opposed to reformulated. And then
25 we have the result that I just explained to the judge,

1 which is probably a slight increase in Opana ER and a
2 big decline in Impax. But in addition to that,
3 there's authorized AG, which is just Opana sold as a
4 generic, and that price would have been lower, so you
5 would have had -- you would have gone from one price in
6 the market to three prices, one of which was a little
7 higher, one of which was lower, and one of which was a
8 lot lower.

9 Q. And I apologize. I asked an incomplete
10 hypothetical.

11 A. Okay.

12 Q. I'm asking you to assume that the litigation
13 continues, Impax does not enter, the 30-month stay,
14 however, has passed, and Impax is waiting for a
15 decision, for example, from the district court.

16 At that point in time, does it have any effect
17 on Endo's prices?

18 A. Well, in principle, yes. But in practice,
19 from studying generic drug markets, the result we have
20 is usually there isn't a price effect of impending
21 generic entry until the generic entry actually
22 happens.

23 Q. So there's not an actual constraining effect
24 until there's actual entry; right?

25 A. I don't understand the question.

1 Q. Impax does not have a constraining effect on
2 Endo's prices until it actually enters; right?

3 A. Well, in principle, it could, in terms of
4 trying to get some sales out there that would affect
5 subsequent behavior, but in general, no.

6 I mean, you're -- it's hard to give a hundred
7 percent answers to any question in economics.

8 All right.

9 Yes, in general, what you say is true except
10 that expectation of entry sometimes does have an effect
11 on pricing behavior. I would not have expected it to
12 have happened in this case.

13 Q. You agree that one of the things that Impax got
14 out of the settlement was the certainty that it could
15 enter in January of 2013?

16 A. To Impax, yes. They got -- traded uncertainty
17 for certainty.

18 Q. And likewise, they got certainty that they
19 could come on the market and stay on the market
20 notwithstanding the patents that Endo had that were
21 pending at the time.

22 A. That's one of the certainties they achieved.

23 MR. HASSI: Your Honor, I have a few questions
24 that require us to go in camera.

25 JUDGE CHAPPELL: All right. At this time we'll

1 go into in camera session. I'll need to ask those who
2 of you who are not subject to the protective order in
3 this case to vacate the courtroom. You'll be informed
4 when we go back into public session.

5 (Whereupon, the proceedings were held in
6 in camera session.)

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(End of in camera session.)

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1 (The following proceedings continued in
2 public session.)

3 JUDGE CHAPPELL: Go ahead.

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5 REDIRECT EXAMINATION

6 BY MR. MEIER:

7 Q. Professor Noll, earlier today you were asked
8 about saved litigation costs.

9 Why do you only consider saved litigation costs
10 and not all litigation costs?

11 A. Because the resources that have been devoted to
12 litigation have already been used up and what you're
13 concerned about from the standpoint of overall economic
14 welfare or consumer welfare is the resources that still
15 have to be spent, and those are the forward-looking
16 litigation costs that would occur if there were not a
17 settlement.

18 Regardless of how the parties after the fact
19 decided to divide the costs of the sunk costs, the
20 costs are sunk. They've already been used. The people
21 have already been employed, and there's no way to save
22 them to get them back.

23 Q. So you mean the money that's already been spent
24 up to the time of the settlement, that's gone?

25 A. Well, the -- the -- the people that it was

1 spent on, their efforts have already happened, and
2 those efforts are no longer available to do something
3 else. On a forward-looking basis, the efforts of the
4 people involved in the litigation now can be used to do
5 something else if there's a settlement.

6 Q. Based on your economic understanding of the
7 Supreme Court's Actavis decision, is looking only at
8 saved litigation costs consistent with your
9 understanding of Actavis?

10 A. Yes.

11 Q. Earlier today -- I'm going to go back to the
12 good old ELMO. Let's see if I can get it focused.

13 Earlier today, I think Mr. Hassi put this
14 document up. It's a Federal Trade Commission agreement
15 containing consent order to aid public comment in the
16 matter of King Pharmaceuticals and Alpharma.

17 And I think that's tab 13 in the binder that
18 Mr. Hassi gave you. I don't remember what the DX
19 number was.

20 It was a demonstrative; correct?

21 MR. HASSI: It is a demonstrative.

22 I think it may be 5, but we'll locate it.

23 MR. MEIER: All right.

24 BY MR. MEIER:

25 Q. Do you remember looking at this document?

1 A. I do remember looking at this document.

2 Q. And there was some discussion about markets,
3 and there was some confusion about market and relevant
4 market. Do you recall that?

5 A. Yeah. I recall the dispute, and I also recall
6 that I don't know anything about the case.

7 Q. I'd like to show you the FTC's actual complaint
8 in that matter.

9 And I state for the record, Your Honor, that
10 this is a public record available on the FTC's website,
11 and we'll mark it for purposes of identification as
12 CX D-2 if I don't -- I think that's the next
13 demonstrative.

14 And I turn now to page 3 of the complaint where
15 there's a heading that says "The Relevant Market."

16 Do you see that?

17 A. Yes.

18 Q. I think that's as big as I can get it.

19 Are you able to read that?

20 A. Just barely, but I saw the highlighted part.

21 Q. So it says, "For the purposes of this
22 complaint, the relevant line of commerce in which to
23 analyze the effects of the Acquisition is no broader
24 than the manufacture and sale of oral LAOs" -- and then
25 there's a highlighted part that I highlighted -- "and

1 includes the narrower market for oral long-acting
2 morphine sulfate in which Kadian and Avinza compete
3 directly with each other."

4 Do you see that?

5 A. I --

6 Q. Why are you laughing?

7 A. Because it's almost identically what I said
8 without knowing what the case was. I said if it was a
9 case involving two different brands of morphine that
10 that's what I would define as the market.

11 Q. All right. Thank you.

12 A. Yeah.

13 JUDGE CHAPPELL: You're saying this is the
14 complaint; right?

15 MR. MEIER: Yes, Your Honor.

16 JUDGE CHAPPELL: Do you have the answer also?

17 MR. MEIER: This was filed as part of a
18 consent package, so there was no answer to the
19 complaint. When the FTC takes a consent in what's
20 known as Part 2 of our procedures, when a party
21 decides not to go into litigation with us, we issue a
22 complaint and we issue a consent agreement and we
23 issue the thing that Mr. Hassi showed him, the
24 analysis containing these documents.

25 So a party never actually responds to this

1 because they've settled with us.

2 JUDGE CHAPPELL: What we saw earlier was the
3 public record; correct?

4 MR. MEIER: These are all documents on the
5 public record. What we saw earlier was what's known
6 as the agreement containing the consent order to aid
7 public comment. It's put on the Federal Register so
8 that people can know about this and can comment on this
9 complaint and the order at that time. The commission
10 then takes 30 days to review that and then decides to
11 issue it as a final document, so --

12 JUDGE CHAPPELL: Just so we're clear, the
13 Federal Register that we saw, is that complaint that
14 you've just asked about included in the
15 Federal Register?

16 MR. MEIER: There's links to it, and it's also
17 linked on the FTC's website. This is --

18 JUDGE CHAPPELL: Is this the final? You said
19 this was put out for comment. Is this final?

20 MR. MEIER: This is the final complaint. This
21 was the public comment, asking people to comment on
22 this complaint and the consent.

23 JUDGE CHAPPELL: And my question is, after the
24 Federal Register document which we've seen earlier, was
25 there anything published after that?

1 MR. MEIER: What would be published after that
2 would be the commission would issue the final order in
3 the case after it's taken into account whatever public
4 comments are given.

5 Sometimes people do write comments to us and we
6 write responses back, and that's also filed on the
7 FTC's website. Sometimes the commission goes back and
8 modifies the order as a result of the public comments.
9 In most instances, the commission takes the public
10 comments into account but leaves the order and the
11 complaint the way it initially issued it.

12 JUDGE CHAPPELL: And timing-wise, the complaint
13 came first; correct?

14 MR. MEIER: The complaint came first.

15 JUDGE CHAPPELL: And this public --

16 MR. MEIER: And then the public notice goes up
17 after the commission accepts this complaint.

18 JUDGE CHAPPELL: And since you brought this up,
19 did this language in the register that identified what
20 the market was for LAOs, did that language change at
21 any point in what was published?

22 MR. MEIER: No, it did not change.

23 JUDGE CHAPPELL: All right. Thank you.

24 MR. MEIER: In fact, if we -- we can verify
25 that by taking a look at the public register notice, if

1 I can find it again. It's kind of hard to read on
2 the -- I apologize. Let me see if I can find it fairly
3 quickly.

4 JUDGE CHAPPELL: I'll accept your
5 representation. That's your bailiwick.

6 MR. MEIER: It did not change.

7 BY MR. MEIER:

8 Q. Earlier today in questioning by Mr. Hassi about
9 what he called actual anticompetitive effects --

10 JUDGE CHAPPELL: You might want to turn the
11 ELMO off if you're through with it. He's getting some
12 age on him, been sitting there for twenty years.

13 MR. MEIER: Well, I'm an old guy myself,
14 Your Honor.

15 BY MR. MEIER:

16 Q. Earlier today, Professor Noll, in questioning
17 by Mr. Hassi, he asked you about something he called
18 actual anticompetitive effects.

19 In your opinion, if a payment leads to a
20 settlement that prevents the risk of competition, is
21 that an actual anticompetitive effect?

22 A. Of course.

23 Q. Earlier there was also some questioning about
24 whether you put an actual dollar number on the amount
25 of the anticompetitive effects in this case.

1 Why didn't you put an actual dollar number on
2 the anticompetitive effects in this case?

3 A. Because once I knew that the lower bound was as
4 big as it is, I didn't need to estimate the actual
5 value, number one.

6 And number two, estimating it would have
7 required doing expected value calculations over
8 contingent events that are impossible to do, so I -- I
9 stopped at satisfying the inequality. I know that the
10 effect is X, is at least X dollars, which is greater
11 than zero, and it could be more.

12 Q. What do you mean by "put a lower bound on it"?

13 A. I mean that the anticompetitive effect, the
14 harm to consumers, has to be at least that much and it
15 is probably more. It could be equal to it, but it's
16 probably more.

17 Q. Yesterday, during Mr. Hassi's
18 cross-examination, there was some discussion about the
19 real world.

20 In the real world, based on your analysis of
21 the data in this case, what happened to the sales and
22 price of branded Opana ER when Impax' generic
23 oxymorphone eventually entered the market after
24 January 1, 2013?

25 A. The price of Opana ER went up slightly, the

1 sales of Opana ER dropped dramatically, and the average
2 price for all oxymorphone ER dropped.

3 Q. Is that discussed in your expert report?

4 A. Yes.

5 Q. Based on your analysis --

6 JUDGE CHAPPELL: Hold on a second.

7 Just so we're clear, based on something you
8 said to me earlier, when you say "Opana ER," are you
9 talking about the alternate version that's crushproof
10 or the original brand name Opana ER?

11 THE WITNESS: At the time Impax entered, the
12 crushproof version was the one that's on the market.

13 JUDGE CHAPPELL: So even though you're saying
14 "Opana ER," you're talking about crushproof.

15 THE WITNESS: Yeah. Well, in -- I'm talking
16 about -- unfortunately, it's -- I try to say
17 reformulated versus original, but I don't always do it
18 because it's always called Opana ER. But at the time
19 Impax entered, the only version of Opana on the
20 market -- Opana ER on the market was the crushproof
21 version.

22 MR. MEIER: Your Honor, I'll try to make a
23 little bit of clarification on that.

24 BY MR. MEIER:

25 Q. When you defined the market in this case, you

1 defined it as oxymorphone ER; is that correct?

2 A. That's the relevant market. Yes.

3 Q. And how many different actual oxymorphone ER
4 products were in your relevant market at any given time
5 in the analysis of this case?

6 A. There are seven different dosages produced by
7 three different firms, and then one of the firms,
8 Endo, produced two different versions of it, the
9 original formulation and the crushproof formulation.

10 Q. And so all of those different doses and forms
11 are in your oxymorphone product market in this case.

12 A. That's correct.

13 Q. So I want to get back to talking about the real
14 world.

15 In the real world, based on your analysis of
16 the data in this case, what happened to the sales and
17 price of branded Opana ER when generic oxymorphone IR
18 products became available?

19 A. Nothing. It had no impact. The price and
20 sales were unaffected by the entry of generic
21 oxymorphone IR.

22 Q. And in the real world, based on your analysis
23 of the data in this case, what happened to the sales
24 and price of branded Opana ER when generic forms of
25 other long-acting opioids became available?

1 A. The same answer. Nothing. It had no effect.

2 Q. And is that discussed in your expert report?

3 A. Yes, it is.

4 Q. In the real world, based on your analysis in
5 this case, how much did Endo pay Impax under the terms
6 of their June 8, 2010 settlement agreement?

7 A. \$112 million.

8 MR. MEIER: No further questions, Your Honor.

9 JUDGE CHAPPELL: Recross?

10 MR. HASSI: No, Your Honor.

11 JUDGE CHAPPELL: Thank you. You're excused.

12 THE WITNESS: Okay.

13 JUDGE CHAPPELL: What's the anticipated time
14 we'll need for the next witness?

15 MR. LOUGHLIN: For the direct I think about
16 90 minutes.

17 JUDGE CHAPPELL: Any idea about cross?

18 MR. HASSI: I would think less than an hour,
19 Your Honor.

20 JUDGE CHAPPELL: Do we have another witness
21 lined up after this witness?

22 MR. LOUGHLIN: This is our last witness,
23 Your Honor, so we will rest, other than our rebuttal
24 expert, after this witness.

25 JUDGE CHAPPELL: All right. I wasn't sure

1 about this, so now we know.

2 All right. We'll go ahead and take our usual
3 hour. We'll reconvene at 2:20.

4 We're in recess.

5 (Whereupon, at 1:19 p.m., a lunch recess was
6 taken.)

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1 case.

2 JUDGE CHAPPELL: Okay.

3 BY MR. LOUGHLIN:

4 Q. Mr. Engle, what is your current position at
5 Impax?

6 A. My title is vice president, sales and
7 marketing, for the generics division.

8 Q. And who do you currently report to?

9 A. Doug Boothe.

10 Q. And how long have you reported to Mr. Boothe?

11 A. Since August 2016.

12 Q. And who did you report to before you reported
13 to Mr. Boothe?

14 A. Immediately prior to Mr. Boothe I was reporting
15 to Fred Wilkinson.

16 Q. And how long was that?

17 A. I would -- approximately one and a half years.

18 Q. So mid-2014?

19 A. Approximately.

20 Q. And how about before Mr. Wilkinson?

21 A. Immediately prior to Mr. Wilkinson I was
22 reporting to Carole Ben-Maimon.

23 Q. Now, your responsibilities relate primarily to
24 generic products; correct?

25 A. Yes.

1 Q. You're familiar with Impax' efforts to develop
2 a generic form of Opana ER; correct?

3 A. I am.

4 Q. And in 2010, Impax was eligible for 180-day
5 exclusivity for five dosages of Opana ER. Are you
6 aware of that?

7 A. Yes.

8 Q. And those were the five most popular dosages of
9 Opana ER; correct?

10 A. I believe they were the more highly prescribed
11 strengths.

12 Q. And are you familiar with the term
13 "authorized generic"?

14 A. Yes.

15 Q. What is an authorized generic?

16 A. It's my understanding an authorized generic is
17 a --

18 JUDGE CHAPPELL: Sir, please limit your
19 answers to what you know, not your understanding or
20 your belief or what you think. Let's stick with what
21 you know.

22 THE WITNESS: Impax -- I have sold authorized
23 generic drugs that -- they're -- that I've -- I've sold
24 them. I don't know if I can answer the rest of the
25 question.

1 BY MR. LOUGHLIN:

2 Q. Do you understand that an authorized generic is
3 a generic sold by the patent holder or a licensee of
4 the patent holder?

5 A. Yes.

6 Q. And if -- when Impax has 180 days of
7 exclusivity, you understand that that does not
8 prevent -- that the -- that does not prevent the brand
9 from selling an authorized generic; correct?

10 A. That's correct.

11 Q. In your experience, how does an authorized
12 generic affect the sales of the generic filer with
13 180 days of exclusivity?

14 A. Similar to other suppliers, there would be --
15 it's another competitor in the market, and we may -- it
16 may have an impact on sales.

17 Q. An impact on sales in terms of the amount of
18 sales that Impax gets from its generic?

19 A. Yes.

20 Q. It would lower the amount of sales that Impax
21 gets from its generic; correct?

22 A. It could potentially lower the sales.

23 Q. And you would also expect that it would cause
24 Impax to sell at a lower price than it otherwise would;
25 correct?

1 MR. HASSI: Your Honor, objection.

2 Speculation.

3 MR. LOUGHLIN: I'm not asking for speculation,
4 Your Honor.

5 JUDGE CHAPPELL: The way it's phrased, what he
6 would expect, that's speculation. You need to
7 rephrase.

8 MR. LOUGHLIN: All right.

9 BY MR. LOUGHLIN:

10 Q. In your experience, competition from an
11 authorized generic lowers the price that Impax sells
12 its generic product at; correct?

13 A. I have seen -- I have experienced additional
14 competition resulting in a lower selling price.

15 Q. Additional competition from an authorized
16 generic; correct?

17 A. Correct.

18 Q. And additional competition from an authorized
19 generic during the 180-day exclusivity period;
20 correct?

21 A. Correct.

22 Q. Now, the primary way that AB-rated generics
23 make sales is by substitution for the branded product;
24 correct?

25 A. I'm not -- can you -- I'm not sure if I

1 understand what your question is.

2 Q. Okay. In your experience selling generic
3 products at Impax, sometimes Impax' generic product is
4 called AB-rated to the branded product; correct?

5 A. Correct.

6 Q. Do you understand what an AB rating means?

7 A. Yes.

8 Q. Can you tell us what an AB rating is?

9 A. It's when the product is A-rated in the
10 Orange Book by FDA that it is substitutable for a --
11 its reference brand product.

12 Q. And the primary way that Impax makes sales of
13 an AB-rated generic drug is through that substitution
14 for the branded product; correct?

15 A. Yes.

16 Q. Now, when Impax launched its generic form of
17 oxymorphone ER in 2013, it was not AB-rated to the
18 current version of Opana ER that was on the market at
19 the time; correct?

20 A. Correct.

21 Q. In 2013, when Impax launched its generic
22 product, Endo had reformulated and launched a
23 reformulated version of Opana ER; correct?

24 A. Correct.

25 Q. And that affected Impax' ability to sell its

1 generic version of Opana ER; correct?

2 A. It -- it doesn't impact the ability to sell.

3 We -- Impax was still able to sell.

4 Q. But you weren't able to rely on automatic
5 substitution by pharmacists for the branded product;
6 correct?

7 A. I understand that in twenty -- approximately
8 twenty states there are -- that the state pharmacies
9 have the ability to substitute in those states, but the
10 remaining states do not have the authorization to
11 automatically substitute the product.

12 Q. When Impax launched its generic version of
13 Opana ER in 2013, it was not able to rely on automatic
14 substitution for the branded product where those states
15 allowed it; right?

16 A. I'm not sure what you mean by "where those
17 states allowed it."

18 Q. In whatever states allowed for automatic
19 substitution for the brand, for the branded product, in
20 the context of an AB-rated generic, Impax was not able
21 to rely on that when it launched its generic version of
22 Opana ER; correct?

23 A. I believe in the -- no. I disagree with your
24 statement.

25 Q. So you're saying when Impax launched --

1 JUDGE CHAPPELL: Could you lay a better
2 foundation, what knowledge, if any, this witness has of
3 this substitution you're referring to.

4 I mean, he's a sales and marketing person, but
5 I don't know if he knows anything about pharmacists.

6 MR. LOUGHLIN: Okay. I thought he had
7 testified that he understood that substitution was the
8 main way that they made sales, but I can ask that
9 again.

10 BY MR. LOUGHLIN:

11 Q. Mr. Engle, in your experience, the main way
12 that Impax makes sales of its AB-rated generics is
13 through substitution at the pharmacy level, right, the
14 pharmacy substituting the brand -- the generic for the
15 branded product; correct?

16 A. Correct.

17 Q. And when Impax launched its generic version of
18 Opana ER in 2013, it was not AB-rated to the Endo
19 branded product on the market at the time; correct?

20 A. That's correct.

21 Q. Now, Mr. Engle, can you describe what your
22 responsibilities are as vice president of sales and
23 marketing at Impax.

24 A. I manage the field sales team on the generic
25 division. I am responsible for forecasting both sales

1 and operationally how much production. I'm responsible
2 for the customer service group processing orders.

3 And at the time of the launch of
4 oxymorphone ER, I was also responsible for the
5 contract administration group, rebates, admin fees,
6 chargebacks.

7 Q. Now, in terms of generic sales, one category of
8 customers is wholesalers; right?

9 A. Yes.

10 Q. And for the big wholesalers, they generally
11 have a preferred list of suppliers from which they buy
12 generic pharmaceuticals; correct?

13 A. I'm not aware of a preferred list of generic
14 suppliers.

15 Q. You're not aware that big wholesalers often
16 have a list of preferred suppliers from which they buy
17 specific generic products?

18 A. I'm -- I'm familiar with preferred lists of
19 drugs or winning formulary positions, but I'm not --
20 I'm not aware of a preferred list of suppliers.

21 Q. So when wholesalers have a preferred list of
22 drugs, they're buying that particular generic drug from
23 a specific supplier; correct?

24 A. That's correct.

25 Q. And that means that, in your experience, when

1 Impax is selling a generic along with other companies
2 that are selling the same generic version, the
3 wholesaler won't buy from all of the generic companies;
4 correct?

5 A. Correct.

6 Q. In other words, the wholesaler will select one
7 or maybe a couple generic companies from which to buy
8 the specific generic product; correct?

9 A. That is correct.

10 Q. And Impax has to compete against other generic
11 companies to get on this preferred list by -- of the
12 wholesaler; right?

13 A. I think you're describing what I refer to as
14 winning a formulary position, so we might win the
15 primary spot in a formulary award.

16 Q. And this is a formulary put together by the
17 wholesaler; right?

18 A. Correct.

19 Q. And Impax competes on price against other
20 generics to get on this wholesaler formulary; correct?

21 A. Correct.

22 Q. Now, in your experience, when Impax has
23 180 days of exclusivity, the wholesaler will put
24 Impax, Impax' generic, on its wholesaler formulary;
25 right?

1 A. It may, if we had agreed to a price.

2 Q. Well, the wholesaler -- when Impax has 180 days
3 of exclusivity, the wholesaler's only choice for a
4 generic version of the brand product is either Impax or
5 potentially an authorized generic; correct?

6 A. That's their choice if they can agree to a
7 price, right.

8 Q. And if they don't agree to a price, then they
9 don't have any generic product; is that what you're
10 saying?

11 A. Yes.

12 Q. Have you had an experience where Impax did not
13 agree on a price with a wholesaler in order to get its
14 product on the formulary when it had 180 days of
15 exclusivity?

16 A. I don't recall in a situation like that.

17 JUDGE CHAPPELL: Can you give us an example of
18 who are these wholesalers we're talking about?

19 THE WITNESS: The three big national
20 wholesalers would be AmerisourceBergen, Cardinal Health
21 and McKesson Health.

22 JUDGE CHAPPELL: So insurance companies or
23 insurance company wholesalers?

24 Are they connected to insurance companies?

25 THE WITNESS: No, they are not.

1 JUDGE CHAPPELL: So these are just drug
2 wholesalers.

3 THE WITNESS: Correct.

4 JUDGE CHAPPELL: Thank you.

5 BY MR. LOUGHLIN:

6 Q. Now, another category of customers for Impax'
7 generic products are the big pharmacy chains; correct?

8 A. Yes.

9 Q. And the big pharmacy chains are Rite Aid, CVS
10 and Walgreens; correct?

11 A. Yes. They are three big ones.

12 Q. And in your experience, when Impax is selling a
13 generic version of a branded product along with other
14 generic companies, the big chain pharmacies don't
15 generally buy from all those generic companies;
16 correct?

17 A. They generally pick one or two suppliers.

18 Q. One or two suppliers for a specific generic
19 drug; right?

20 A. Correct, for a specific generic drug.

21 Q. And Impax has to compete on price to get its
22 generic version of a specific branded product into
23 those big chain pharmacies; correct?

24 A. Yes.

25 Q. Now, I think you said that another one of your

1 responsibilities as vice president of sales and
2 marketing is forecasting; is that correct?

3 A. Yes.

4 Q. And you do forecasting for products that Impax
5 currently sells; correct?

6 A. Correct.

7 Q. And you also do forecasting for products that
8 Impax expects to launch in the future; correct?

9 A. Correct.

10 Q. And one goal of forecasting is to provide
11 information to the operations group for production
12 planning; correct?

13 A. Correct.

14 Q. And another goal is to provide information to
15 management to help them make decisions to run the
16 company; right?

17 A. Correct.

18 Q. Now, Mr. Engle, when you're forecasting sales
19 of a generic product that has not yet been launched,
20 there are a number of assumptions you make in those
21 forecasts; correct?

22 A. Yes.

23 Q. One assumption that you make is the launch date
24 for that generic product; right?

25 A. Correct.

1 Q. And in addition to the launch date, another
2 assumption you'll make is about the number of
3 competitors that Impax will face for its generic
4 product; right?

5 A. Yes.

6 Q. And your practice in doing forecasting is that
7 when you forecast that Impax is going to be the only
8 generic on the market, you assume that in the first
9 month on the market 60 percent of the sales of the
10 product will go to the generic; correct?

11 A. That's a -- that's a good milestone or marker
12 that I generally default to as a first step.

13 Q. And the percentage of sales that go to the
14 generic, is that sometimes referred to as generic
15 penetration rate?

16 A. Yes.

17 Q. And if in your -- when you're forecasting and
18 your assumption is that Impax will be the only generic
19 version on the market, you would forecast that all of
20 the generic sales would go to Impax; correct?

21 A. Yes.

22 Q. And your practice is, when you are forecasting
23 a second generic competitor to be on the market, you
24 would assume that Impax and the other generic would
25 split the generic sales in some fashion; correct?

1 A. I would assume that there would -- Impax would
2 not have a hundred percent of that generic market.

3 Q. In other words, Impax would get some of those
4 generic sales, and the other generic company would get
5 some of those generic sales; correct?

6 A. Yeah. That's what I use for my assumptions.

7 Q. And in your practice, when you're forecasting a
8 second generic competitor on the market, you would
9 assume that 60 percent of this total sales would go
10 generic in the first month but that sales would
11 increasingly go generic in subsequent months; correct?

12 A. Would you mind repeating that question.

13 Q. I would not mind at all.

14 In your practice doing forecasting, when
15 you're forecasting that Impax and another generic
16 company will be on the market together, your practice
17 is to assume that 60 percent of the total sales of the
18 product will be generic in the first month and that
19 sales would increasingly go generic in subsequent
20 months; correct?

21 A. Yes. That's similar to what I do with one
22 supplier.

23 Q. And you make an assumption about increasing
24 generic sales, in other words, increasing generic
25 penetration, whether the second generic competitor is

1 an authorized generic or some other generic; correct?

2 A. Correct.

3 Q. In other words, you treat an authorized generic
4 no differently than you would some other kind of
5 generic for purposes of forecasting; correct?

6 A. Actually, I treat it -- I try to think about
7 the suppliers. I try to think about what I know about
8 a supplier and not -- not just on a number but maybe my
9 past experience with an alternative supplier.

10 Q. I see.

11 So you would be forecasting not only how many
12 generic competitors Impax would face but which generic
13 competitors those would be?

14 Is that right?

15 A. If I know who might be there, I might take that
16 into my thinking as well, because I try to come up with
17 kind of a broad range of possibilities in my
18 assumptions.

19 Q. In general, in your practice in forecasting,
20 if you expect or when you forecast that there are
21 going to be more than two generic competitors, you
22 would assume an even faster rate of generic
23 penetration than 60 percent; correct?

24 A. I can't conclude that. I don't do it the same
25 way all the time.

1 Q. Okay. Let me ask it this way then.

2 In your practice when you are forecasting that
3 there will be more than two generic companies on the
4 market, you forecast a greater rate of generic
5 penetration than you would if there were fewer generic
6 competitors on the market; correct?

7 A. I don't do that as a normal course of
8 practice.

9 Q. You don't?

10 A. No. I don't believe so.

11 Q. You're saying that you don't generally
12 increase the penetration rate when there are more
13 generics than when there are fewer generics in your
14 forecasting?

15 A. I'm not sure I do it consistently. It may be
16 more of a feel for the situation.

17 JUDGE CHAPPELL: We seem to be spinning wheels
18 here about all these scenarios. Any reason why you're
19 not asking this fact witness what he did in this case
20 regarding the drug at issue in this case?

21 MR. LOUGHLIN: I am going to ask him that,
22 Your Honor, but first I wanted to establish his general
23 practice. I think his general practice is relevant to
24 this case.

25 JUDGE CHAPPELL: It may be relevant, but it's

1 not any more relevant than what he actually did in this
2 case.

3 MR. LOUGHLIN: I plan to go over both,
4 Your Honor.

5 BY MR. LOUGHLIN:

6 Q. Now, in your experience, Mr. Engle, another
7 assumption that you need to make when you're
8 forecasting sales of a generic product is the average
9 net selling price; correct?

10 A. Correct.

11 Q. And your practice is that when you forecast an
12 average net selling price, you use a discount off the
13 brand's list price; correct?

14 A. Correct.

15 Q. And that list price is sometimes called the --
16 a WAC price, W-A-C; is that right?

17 A. Correct.

18 Q. What does WAC or W-A-C stand for?

19 A. The wholesale acquisition cost.

20 Q. And in your forecasting, you always assume a
21 discount off the reference brand's list price and not
22 the prices of other branded products; correct?

23 A. Correct.

24 Q. And so, for example, in doing forecasts for
25 oxymorphone ER, you used a discount off the list price

1 of Opana ER and not other branded long-acting opioid
2 products; correct?

3 A. Correct.

4 Q. And your practice is that when you forecast
5 Impax to be the only generic on the market, you use a
6 discount of 20 percent off the brand's list price; is
7 that right?

8 A. I think that a -- can you restate that
9 question, please.

10 Q. Sure.

11 Your general practice is that when you're
12 forecasting Impax to be the only generic on the market,
13 you use a discount of 20 percent off the brand's list
14 price; correct?

15 A. What price am I trying to get to? I'm not sure
16 if I'm following your question.

17 Q. Sure.

18 When you're trying to forecast the generic's
19 average net selling price and if you're forecasting
20 that Impax is going to be the only generic on the
21 market, you would use a discount of 20 percent off the
22 brand's list price for Impax' average net selling
23 price; correct?

24 A. No. I -- when Impax is the first and only
25 generic, I generally assume that the average net price

1 Impax will experience is approximately 55 percent of
2 the brand's WAC price.

3 Q. Okay. So 55 percent when Impax is the only
4 generic; correct?

5 A. Correct.

6 Q. And your practice is that when you're
7 forecasting that Impax and another generic will launch
8 their generics on the same day, you assume a lower
9 generic price; correct?

10 A. Correct.

11 Q. And the reason that you use a lower average --
12 net average selling price for Impax' generic is that
13 when there are more generics on the market, you expect
14 that the additional generic competition will compete
15 down the price; correct?

16 A. Yes, I do expect that will compete down the
17 price.

18 Q. And the fact that those -- that additional
19 generic competition will compete down the price is why
20 you also assume a higher generic penetration rate when
21 there are more generic competitors; right?

22 A. I'm not sure I always equate the price with a
23 generic penetration rate.

24 Q. But you do agree that as price goes down,
25 ultimately the brand has less ability to compete on

1 price, and so over time generic competitors take more
2 and more sales; correct?

3 A. I don't agree that the brand cannot compete on
4 price. I -- I don't conclude that. Too many factors
5 would be involved in that.

6 Q. Do you recall testifying in this case in 2014?

7 A. Yes.

8 Q. Do you recall whether you testified that
9 eventually the brand product couldn't lower its price
10 enough to actually be competing with the generic
11 products?

12 A. It sounds familiar, but I think also that I
13 have new experience that says I have seen brand
14 products compete with generics over the past several
15 years.

16 Q. I see.

17 So as of 2014, you agree that there was a
18 point at which the brand product couldn't continue to
19 lower its price to compete with generic products, but
20 since then things have been different; is that your
21 testimony?

22 A. I can only respond based on my experience, and
23 my experience has evolved. I have more years of
24 experience now.

25 Q. Okay. I understand that. I want to make sure

1 I understand that.

2 You believe that your testimony in 2014 that
3 there's a point at which brand products can no longer
4 compete with generics was accurate as of 2014.

5 A. Correct.

6 Q. Okay. Now, Mr. Engle, one of the forecasts
7 that you're involved with at Impax is called the
8 five-year plan; correct?

9 A. Correct.

10 Q. And the five-year plan forecasts the
11 performance of Impax over the next five years;
12 correct?

13 A. Well, it is a draft with many, many
14 assumptions that I put together, so it -- it's -- it's
15 a first draft.

16 Q. Fine.

17 It's a draft that tries to forecast
18 performance of Impax over the next five years;
19 correct?

20 A. Correct.

21 Q. And that forecast is something that Impax does
22 in the regular course of business; right?

23 A. Correct.

24 Q. And it's updated quarterly; correct?

25 A. Correct.

1 Q. And the purpose of the five-year plan is to
2 help senior management with business planning;
3 correct?

4 A. Correct.

5 Q. And so you try to be as accurate as you can in
6 your assumptions in the five-year plan; correct?

7 A. I try to give a good range of possibilities
8 and recognizing the fact that I don't know everything
9 and they -- senior management may have other
10 information I don't have, so it's a -- it's a starting
11 point, which they can use to make their judgments and
12 their decisions.

13 Q. Sure.

14 But when you put together the five-year plan,
15 you're trying to do your best to make sure that it's
16 accurate based on the information you have; correct?

17 A. I try to be accurate, but I'm trying to be in
18 the ballpark and to be reasonably correct and provide
19 management with those tools.

20 Q. Sure.

21 And when you said earlier that it was a draft,
22 you meant that it's a draft because it's constantly
23 evolving; correct?

24 A. Well, I provide the forecast that we were
25 referring to, I provide that to our finance department,

1 and they do whatever they do to it, which I'm not
2 involved with.

3 Q. Let me -- let's -- Mr. Engle, next to you --
4 first, there's a bottle of water, so if you need that,
5 that's for you. Okay?

6 A. Okay.

7 Q. Second, there is a binder full of documents
8 next to you. I'm going to ask you to turn in the
9 binder to CX 004. The document is also going to be
10 displayed on the screen in front of you, so if that's
11 easier, you can look at it on the screen. It's up to
12 you.

13 (Document review.)

14 Now, Your Honor, I'll note for the record that
15 CX 0004 has been admitted as part of JX 2 and it is not
16 in camera.

17 Now, Mr. Engle, do you see that the cover
18 e-mail here is from someone named Kevin Sica and it's
19 copied to you?

20 Do you see that?

21 A. Yes.

22 Q. And it's dated February 19, 2010.

23 Do you see that?

24 A. Yes.

25 Q. Now, what was Mr. Sica's role in February of

1 2010?

2 A. He worked for me. I think his title was
3 manager of sales planning.

4 Q. Was he involved in the five-year plan?

5 A. Yes.

6 Q. And in February 2010 you had input into the
7 five-year plan; correct?

8 A. Yes.

9 Q. Can I ask you to turn to CX 0004-014.

10 Can you actually show the very top part of it
11 where it says "Oxy."

12 Mr. Engle, do you see up at the top of
13 CX 0004-014 where it says "Oxy 5, 10, 20 and 40"?

14 A. Yes.

15 Q. And that -- this page is a forecast for sales
16 of Impax' generic Opana ER in those dosages; correct?

17 A. Correct.

18 Q. And it forecasts Impax' sales of generic
19 Opana ER in both units and dollars; correct?

20 A. Correct.

21 Q. Now, along the left side, do you see that there
22 are rows, some of which say "Upside" and some of which
23 say "Base"?

24 A. Yes.

25 Q. And upside is a more optimistic forecast;

1 correct?

2 A. Correct.

3 Q. And base is a more conservative forecast?

4 A. Correct.

5 Q. And the three rows on the left-hand side that
6 say "Upside" show the assumptions that are being made
7 in this forecast for the upside forecast; correct?

8 A. I believe that's correct.

9 Q. And so, for example, on the upside forecast for
10 Impax generic market share, in the first column it says
11 "100 percent"; right?

12 Do you see that?

13 A. Yes.

14 Q. And the first column is June of 2010?

15 A. Correct.

16 Q. So this forecast is assuming that Impax'
17 generic oxymorphone ER would be on the market in June
18 of 2010; correct?

19 A. Correct.

20 Q. And this forecast in the upside is assuming
21 that Impax would be the only generic on the market in
22 June of 2010; correct?

23 A. Correct. That's what this upside shows.

24 Q. And you can see that because you're projecting
25 or you're assuming a hundred percent of the generic

1 market share; correct?

2 A. Correct.

3 Q. And now, below the generic market share, still
4 under the upside section, there's an assumption for the
5 Impax net price as a percentage of brand WAC.

6 Do you see that?

7 A. Yes.

8 Q. And as we talked about before, that's the
9 percentage of the brand's list price; correct?

10 A. Correct.

11 Q. And the brand in this forecast is Opana ER --
12 is Endo's Opana ER; correct?

13 A. Correct.

14 Q. And in the upside scenario, Impax is
15 forecasting that its net price is going to be
16 55 percent of Endo's brand list price when it enters in
17 June of 2010; correct?

18 A. Just to be specific, that would be the average
19 of all the customers would be approximately
20 55 percent.

21 Q. Okay. Thank you for that clarification.

22 And below the Impax net price as a percentage
23 of brand WAC there's a row that says "Generic
24 substitution."

25 Do you see that?

1 A. Yes.

2 Q. And again we're still in the upside scenario,
3 and the generic substitution rate is 50 percent;
4 correct?

5 A. Correct.

6 Q. And so you're assuming that in the first month
7 on the market, generics -- excuse me -- let me start
8 that over.

9 You're assuming that in June of 2010, the first
10 month that Impax' generic oxymorphone ER would be on
11 the market, that Impax' generic oxymorphone ER would
12 capture 50 percent of the brand's prescriptions;
13 correct?

14 A. Correct.

15 Q. Now, underneath the upside assumptions are
16 three similar rows for the base scenario; correct?

17 A. Yes.

18 Q. And if you look at June of 2010, generic market
19 share is zero in the base scenario; correct?

20 A. I'm sorry. I don't see where you're referring
21 to.

22 Q. Okay. Do you see under Generic Substitution in
23 the upside it says "50 percent"? Where we were just
24 looking?

25 A. Yes.

1 Q. The next row underneath it says Impax generic
2 market share of zero in that first column?

3 Do you see that?

4 A. Yes, I see that.

5 Q. And that's a zero under the base-case scenario;
6 correct?

7 A. Yes. That's what the assumption is.

8 Q. Okay. And so if you turn to CX 0004-015, which
9 is the next page of this forecast, do you see that for
10 the base-case scenario there isn't -- there isn't
11 anything in the Impax generic market share row until
12 July of 2011.

13 Do you see that?

14 A. Yes. I notice -- I see that assumption.

15 Q. And so the base-case scenario is assuming that
16 Impax would launch its generic version of Opana ER in
17 July of 2011; correct?

18 A. Yes. That's what this model shows.

19 Q. And the base-case assumption is that with
20 respect to generic substitution -- or excuse me. Let
21 me start that over.

22 The base-case assumption is that Impax' generic
23 market share when it launches in July of 2011 would be
24 50 percent; correct?

25 A. Yes. I see that assumption.

1 Q. That means that Impax was assuming in this
2 forecast that there would be another generic on the
3 market in July of 2011; correct?

4 A. I don't know that I would say that it's Impax.
5 I think that it just shows that this model shows that.

6 Q. Okay. I -- thank you for that correction.

7 This forecast that Impax or that people
8 from -- employees of Impax put together shows that
9 under the base-case scenario, in July of 2011, the
10 Impax employees were assuming that there would be
11 another generic on the market along with Impax;
12 correct?

13 A. That's what this model shows. Yes.

14 Q. And Impax would get 50 percent of the sales,
15 the generic sales, and the other company would get the
16 other 50 percent; correct?

17 A. It would get 50 percent of the units; right?
18 It's packages; right?

19 Q. Yes. Thank you for that correction.

20 Now, continuing with the base scenario, the row
21 below Impax generic market share says "Impax net price
22 as a percentage of brand WAC."

23 Do you see that?

24 A. Yes.

25 Q. And in the base-case scenario, Impax' net price

1 as a percentage of brand WAC is 35 percent in
2 July 2011; correct?

3 A. Correct.

4 Q. So Impax would be entering at a lower price
5 than it was in the upside scenario; correct?

6 A. That's correct.

7 Q. Now, Mr. Engle, can I ask you to turn back a
8 page to CX 0004-014, the original page we were looking
9 at.

10 Do you have it?

11 A. I have it. Thank you.

12 Q. Now --

13 JUDGE CHAPPELL: I have a question.

14 I heard you tell us earlier that you prepare a
15 forecast, send your work to finance, and then you have
16 nothing to do with what they do from that point;
17 correct?

18 THE WITNESS: I said that, yes. I did say
19 that.

20 JUDGE CHAPPELL: Is that correct?

21 That's true; right? Not that you said it, but
22 that's true.

23 THE WITNESS: It is true. I send my work to
24 finance. And in this particular case, I can see that
25 Mr. Mengler had asked for information. But, yeah, we

1 produce the forecast.

2 JUDGE CHAPPELL: I'm just trying to figure out
3 with this document you've been talking about for oh so
4 many minutes, is this the version you did or is this
5 after you passed it on and someone worked on it?

6 THE WITNESS: I believe this is the version
7 that Kevin Sica and I worked on together and we passed
8 it on to Mr. Mengler.

9 JUDGE CHAPPELL: So this appears to be your
10 work you're talking about?

11 THE WITNESS: It does appear to be my work.

12 JUDGE CHAPPELL: Who was the other gentleman
13 you named?

14 THE WITNESS: Kevin Sica is a manager who
15 reports in to me.

16 JUDGE CHAPPELL: So you and he would work on
17 these forecasts?

18 THE WITNESS: Right.

19 JUDGE CHAPPELL: All right. Thank you.

20 BY MR. LOUGHLIN:

21 Q. And you were Mr. Sica's boss; correct?

22 A. Correct.

23 Q. And Ms. Clark, can we go back to the front page
24 of this document.

25 And if you look up at the top, this version of

1 the five-year plan that we're looking at was sent
2 directly to Chris Mengler; correct?

3 A. Correct.

4 Q. And Chris Mengler was the president of Impax'
5 generic division at the time; correct?

6 A. Correct.

7 Q. Okay. All right. Can we go back to
8 CX 0004-014.

9 Now, Mr. Engle, at the bottom of the first
10 table, four lines up -- four rows up -- excuse me -- do
11 you see the line that says "Impax net sales"?

12 A. Yes.

13 Q. That's the -- that represents the projected net
14 sales under this forecast for Impax' generic version of
15 Opana ER; correct?

16 A. Correct.

17 Q. And that's dollar sales in this forecast;
18 correct?

19 A. Yes.

20 Q. And do you see the upper left-hand corner where
21 it says -- there is a box that says "Upside"?

22 A. I see that.

23 Q. This is indicating that the net sales are being
24 calculated based on the upside scenario; right?

25 A. Correct.

1 Q. And in June of 2010, the Impax net sales row
2 says sales of 2,922.

3 Do you see that?

4 A. I do.

5 Q. And that's in thousands; correct?

6 A. Correct.

7 Q. So that would be \$2.922 million.

8 A. Correct.

9 Q. And for July of 2010, under the upside
10 scenario, net sales are projected to be \$8.181 million;
11 correct?

12 A. Correct.

13 Q. And then in August of 2010, Impax' net sales of
14 generic Opana ER under the upside scenario are
15 projected to be 3.347 million; correct?

16 A. Correct.

17 Q. And the forecast assumes that in August of
18 2010 the generic market -- Impax' generic market share
19 goes from 100 percent to 60 percent; correct?

20 A. Correct.

21 Q. In other words, rather than getting all the
22 generic sales, you're projecting that Impax would get
23 60 percent of the generic sales in August of 2010;
24 correct?

25 A. Correct.

1 Q. And the reason that this forecast assumes that
2 market share -- generic market share would go from
3 100 percent to 60 percent is that the forecast is
4 assuming that another generic enters in August of 2010;
5 correct?

6 A. It seems logical, but I can't tell from this
7 forecast for sure.

8 Q. The additional generic competitor would be an
9 authorized generic; correct?

10 A. I don't know.

11 Q. Well, you understood that Impax had 180 days of
12 exclusivity at this time period; correct?

13 A. I'm just not sure what -- I -- I -- I'm just
14 not sure about the understanding of this specific
15 model at this time and what all the assumptions were
16 without seeing -- a lot of times there's -- it might
17 mention how many generic competitors are there.

18 Q. Regardless of the -- of which type of generic
19 competitor it is, in August of 2010, the introduction
20 of that additional generic competitor under the upside
21 scenario causes the price to go from 55 percent of the
22 brand WAC to 35 percent.

23 Do you see that?

24 A. Yes. I see that assumption.

25 Q. And that results in August of 2010 forecasted

1 net sales of \$3.347 million; right?

2 A. Correct. I see that.

3 Q. And then in September of 2010, the forecast
4 projects sales of Impax' generic oxymorphone ER of
5 3.57 million.

6 Do you see that?

7 A. Yes, I do.

8 Q. And the reason that sales increased from August
9 to September of 2010 is that the forecast is assuming
10 that the generic penetration rate increased from
11 75 percent to 80 percent; correct?

12 A. Yes. I see that change.

13 Q. And then sales go down again in December of
14 2010 to 2.975 million.

15 Do you see that?

16 A. Yes, I see that.

17 Q. And that corresponds to a lower generic market
18 share for Impax under the upside scenario.

19 Do you see that?

20 A. Yes, I see that change.

21 Q. And that's -- and you're making that change
22 because you're assuming that there would be additional
23 generic entrants in December of 2010; correct?

24 A. Most likely.

25 Q. And that's because Impax' 180-day exclusivity

1 would have expired by December of 2010; correct?

2 A. I believe so.

3 Q. Now, down at the very bottom of this page, it
4 has a forecast summary in thousands.

5 Do you see that?

6 A. Yes.

7 Q. And it shows Impax net sales?

8 Do you see that?

9 A. Yes.

10 Q. And under this upside scenario, Impax'
11 projected net sales for the entirety of 2010 are
12 28,132,000; correct?

13 A. Correct.

14 Q. And for 2011, you're projecting total sales of
15 Impax' generic oxymorphone ER of \$8,064,000; correct?

16 A. Yes. I see that number.

17 Q. And the drop-off in sales between 2010 and
18 2011 is the effect of additional generic competition;
19 correct?

20 A. Possibly. This model doesn't show that. You
21 can't see it, but...

22 Q. Ms. Clark, can you show more of the document.

23 Well, if you look at the Impax generic market
24 share in March of 2011, it goes down to 40 percent;
25 correct?

1 A. Yes. I see that number now.

2 Q. Can I ask you to turn to the next page.

3 And it continues at 40 percent and then
4 declines down to 35 percent later; correct?

5 A. Yes. I see that.

6 Q. And so 40 percent of Impax' generic market
7 share is a lower number than we saw in 2010; correct?

8 A. Correct.

9 Q. Now, the base scenario has more conservative
10 assumptions about the generic's entry date, price and
11 market share; correct?

12 A. Yes. They're all lower.

13 Q. Right.

14 So you assume a later generic entry date than
15 the upside scenario; correct?

16 A. Did you say "in the upside scenario"?

17 Q. In the base-case scenario you assume a later
18 generic entry date than you did in the upside scenario;
19 correct?

20 A. Correct. In this model, yes.

21 Q. And you assume a lower generic price in the
22 base scenario as compared to the upside scenario;
23 correct?

24 A. Correct.

25 Q. And you assume a lower generic market share in

1 the base scenario than you do in the upside scenario;
2 correct?

3 A. That's correct. In this model.

4 Q. And so you would expect that the base scenario
5 would have even lower projected net sales for 2010 and
6 2011 than the upside scenario; correct?

7 A. Correct.

8 Q. In fact, in 2010 it would be zero; correct?
9 Under the base scenario.

10 A. Correct.

11 Q. You can take that down, Ms. Clark.

12 Now, Mr. Engle, you're aware of a term in the
13 settlement agreement between Endo and Impax called the
14 Endo credit?

15 A. Yes. I'm familiar with that term.

16 Q. And you're aware that Endo paid Impax
17 approximately \$102 million as part of the settlement
18 under the Endo credit provision; correct?

19 A. Yes.

20 Q. And you participated in a steering committee of
21 Impax and Endo personnel related to the Endo credit
22 provision; correct?

23 A. Only to the extent that we compared quarterly
24 data to make sure we were on the same page.

25 Q. Right.

1 The steering committee would meet or perhaps
2 talk on the phone quarterly to look at the IMS data,
3 the peak sales information, that would ultimately be
4 used for purposes of calculating the Endo credit;
5 correct?

6 A. Partially correct because I believe Endo used
7 one source of data, IMS, and Impax was using a
8 different source of data provided by Wolters Kluwer,
9 and we just wanted to make sure that they were
10 approximately in alignment.

11 Q. And you would do that quarterly with Endo
12 employees; correct?

13 A. Correct.

14 Q. Are you familiar with the actual settlement
15 agreement in this case?

16 A. I -- really only bits and pieces of it, such as
17 previously I'd worked with just this section about
18 calculating the credit.

19 Q. Well, let me put up -- actually, let me ask you
20 to turn in your binder to RX 364.

21 And you recognize RX 364 as at least the first
22 page of the settlement and license agreement between
23 Impax and Endo?

24 A. Yes.

25 Q. Can I ask you to turn to RX 364-0012.

1 And do you see this the middle there's a
2 section 4.4?

3 A. I see that.

4 Q. And it says "Endo Credit."

5 Do you see that?

6 A. Yes.

7 Q. This is a provision that you worked with;
8 correct?

9 A. I believe it is. The part I remember was kind
10 of a complicated formula.

11 Q. I'll show you the portions where they have the
12 formula.

13 A. Okay.

14 Q. Okay. But before we get there, I want to just
15 direct you to section 4.5 which is right underneath the
16 "Endo Credit" language.

17 Do you see that?

18 A. Yes.

19 Q. And it's entitled Steering Committee.

20 Do you see that?

21 A. Yes.

22 Q. And the first sentence says, "Promptly after
23 the Effective Date, the Parties will form a committee
24 (the 'Steering Committee'), equally represented by Endo
25 and Impax, to meet within forty-five days after the end

1 of each quarter, beginning with the quarter ending
2 June 30, 2010, to determine in good faith Prescription
3 Sales figures for the Opana ER Products (for which
4 dosage strengths Impax has obtained first applicant
5 status, as described in Section 505(j)(5)(B)(iv) of the
6 FD&C Act), including the Quarterly Peak, if any."

7 Do you see that language?

8 A. Yes, I do.

9 Q. And that is the steering committee that you
10 participated in; correct?

11 A. I believe it is.

12 Q. And on a quarterly basis, you did those things;
13 right? You got together and compared sales numbers;
14 correct?

15 A. Correct.

16 Q. And the meetings were actually done typically
17 by conference call; right?

18 A. Correct.

19 Q. And they usually lasted about five or ten
20 minutes?

21 A. Correct.

22 Q. There weren't really any disputes between Impax
23 and Endo over the sales numbers?

24 A. Correct.

25 Q. In general, the information that you were

1 discussing with Endo was pretty straightforward;
2 correct?

3 A. Correct.

4 Q. And when it came to determining the actual Endo
5 credit amount, there wasn't any dispute between Impax
6 and Endo about what numbers should be plugged into the
7 Endo credit formula; correct?

8 JUDGE CHAPPELL: You mean to his knowledge?
9 Because he's not all of Impax. Your question is pretty
10 broad for someone sitting here who's a single employee
11 of the company.

12 MR. LOUGHLIN: Okay. Thank you, Your Honor.
13 I'll make it more precise.

14 BY MR. LOUGHLIN:

15 Q. To your knowledge -- let me start that over.

16 You testified earlier that you were involved in
17 helping to calculate the Endo credit; correct?

18 A. I was involved to a certain extent.

19 Q. Okay. And to your knowledge, when it came to
20 determining the actual Endo credit payment, there
21 wasn't any dispute between Impax and Endo about what
22 numbers should be put into the Endo credit formula;
23 correct?

24 A. Could you clarify whether you're referring to
25 the -- at the final payment?

1 Q. Yes. Thank you.

2 I am referring to, when it came down to
3 determining the actual final payment that Endo was
4 going to make to Impax, to your knowledge, there wasn't
5 any dispute between Impax and Endo about what numbers,
6 what sales numbers, should be put into the Endo credit
7 formula; correct?

8 A. I'm not aware of a dispute, but I -- I gave the
9 data to accounting and accounting took care of working
10 with Endo, so I wasn't involved in the final steps of
11 the process.

12 Q. But those numbers would have been agreed upon
13 by Endo and Impax as part of the steering committee
14 meetings; correct?

15 A. I don't recall ever having a final steering
16 committee meeting. We would just meet periodic -- at
17 the quarterly along the way, but when it reached the
18 end, I don't recall ever having a final meeting or
19 participating in a final meeting with Endo.

20 Q. You don't recall that there was a final
21 quarterly meeting to discuss the quarterly sales at the
22 end of the Endo credit?

23 A. I don't recall that, no.

24 Q. Mr. Engle, could I ask you to turn in your
25 binder to CX 3438.

1 And Ms. Clark, can you put up -- well, let me
2 just state for the record, Your Honor, that CX 3438 has
3 been admitted as part of JX 2. It is partially
4 in camera, but we have redacted out the in camera
5 portions, and I don't intend to ask about any of those
6 portions.

7 JUDGE CHAPPELL: You know what I meant to say
8 also, I appreciate the parties have done a heckuva job
9 preventing numerous in camera sessions the way you've
10 redacted and limited your questions. I appreciate it.

11 MR. LOUGHLIN: Thank you, Your Honor.

12 BY MR. LOUGHLIN:

13 Q. Could I ask you to turn to CX 3438-002,
14 Mr. Engle. That's the second page in that document.

15 Are you there, Mr. Engle?

16 A. Yes, sir.

17 Q. Now, this is a presentation that you made to
18 Impax' board of directors on August 22, 2012; correct?

19 A. Correct.

20 Q. And you tried to present accurate information
21 to the board; correct?

22 A. Correct.

23 Q. Now, if I could ask -- direct your attention to
24 CX 3438-0023.

25 A. Okay. I'm there.

1 Q. Okay. Do you see the title says
2 "Oxymorphone ER Go-to-Market Strategy"? Do you see
3 that heading?

4 A. Yes.

5 Q. Okay. And under the first bullet that says
6 "Settlement with Brand," do you see the second sort of
7 subbullet says "Compensation for declining market"?

8 A. I see that.

9 Q. And you wrote that bullet, "Compensation for
10 declining market"; correct?

11 A. Yes.

12 Q. And you wrote that because the purpose of the
13 Endo credit payment was to compensate Impax for the
14 decline in the market for the original formulation of
15 Opana ER; correct?

16 MR. HASSI: Objection. Foundation,
17 Your Honor.

18 There's been no foundation that -- I don't
19 want to make a speaking objection. Objection.
20 Foundation.

21 MR. LOUGHLIN: Your Honor, he wrote the
22 sentence. I'm asking what he meant by the words in his
23 own document.

24 MR. HASSI: And my objection, Your Honor, is
25 to any testimony from this gentleman about the purpose

1 of the Endo credit, which we've only elicited he was
2 involved in calculating the numbers after the fact.

3 JUDGE CHAPPELL: And based on your explanation
4 that you're asking him because he wrote it, then just
5 ask him what he meant by what he wrote. You're leading
6 him, but the way you're leading him, there's no
7 foundation for that area.

8 Sustained.

9 MR. HASSI: Thank you, Your Honor.

10 BY MR. LOUGHLIN:

11 Q. Mr. Engle, when you wrote "Compensation for
12 declining market," you meant that the Endo credit
13 payment was to compensate Impax for the decline in the
14 market for the original formulation of Opana ER;
15 correct?

16 A. I really don't know what I meant at the time.
17 It was many years ago.

18 Q. Could I refresh your recollection by showing
19 you your testimony from 2014?

20 A. Okay.

21 Q. Could I ask you to turn in your binder to the
22 tab that says "IH."

23 JUDGE CHAPPELL: Hold on.

24 What testimony in 2014 are you referring to?

25 MR. LOUGHLIN: His investigational hearing

1 testimony, Your Honor.

2 BY MR. LOUGHLIN:

3 Q. And specifically page 271 at line 9 through 14.

4 Do you see where it says, the question is:

5 "What is 'compensation for declining market'?

6 "ANSWER: It refers to the size of the
7 oxymorphone market -- the original formulation of the
8 market -- I think it's original formulation of the
9 market declining."

10 Do you see that?

11 A. I'm sorry. Did you say page 271?

12 Q. Yes. At line 9.

13 271. There should be four boxes on the page.

14 Do you see that?

15 A. Are you looking at CX 4004-044?

16 Q. No. I'm looking at CX 404-069 (sic). In the
17 upper right-hand corner there should be a page that has
18 271 in the upper right-hand corner.

19 Do you see that?

20 A. Okay. So page 271?

21 Q. Page 271 -- so, yeah, on what's marked
22 CX 404-069 (sic) there should be four boxes of
23 testimony. Do you see that? And in the upper
24 right-hand corner there's one that says "271"?

25 A. Yes, I see that.

1 Q. Okay. And do you see the line number 9?

2 A. I see that.

3 Q. And it says, "What is 'compensation for
4 declining market'?" And your answer was: "It refers
5 to the size of the oxymorphone market -- the original
6 formulation of the market -- I think it's original
7 formulation of the market declining."

8 Do you see that?

9 A. Yes, I see that.

10 Q. Does that refresh your recollection of what
11 you meant by "compensation for declining market" in
12 CX --

13 JUDGE CHAPPELL: That's not exactly the
14 question you had asked earlier that was objected to.

15 MR. LOUGHLIN: I know it wasn't, Your Honor. I
16 was refreshing his recollection.

17 JUDGE CHAPPELL: All right.

18 THE WITNESS: I see that.

19 BY MR. LOUGHLIN:

20 Q. Ms. Clark, can you put back up CX 3438 and back
21 on page CX 3438-023.

22 Are you there, Mr. Engle?

23 A. Yes, sir.

24 Q. So looking back at the same subbullet where it
25 says "Compensation for declining market," do you see

1 next to it it says "approximately \$110 million"?

2 A. Yes, I see that.

3 Q. That's the payment at the time you were
4 expecting Impax would get from Endo under the Endo
5 credit provision of the settlement; correct?

6 A. Correct.

7 Q. And you calculated the \$110 million?

8 A. I don't recall if I did it. It may have
9 been -- I don't recall if I did it, did the calculation
10 for this particular slide.

11 Q. Do you recall where you would have gotten that
12 \$110 million if not a calculation by yourself?

13 A. It may have come from --

14 MR. HASSI: Calls for speculation, Your Honor.

15 THE WITNESS: It may have come from one of my
16 coworkers.

17 BY MR. LOUGHLIN:

18 Q. Did you supervise --

19 JUDGE CHAPPELL: Hold it.

20 He answered it may have come from a coworker.

21 Do you withdraw your objection?

22 MR. HASSI: Yes, Your Honor.

23 BY MR. LOUGHLIN:

24 Q. Did you supervise the calculation of the
25 \$110 million estimate of the Endo credit payment in

1 this -- that's listed in this document, CX 3438?

2 A. I don't recall. I just don't recall that.

3 Q. Do you recall running calculations of the Endo
4 credit payment --

5 A. I do. I do recall running calculations.

6 Q. And when you did that -- let me start that
7 over.

8 Let me ask you to turn back to RX 364-0003.

9 And do you see up at the top it says -- there's
10 "Endo Credit" and it has a definition?

11 A. I see that.

12 Q. Is this the formula that you mentioned before
13 having recognized as having worked with?

14 A. I believe that's it.

15 Q. And you used this formula to calculate the Endo
16 credit payment at some point in time?

17 A. I did it, but others did it as well.

18 Q. At what point in time did you do it?

19 A. I don't -- I think right when we thought the
20 trigger was hit I think we, Kevin and I -- I say "we"
21 because I'm referring to Kevin Sica and myself -- we
22 took a shot at calculating it.

23 Q. Do you see in the first line -- looking back at
24 RX 364-003, in the first line under Endo Credit, it
25 says, "'Endo Credit' means an amount equal to the

1 product obtained by multiplying (i) the difference
2 between the Trigger Threshold and the Pre-Impax Amount
3 by (ii) the Market Share Profit Value."

4 Do you see that?

5 A. Yes.

6 Q. And could I ask you to look at RX 364-0005.

7 And specifically the definition of "Pre-Impax
8 Amount," do you see that?

9 A. I see that.

10 Q. And based on this, one of the things you would
11 need to determine the pre-Impax amount is the
12 prescription sales of the Endo product for the three
13 months from October 1, 2012 through December 31, 2012.

14 Do you see that?

15 A. I do see that.

16 Q. And the Endo product is Opana ER; correct?

17 A. Correct.

18 Q. When you were doing your calculation of the
19 Endo credit, did you have information regarding the
20 prescription sales of Opana ER from October 1, 2012
21 through December 31, 2012?

22 A. I believe this is all driven off of
23 Wolters Kluwer data or IMS data, so we probably just
24 queried that data.

25 Q. But were you doing this after

1 December 31, 2012 such that you had that data or were
2 you doing it beforehand?

3 A. I don't recall.

4 Q. You don't recall whether you had the data or
5 you had to make assumptions about the data?

6 A. Correct.

7 Q. Okay. Looking back at the "Pre-Impax Amount"
8 definition -- can you put that back up, Ms. Clark --
9 the other thing that you would need is the quarterly
10 peak.

11 Do you see that?

12 A. I see that.

13 Q. Okay. And "Quarterly Peak" begins at the
14 bottom of RX 364.0005 and continues onto the next page,
15 RX 364.0006.

16 Do you see that?

17 A. I see it.

18 Q. And according to this definition, it says the
19 "'Quarterly Peak' means the highest Prescription Sales
20 of the Endo Product during any calendar quarter period
21 from July 1, 2010 through September 30, 2012."

22 Do you see that?

23 A. Yes.

24 Q. Do you recall when you were doing the Endo
25 credit calculation whether you had information

1 regarding the sales between July 1, 2010 through
2 September 30, 2012?

3 A. I don't recall the circumstances around it.

4 Q. You don't recall whether you had the
5 information or had to make assumptions about the
6 information?

7 A. I don't recall.

8 Q. Mr. Engle, can I ask you to turn to, in your
9 binder, CX 3347.

10 And I will note for the record, Your Honor,
11 that CX 3347 has been admitted as part of JX 2 and it
12 is not in camera.

13 Do you have it there, Mr. Engle?

14 A. Yes.

15 Q. Now, this is an e-mail that you sent; correct?

16 A. Correct.

17 Q. And you sent it on February 2, 2010?

18 A. Correct.

19 Q. And among the recipients are Chris Mengler.

20 Do you see that?

21 A. Yes.

22 Q. And as we said earlier, Mr. Mengler is the
23 president -- or at the time was the president of Impax'
24 generic division; correct?

25 A. Correct.

1 Q. You also sent this to Larry Hsu.

2 Do you see that?

3 A. Yes.

4 Q. And Dr. Hsu in 2010 was the CEO of Impax;
5 correct?

6 A. Correct.

7 Q. And do you see the subject is Quarterly Launch
8 Planning Meeting Background Documentation?

9 A. Yes, I see that.

10 Q. And if you -- the remaining pages of CX 3347 is
11 the documentation on the products that you intend to
12 cover at the quarterly launch planning meeting on
13 February 2, 2010; correct?

14 A. Correct.

15 Q. And at this time, in February of 2010, you
16 coordinated the quarterly launch planning meeting;
17 correct?

18 A. Correct.

19 Q. And at quarterly launch planning meetings,
20 Impax discussed launch plans for products in the
21 pipeline that were going to be launched in the future;
22 correct?

23 A. Correct.

24 Q. And you say in your cover e-mail, "It is
25 important for us to get through the following products

1 today."

2 Do you see that?

3 A. Yes, I do.

4 Q. And the first one on your list is oxymorphone?

5 Do you see that?

6 A. I do.

7 Q. That's oxymorphone ER; correct?

8 A. Correct.

9 Q. Could I ask you to turn to the second page of
10 this document, CX 3347-002.

11 And this is the documentation you provided to
12 the -- for the quarterly launch planning meeting
13 regarding oxymorphone ER; correct?

14 A. Correct.

15 Q. And if you look at CX 3347-003, at the very
16 bottom of that page there's a box labeled
17 Recommendation.

18 Do you see that?

19 A. I do.

20 Q. And it says, "Prepare to launch June 14, 2010;
21 Consider obtaining board approval for an at-risk
22 launch"; correct?

23 A. Yes.

24 Q. So as of February 2010, the recommendation was
25 to launch generic Opana ER on June 14, 2010; correct?

1 A. No. It actually -- I wrote in here that the
2 next logical step would be consider obtaining board
3 approval. I didn't -- I didn't -- it doesn't recommend
4 a launch. It says...

5 Q. Did you -- I'm sorry. Did you finish your
6 answer?

7 A. Yes.

8 Q. Okay. Let me rephrase it. Okay?

9 As of February 2010, the recommendation was to
10 prepare to launch on June 14, 2010; correct?

11 A. I see that, yeah.

12 Q. And you hadn't yet decided -- or let me start
13 that over.

14 Impax hadn't yet decided whether to launch, but
15 you would need board approval; correct?

16 A. Can you restate your question, please.

17 Q. Sure.

18 When you said, "Consider obtaining board
19 approval for an at-risk launch," what you meant was
20 Impax or at least the quarterly planning launch
21 committee hadn't yet decided whether to recommend a
22 launch; correct?

23 A. Well, this -- this particular committee
24 doesn't make that decision. It is about preparing for
25 launch, so this was just my recommendation that

1 consider it, that this is -- this committee -- this
2 committee doesn't make that decision to launch or --

3 Q. I see.

4 So your recommendation was that Impax should
5 prepare to launch on June 14 and consider obtaining
6 board approval for such a launch; is that right?

7 A. That's right.

8 Q. Okay. Can I ask you to turn to CX 3348.

9 Are you there?

10 A. I am there.

11 Q. Okay. And this is another e-mail from you;
12 correct?

13 A. Correct.

14 Q. This is the -- again related to the quarterly
15 launch planning meeting; correct?

16 A. Correct.

17 Q. This one is dated May 20, 2010; correct?

18 A. Right. Correct.

19 Q. And so this is the next quarterly meeting of
20 the launch planning committee after February 2010;
21 right?

22 A. Correct.

23 Q. And again, this is you sending the
24 documentation regarding the products that were to be
25 discussed at the May 20, 2010 quarterly launch planning

1 meeting; correct?

2 A. Correct.

3 Q. And if you turn to CX 3348-002, which should be
4 the next page in your document, you see that the first
5 item listed is Oxymorphone ER Tablets June 2010? Do
6 you see that?

7 A. I do.

8 Q. And that's generic Opana ER; correct?

9 A. Correct.

10 Q. And looking at CX 3348-003 to CX 3348-004,
11 this is the information regarding oxymorphone ER;
12 correct?

13 A. Correct.

14 Q. And if you look at CX 3348-004, your
15 recommendation is still "Prepare to launch June 14,
16 2010; Consider obtaining board approval for an at-risk
17 launch"; right?

18 A. Correct.

19 Q. And that was the current launch plan as of
20 May 20, 2010.

21 A. That was my current recommendation.

22 Q. That was your current recommendation as of
23 May 20, 2010.

24 A. Correct.

25 Q. That was your recommendation to the quarterly

1 launch planning committee, which included Mr. Mengler
2 and Dr. Hsu; correct?

3 A. Correct.

4 Q. Now, can I ask you to turn back to the prior
5 page, CX 3348-003, and do you see a box sort of in the
6 middle of the page labeled Competitors?

7 A. Yes, I see that.

8 Q. And it lists Endo, Sandoz, Teva, Actavis and
9 Roxane.

10 Do you see that?

11 A. Yes, I do.

12 Q. And these are all companies that could launch a
13 generic version of Opana ER; correct?

14 A. Correct.

15 Q. And so the only competitors you're looking at
16 in this document are generic companies and the branded
17 company Endo; right?

18 A. Right. They're my assumptions.

19 Q. And for Endo it says "potential AG, may have
20 potential to launch AG immediately."

21 Do you see that?

22 A. I do see that.

23 Q. "AG" means authorized generic; right?

24 A. Yes. That's what I was referring to.

25 Q. You were concerned that Endo could launch an

1 authorized generic version of Opana ER immediately upon
2 Impax' launch; correct?

3 A. Yes. I have that assumption.

4 Q. Do you see down at the bottom of that same
5 large box under Commercial it says "Comments"?

6 A. Yes, I see it.

7 Q. And the comments are: "PV completed; launch
8 build is bright stocked."

9 Do you see that?

10 A. Yes, I see that.

11 Q. And PV is process validation; correct?

12 A. Correct.

13 Q. And that means that the manufacturing has been
14 scaled up to commercial requirements; correct?

15 A. Well, in addition to it being scaled up, it's
16 also been validated.

17 Q. In other words, it's been -- it works. The
18 manufacturing process works for commercial
19 manufacturing?

20 A. Correct.

21 Q. And it also means that the process validation
22 batches have been manufactured; correct?

23 A. Correct.

24 Q. And with respect to the comment that says
25 "launch build is bright stocked," do you see that one?

1 A. I do see that.

2 Q. That means that the product has been
3 manufactured into tablets, packaged into bottles, but
4 there's no labeling on them yet; correct?

5 A. Correct. It means the product is packaged and
6 no labels.

7 Q. In other words, there would be no labeling
8 because at this point in May of 2010 Impax would still
9 be working with the FDA on final labeling; is that
10 right?

11 A. Correct.

12 Q. Now, occasionally at Impax the company prepares
13 product but then doesn't launch; correct?

14 A. Correct.

15 Q. And when that happens, the product might
16 expire?

17 A. Yes. Correct.

18 Q. And then Impax has to throw away the expired
19 product; right?

20 A. Correct.

21 Q. But if Impax has to throw away a small amount,
22 it's not really a big deal; correct?

23 A. I would -- I believe management would have
24 varying levels of tolerance for how much product is
25 thrown away.

1 Q. Well, not just your assumption, right, you
2 know that a small amount in the range of \$50,000 of
3 finished goods being thrown away is not a big deal;
4 right?

5 A. Correct. I -- I see that routinely.

6 Q. Right.

7 Whereas a million dollars of finished product
8 being thrown away, that would be a large amount;
9 correct?

10 A. Well, it's certainly larger and would attract
11 attention.

12 Q. And for oxymorphone ER, Impax had to throw away
13 over \$1.5 million in product; correct?

14 A. I don't recall the amount.

15 Q. You don't?

16 A. No.

17 Q. Okay. Well, can I ask you to turn to CX --
18 well, actually, let me start over.

19 Now let me ask you to turn to CX 0006,
20 Mr. Engle.

21 Are you there?

22 A. Yes, I am there.

23 Q. This is an e-mail from you, dated May 28, 2010.

24 Do you see that?

25 A. Yes, I see that.

1 Q. And if you turn to the page CX 0006-003 --

2 A. Okay.

3 Q. -- this is information that you put together
4 showing what would be needed for a launch of
5 oxymorphone ER; correct?

6 A. Correct.

7 Q. And you see where it says "PV cost"?

8 A. Yes.

9 Q. That refers to the process validation batches
10 that were already manufactured by Impax; correct?

11 A. Correct.

12 Q. And if you look down at the bottom of that
13 column, the cost is over \$1.5 million?

14 A. I see that.

15 Q. And that's the cost to make that product;
16 correct?

17 A. Correct.

18 Q. And Impax had to throw away all that process
19 validation product; correct?

20 A. I don't recall specifically, but it's
21 possible.

22 Q. You don't recall that because of the
23 settlement, Impax did not launch in 2010; correct?

24 A. I do remember that part.

25 Q. And the product that it had on hand in June of

1 2010 expired before Impax could use it for marketing in
2 2013; correct?

3 A. Okay. You're right.

4 Q. And so Impax had to throw away all of that
5 product that it had on hand as of June of 2010;
6 correct?

7 A. Correct.

8 Q. And that would include all of the process
9 validation batches that are listed in CX 0006;
10 correct?

11 A. Correct.

12 MR. LOUGHLIN: All right.

13 JUDGE CHAPPELL: How much more time do you
14 think you need?

15 MR. LOUGHLIN: Actually, I'm finished,
16 Your Honor.

17 JUDGE CHAPPELL: All right.

18 Cross?

19 MR. HASSI: Yes.

20 MR. LOUGHLIN: Thank you, Mr. Engle.

21 JUDGE CHAPPELL: Mr. Hassi, has your estimate
22 changed from an hour?

23 MR. HASSI: I'm sorry, Your Honor?

24 JUDGE CHAPPELL: Has your time estimate
25 changed?

1 MR. HASSI: I think it will be shorter than an
2 hour. Yes, Your Honor.

3 JUDGE CHAPPELL: I think we'll take a short
4 break since we've been going over an hour and a half
5 now.

6 Take a seat. It will be a minute.

7 MR. HASSI: Yes, Your Honor.

8 JUDGE CHAPPELL: I've got to finish some notes
9 here.

10 (Pause in the proceedings.)

11 All right. We'll reconvene at 4:15.

12 We're in recess.

13 (Recess)

14 JUDGE CHAPPELL: Back on the record.

15 Go ahead.

16 MR. HASSI: Yes, Your Honor.

17 - - - - -

18 CROSS-EXAMINATION

19 BY MR. HASSI:

20 Q. Good afternoon, Mr. Engle.

21 Sir, in your role in sales and marketing at
22 Impax, are you ever involved in settlement
23 negotiations?

24 A. No, sir.

25 Q. Are you ever involved in patent litigation?

1 A. No.

2 Q. Were you involved in the settlement
3 negotiations between Impax and Endo?

4 A. No.

5 Q. Were you aware that Impax and Endo entered
6 into a settlement of that patent litigation at some
7 point?

8 A. Yes. I became aware.

9 Q. When did you first learn that Impax and Endo
10 were in settlement negotiations?

11 A. I don't recall when I learned, but there were
12 negotiations ongoing.

13 Q. When did you first learn of the settlement?

14 A. I believe it was when the settlement was
15 announced.

16 Q. Did you have any involvement in drafting any
17 terms of the settlement?

18 A. No.

19 Q. You were asked some questions about the Endo
20 credit.

21 Were you involved in any way, shape or form in
22 the drafting of the Endo credit?

23 A. No.

24 Q. When did you first hear about the Endo credit?

25 A. Upon the settlement being announced.

1 Q. And you were asked some questions about a board
2 slide by complaint counsel in which you note a payment
3 resulting from the Endo credit.

4 On what did you base your understanding of that
5 payment?

6 A. It was my interpretation of that section of the
7 agreement.

8 Q. And I take it that was an interpretation you
9 made reading the settlement agreement after the
10 settlement was finalized?

11 A. Correct.

12 Q. And you were involved in calculating the
13 payment under the agreement?

14 A. I did a draft of it. As I mentioned earlier,
15 accounting took over and finished up the work with
16 Endo.

17 Q. And was that sometime near the date on which
18 the payment became due from Endo?

19 A. I don't recall the date.

20 Q. Let's look at those slides.

21 If we can bring up -- it's CX 3438. And if you
22 could just blow up the cover e-mail.

23 Sir, was it around the time of this board
24 presentation that you were first asked to calculate the
25 amount of the Endo credit?

1 A. Yes.

2 Q. So sometime in the third quarter of 2012?

3 A. That's correct.

4 Q. Had you done any calculations of what the Endo
5 credit might be before that?

6 A. I don't remember doing any of those
7 calculations before that.

8 Q. You talked at length this afternoon about
9 forecasts.

10 What role do assumptions play in a forecast?

11 A. The assumptions really drive the potential
12 outcomes of the model.

13 So I -- I have a wide range of assumptions
14 and...

15 Q. Do you use different assumptions based on the
16 purpose of a forecast? You can put the binder aside.
17 I'm sorry.

18 Do you use different assumptions depending upon
19 the purpose of a forecast?

20 A. I do.

21 Q. And tell us, what are the different types of
22 forecasts you prepare at Impax?

23 A. I prepare forecasts for operations that
24 forecast market packages that we believe we will sell.
25 And I also forecast net sales, which I believe,

1 you know, were taking those operational forecasts and
2 turning it into a net sales forecast.

3 Q. Do you ever prepare forecasts on a one-off
4 basis?

5 A. I do.

6 Q. And under what circumstances would you prepare
7 a one-off forecast?

8 A. If someone in management would ask me to
9 produce one.

10 Q. And you were asked a number of questions about
11 CX 4.

12 Can you bring that up, please. And just blow
13 up the cover, yeah, the top third.

14 Do you recall being asked about this document?

15 A. Yes, I do.

16 Q. And it's an e-mail you sent to Mr. Mengler?

17 I'm sorry. Mr. Sica sent --

18 A. Copied on.

19 Q. Okay. Would this have been part of the normal
20 five-year planning process based on this e-mail?

21 A. No. This doesn't look like a normal five-year
22 planning process forecast.

23 Q. Do you know why Mr. Mengler asked you for this
24 information, you and Mr. Sica?

25 A. I'm looking at the first line, which refers to

1 his slides, so it looks like Mr. Mengler was working on
2 slides.

3 Q. And do you know what the source of the
4 assumptions you used in this five-year forecast were?

5 A. Not specifically.

6 Q. Do you know what Mr. Mengler was doing -- would
7 be doing with this information?

8 A. I don't recall. I can't really tell from this
9 e-mail.

10 Q. And other than reading this e-mail, do you have
11 any recollection as to why you prepared -- you and
12 Mr. Sica prepared the forecast that you went through at
13 length this afternoon?

14 A. No.

15 Q. And do you have any information as to who
16 developed the assumptions that were used in that
17 forecast?

18 A. No, I don't.

19 Q. Is one of the assumptions that you come up
20 with in your forecasting process a launch date
21 assumption?

22 A. It is.

23 Q. And how do you select a potential launch date
24 for a Paragraph IV pipeline product?

25 A. I use the expiration date of the 30-month

1 stay.

2 Q. And I should back up a second. I asked you
3 Paragraph IV.

4 Do you know what a Paragraph IV is generally?

5 A. I do.

6 Q. And you referenced a 30-month stay.

7 What is a 30-month stay in connection with a
8 Paragraph IV?

9 A. It's my understanding, when there's a
10 Paragraph IV filing, there is a 30-month stay granted
11 automatically, so that's the -- the 30-month stay is
12 the earliest possible date a company could get on the
13 market.

14 Q. And so why do you use the end of the 30-month
15 stay as a potential launch date in your forecasting
16 assumptions?

17 A. Because it is the earliest possible date --
18 from the legal perspective, that's the earliest
19 possible date, so we're just trying to be ready on day
20 one.

21 Q. We saw in your forecast that you looked at this
22 afternoon a base case.

23 What does "base case" mean when you forecast
24 it?

25 A. That's really my starting point. I have to

1 start modeling out some point, and then once I do a --
2 that first version, I try to think, if everything
3 possibly could go really well, what would the
4 optimistic be, to kind of put a range, put guardrails
5 on the range of possibilities.

6 Q. And in addition to a base case, we saw an
7 upside case.

8 What's the upside case?

9 A. That would be the most -- I'd say the
10 optimistic version where everything would go in the
11 opportune situation.

12 Q. Do you recall what date you picked as a
13 potential launch date assumption for Opana ER?

14 A. Well, we looked at the documents earlier which
15 said June 14, 2010.

16 Q. And do you know why you chose that date?

17 A. Well, that was the date of the expiration of
18 the 30-month stay.

19 Q. When you chose that date, were you accounting
20 for any regulatory risk associated with a potential
21 launch of oxymorphone ER?

22 A. No.

23 Q. When you chose that date, were you accounting
24 for any legal risk associated with the potential launch
25 of oxymorphone ER?

1 A. No.

2 Q. Did your forecast of the June 14, 2010 date
3 account for risk in any way?

4 A. No.

5 Q. Who makes the decision whether to launch a
6 Paragraph IV pipeline product?

7 A. Senior management.

8 Q. Are you involved in making the final decision
9 to launch a Paragraph IV product with senior
10 management?

11 A. No, I'm not involved.

12 Q. Were you ever involved with senior management
13 in a discussion about making a decision to launch
14 Opana ER?

15 A. No.

16 Q. You were asked a number of questions about the
17 quarterly launch planning committee.

18 What was your role in that committee?

19 A. Essentially I was asked to do duty as a project
20 manager to run the project or keep the products on
21 track and moving forward, so I was coordinating the
22 launch summary meeting.

23 Q. And we saw some documents, including
24 CX 3347 which I'll bring up in a minute, but did you
25 send that around before the meeting?

1 A. I generally did. I tried to get it out just
2 before the meeting.

3 Q. And what was the purpose in sending it around
4 to people who were going to attend the meeting?

5 A. To refresh the people's recollection of where
6 we are with all the products and create a dialogue
7 about the next steps.

8 Q. Let's bring up CX 3347 if we could, please,
9 Robert.

10 And so is this a quarterly launch planning
11 meeting background document that you sent around?

12 A. What I see here is the e-mail, yes, with -- it
13 probably has an attachment with it.

14 Q. Okay. And you would have sent this in advance
15 of the meeting?

16 A. I would try to. I don't know if I was always
17 successful.

18 Q. Well, let's look at page 2.

19 And if you could highlight the Commercial
20 section, the second section down. Thank you, Robert.

21 Do you see there it says "Projected Launch Date
22 June 14, 2010"?

23 A. Yes, I see that.

24 Q. How was that date chosen?

25 A. Well, that's the date that I put in there for

1 the expiration of the 30-month stay.

2 Q. And tell us again, what's the significance of
3 that date?

4 A. Well, it's my understanding that's the earliest
5 possible date a generic company could potentially
6 launch a product.

7 Q. Under Competitors, you were asked some question
8 about the line "Endo - potential AG, may have potential
9 to launch AG immediately."

10 Did you have any information one way or
11 another as to whether Endo might launch an authorized
12 generic?

13 A. No, I did not.

14 Q. So why did you put that information there?

15 A. It's just one of my assumptions that there's a
16 potential for that.

17 Q. If we could go to page 3.

18 And if you could blow up the Recommendation at
19 the bottom of the block.

20 Who wrote this recommendation, sir?

21 A. I wrote that recommendation.

22 Q. And what were you trying to tell the quarterly
23 launch planning group when you wrote this
24 recommendation?

25 A. Well, that's my recommendation that we would --

1 should prepare to launch and that, you know, my
2 assessment of the next logical step in the process
3 would be there needs to be a discussion about
4 obtaining board approval if that's what they want to
5 do.

6 Q. Does the quarterly launch planning committee
7 make recommendations to the board?

8 A. Not directly as a -- as you can see, there's
9 members, Larry Hsu is a member, but this committee does
10 not make that -- is not involved in that part.

11 Q. Where does the recommendation from this
12 committee go with respect to, for example, a launch?

13 A. Well, this committee actually doesn't produce
14 any recommendations.

15 Q. What happens to the recommendation on this
16 page, if anything?

17 A. Well, because some of the members of this
18 committee are also members of senior management, such
19 as Larry Hsu, all I know is he -- he would go off and
20 do whatever CEOs do. I don't know how he handles it or
21 what he does next with it.

22 Q. Did this recommendation that you wrote include
23 any sort of risk assessment as part of your
24 recommendation?

25 A. No.

1 Q. Did you have any information about the status
2 of the litigation when you wrote this in February of
3 2010?

4 A. No.

5 Q. Did you have any information about the status
6 of settlement discussions when you wrote this in
7 February of 2010?

8 A. No.

9 Q. And we looked at another one of these. It's
10 CX 3348.

11 And if we can just blow up the first page.

12 Can you tell us what this is?

13 A. This would be the May 20 e-mail I sent with an
14 agenda for the second quarter quarterly launch planning
15 meeting.

16 Q. And if we look at the oxymorphone form that
17 starts on page -3 and carries over to page -4, is it
18 essentially the same form?

19 A. It is.

20 Q. What do you do with this form in between the
21 February meeting and the May meeting -- what did you do
22 with this form between the February meeting and the May
23 meeting?

24 A. I don't recall specifically. I might have
25 updated a couple pieces of information.

1 Q. So, for example, on page -- on the first page
2 of it, which is page -3, in Comments -- it's the bottom
3 of that box. No. Further down, please, Robert. Yeah,
4 right there -- do you see -- did you have a comment
5 that says "PV completed; launch build is bright
6 stocked"?

7 A. I see that.

8 Q. Is that something that you added based on
9 information you had from within the corporation?

10 A. I believe I did do -- I did that.

11 Q. Do you know if the full launch build was
12 bright-stocked at that point in time?

13 A. I've seen other documents that show that it
14 wasn't built at that time.

15 Q. Let's go to page -4.

16 At the bottom, did your recommendation change
17 between February and May?

18 A. It looks like it's word for word the same.

19 Q. Did you need to update it in any way?

20 A. I don't believe anything changed.

21 Q. Did -- at the time you wrote this, did you
22 have any information about the status of the
23 litigation?

24 A. No.

25 Q. Any information about the status of settlement

1 discussions?

2 A. No.

3 Q. Did you do any risk adjustment in making this
4 recommendation?

5 A. No.

6 Q. Do you know what happened, if anything, with
7 this recommendation?

8 A. I don't believe it went anywhere.

9 Q. Does this recommendation reflect the thinking
10 at the time of senior management?

11 A. No. That recommendation just reflects my
12 thinking walking into this meeting.

13 Q. Beyond your forecast being used in operational
14 preparedness efforts, what responsibilities do you have
15 at Impax -- or did you have in 2010 at Impax in
16 connection with operational launch preparation?

17 A. Would you mind repeating that.

18 Q. Sure.

19 You talked about providing forecasts to
20 operations; right?

21 A. Correct.

22 Q. Did you have any other responsibilities related
23 to operational preparedness for launching drugs at
24 Impax?

25 A. Yes, I did.

1 Q. What other responsibilities did you have?

2 A. In my role, I'm responsible for sales and
3 marketing and preparing the sales and marketing
4 department to be able to function, to be able to
5 launch the product, to be able to sell the product.

6 I also worked with the folks in operations to
7 be able to secure quota or letters of intent from
8 customers to secure additional quota for a C-II,
9 Schedule II products.

10 Q. Sir, I want to bring up -- let's bring up
11 RX 323.

12 And if you could -- I believe you were asked
13 about another version of this document.

14 If you could bring up the middle e-mail from
15 Mr. Engle.

16 Is this an e-mail you sent?

17 A. It is.

18 Q. And you sent it around May 17?

19 A. Correct.

20 Q. Could you read the first sentence and tell us
21 what you -- well, strike that.

22 Who is Mike Grigsby?

23 A. Mike Grigsby is one of the national account
24 managers, one of our salesmen.

25 Q. And actually, if we could bring up

1 Mr. Grigsby's e-mail below that first.

2 What was Mr. Grigsby asking you here in the
3 first bullet point?

4 A. He was actually asking if a press release was
5 correct and that if we were going to be launching the
6 product oxymorphone ER on June 22.

7 Q. And what was your response?

8 A. I believe I said no. Yeah, right here.
9 There's -- basically I said no, there's not -- it's not
10 ready to launch.

11 Q. You wrote, "A launch decision has not been made
12 yet."

13 Who makes that decision?

14 A. Senior management.

15 Q. What did you tell him that he could tell
16 customers?

17 A. I told him there's nothing to tell customers
18 yet.

19 Q. Okay. And the fourth sentence says, "There has
20 been no decision yet to complete the launch build."

21 Do you see that?

22 A. I do see that.

23 Q. As of May 17, 2010, had the launch build been
24 completed?

25 A. No.

1 Q. What was the legal maneuvering you reference in
2 your e-mail here?

3 A. I actually don't know what was going on with
4 any of the legal stuff, so I just kind of generalized
5 and used that term to respond to this e-mail.

6 Q. In your experience as the person who helps with
7 operational planning, if Impax was going to launch on
8 June 14, would you have had to have had a launch build
9 in process at this point in time?

10 A. Yes.

11 Q. Could you have been ready -- based on not
12 having started the launch build, could you have been
13 ready to launch in June 2010 based on this?

14 A. Not in my opinion.

15 Q. And what makes you say that?

16 A. The time lag between May 17 and that
17 June 14 date, that's just too short to make the rest of
18 the product.

19 JUDGE CHAPPELL: Regarding that, you're in
20 sales and marketing. If you had the product and could
21 load it onto trucks, railroad cars, did you have a
22 wholesaler agreement? Was that stuff already set up?
23 Or would you have been stuck with the product sitting
24 on a dock?

25 THE WITNESS: I don't believe we had any

1 conversations with any of our customers at this time
2 about pricing, so we wouldn't have anywhere to go with
3 the product if it was made.

4 JUDGE CHAPPELL: I mean, when you say your
5 customers, you're referring to the three wholesalers
6 you named for me earlier?

7 THE WITNESS: I'm sorry. Can you --

8 JUDGE CHAPPELL: The Cardinal Health, the three
9 wholesalers you named earlier, is that who you refer to
10 as your customers?

11 THE WITNESS: They are some of our customers.
12 We sell to other customers as well.

13 JUDGE CHAPPELL: And the way this works is
14 Cardinal Health, for example, will buy drugs from your
15 company, and then Cardinal Health handles
16 distribution?

17 THE WITNESS: Correct.

18 JUDGE CHAPPELL: Out to pharmacies, wherever.

19 THE WITNESS: Correct.

20 JUDGE CHAPPELL: All right. Thanks.

21 BY MR. HASSI:

22 Q. Can you just identify, in addition to the
23 wholesalers, who some of your other customers are?

24 A. We sell to some of the larger national
25 pharmacy chains, such as CVS and Walgreens and

1 Rite Aid. We also sell to a number of smaller
2 pharmacy chains, such as Publix or Winn Dixie, and some
3 small national -- or small regional wholesalers and
4 distributors.

5 Q. In May of 2010, had you done any preselling
6 activities to generate market demand for generic
7 Opana ER?

8 A. No.

9 Q. Who was Chuck Hildenbrand in May of 2010?

10 A. He was the head of operations.

11 Q. Let me show you a document that's been marked
12 CX 6.

13 It's on JX 2, in evidence and not in camera.

14 And I think you saw this earlier in response to
15 some questions from complaint counsel.

16 Tell me what you were conveying to
17 Mr. Hildenbrand in this e-mail, please.

18 A. I was conveying what my forecast showed for
19 what additional product needed to be manufactured to be
20 able to complete a launch.

21 Q. How much material did you have available at
22 this point in time, May 28, 2010, if you were to
23 launch?

24 A. Well, I can't tell from this snippet that I see
25 here.

1 Q. You say, in the first sentence, "to be able to
2 launch and have enough material for month one, we would
3 need one lot of 20 milligram and three lots of
4 40 milligram."

5 Do you see that?

6 A. I see that.

7 Q. Does that mean you don't even have enough
8 material to launch for month one?

9 MR. LOUGHLIN: Objection. Leading.

10 MR. HASSI: I'll rephrase.

11 JUDGE CHAPPELL: All right.

12 BY MR. HASSI:

13 Q. What did you mean when you said "we would need
14 one lot of 20 milligram and three lots of
15 40 milligram"?

16 A. So based on my forecast, I'm saying I need one
17 additional lot of 20 milligram and three additional
18 lots of 40 milligram just to meet my month one
19 estimate.

20 Q. And tell us what is a month one estimate.

21 A. Well, a month one estimate is the amount of
22 product I believe I will sell or be able to sell in
23 the very first full 30 days of sales, of selling
24 efforts.

25 Q. And as someone who does forecasting for

1 operations, would you launch a drug if you had less
2 than one month's worth of the first month of sales
3 available to you?

4 MR. LOUGHLIN: Objection. Lack of foundation.

5 MR. HASSI: Your Honor, he's testified he does
6 the forecasting for exactly these purposes. I'm happy
7 to lay a longer foundation, but --

8 MR. LOUGHLIN: Your Honor, he's not the person
9 that does -- decides whether to launch.

10 JUDGE CHAPPELL: Rephrase the question.

11 MR. HASSI: Okay.

12 JUDGE CHAPPELL: Sustained.

13 BY MR. HASSI:

14 Q. As the person who does -- do you do
15 forecasting, among other things, for the launch of
16 products?

17 A. Yes, I do.

18 Q. Okay. And understanding that you don't make
19 the decision, do you do forecasting as to how much
20 product Impax should have available before a launch?

21 A. I do.

22 Q. And based on your experience in forecasting
23 how much product Impax should have available for a
24 launch, is less than one month's worth of product
25 enough to launch a product?

1 A. It's not enough to launch with.

2 Q. What would have happened if you launched with
3 less than one month worth of product at this point in
4 time?

5 A. We would have rapidly run out of product, and
6 most likely I would have started to incur penalties
7 from my customers for not delivering on time.

8 Q. You were asked some questions -- you can take
9 that down, Robert. Thanks.

10 You were asked some questions by complaint
11 counsel about the need to destroy \$1.5 million worth of
12 oxymorphone ER. Do you recall that?

13 A. Yes.

14 Q. Have you in your experience -- well, strike
15 that.

16 Where does that fall in the range of product
17 that has to be set aside or destroyed, in your
18 experience, at Impax?

19 MR. LOUGHLIN: Objection. Vague.

20 JUDGE CHAPPELL: Do you understand the
21 question?

22 THE WITNESS: I believe I do, sir.

23 JUDGE CHAPPELL: Overruled.

24 THE WITNESS: Throwing away product or
25 discarding product in about a 1.5 million range happens

1 frequently and it -- it's not unusual.

2 BY MR. HASSI:

3 Q. Without revealing the product or the time frame
4 involved, have you heard of larger numbers?

5 A. I have heard of larger numbers.

6 Q. Can you give us an order of magnitude of what
7 kind of numbers you've heard about?

8 A. I've -- I've heard about up to -- one more
9 recently this year in 2017 of 25 million.

10 MR. HASSI: Your Honor, I have no further
11 questions.

12 JUDGE CHAPPELL: Any redirect?

13 MR. LOUGHLIN: Yes, Your Honor.

14 JUDGE CHAPPELL: Go ahead.

15 I meant to say redirect within the scope of the
16 cross.

17 MR. LOUGHLIN: Understood, Your Honor.

18 - - - - -

19 REDIRECT EXAMINATION

20 BY MR. LOUGHLIN:

21 Q. Mr. Engle, throwing away \$1.5 million worth of
22 product in 2010 was a large amount; right?

23 A. It is a large amount.

24 Q. It was a large enough amount to attract
25 attention from management; right?

1 A. Correct.

2 Q. I believe respondent's counsel showed you a
3 document RX 23.

4 Can we put that up.

5 MR. HASSI: It might have been 323, Chuck.

6 MR. LOUGHLIN: 323, yes. Thank you. 323.

7 BY MR. LOUGHLIN:

8 Q. And down at the bottom, the e-mail -- you were
9 asked about the e-mail from Mr. Grigsby. Do you recall
10 that?

11 A. Yes, I do.

12 Q. And he mentions -- he says, in the first
13 bullet, "Will the launch date be the June 22nd date
14 listed in the press release?"

15 Do you see that?

16 A. I see that.

17 Q. Had Impax issued a press release regarding the
18 launch of oxymorphone ER as of May 17, 2010?

19 A. I don't recall that.

20 Q. That's what Mr. Grigsby is asking in the
21 e-mail. He's asking about that in the e-mail; right?

22 A. He is asking about a press release. I'm not
23 sure if it's an Impax press release.

24 Q. Oh, I see.

25 But there was -- to your recollection, there

1 was a press release discussing a June 22 launch date
2 for oxymorphone ER?

3 A. There was something in the news.

4 Q. Now, you were also asked by Mr. Hassi regarding
5 promotion to customers about a launch of generic
6 oxymorphone. Do you recall that?

7 A. Yes.

8 Q. Are you aware of whether Impax got letters of
9 intent from customers that those customers would buy
10 from Impax upon launch in June of 2010?

11 A. I do recall asking for letters of intent.

12 Q. From customers.

13 A. Correct.

14 Q. And customers gave you those letters of intent
15 stating that they would buy from Impax upon launch in
16 June of 2010; correct?

17 A. That is correct. But they don't contain
18 pricing or any agreement.

19 Q. Can I ask you to turn to CX 3347. It's in your
20 binder, Mr. Engle. It's the February 2, 2010 quarterly
21 launch planning meeting.

22 A. I have it.

23 Q. And as we see on the first page, some of the
24 recipients of this e-mail were Mr. Mengler; correct?

25 A. Correct.

1 Q. Mr. Hsu; correct?

2 A. Correct.

3 Q. And Mr. Hildenbrand; correct?

4 A. Correct.

5 Q. Were they in senior management at Impax?

6 A. Yes.

7 Q. And if you'd turn to CX 3347-003, and again I'm
8 directing your attention to the recommendation.

9 And that was your recommendation to prepare to
10 launch on June 14, 2010; correct?

11 A. Correct.

12 Q. Did you get any disagreement from anyone in
13 senior management regarding that recommendation?

14 A. I don't recall.

15 Q. Well, why don't you turn to CX 3348. It should
16 be the next document in your tab.

17 And specifically CX 3348-004.

18 Do you have it?

19 A. I have it.

20 Q. And the recommendation prepare to launch
21 June 14, 2010 is the same as it was in the prior
22 document from February of 2010; correct?

23 A. Correct.

24 Q. Would you have put the same recommendation in
25 the May 2010 board -- excuse me -- May 2010 document if

1 you had gotten disagreement from senior management
2 about that recommendation?

3 A. I don't remember getting the agreement or
4 disagreement. I just am putting the same thing down.
5 I don't always expect that the CEO is going to tell me
6 everything he's thinking.

7 Q. But does the fact that the recommendation is
8 the same from February to May indicate to you that you
9 were not told by anybody, "Hey, that's wrong"?

10 A. I don't think anyone told me that was wrong.

11 Q. Could you turn back to CX 3348-003. It's the
12 prior page in the same document.

13 And do you see under Commercial the row that
14 says "Forecast Assumptions"?

15 A. Yes, I see that.

16 Q. And it says "200 percent launch build."

17 Do you see that?

18 A. I see that.

19 Q. That means you wanted twice as much as you
20 needed to launch; correct?

21 A. Correct.

22 Q. Mr. Engle, can you turn to CX 3438 and page --
23 specifically CX 3438-002.

24 Do you have it, Mr. Engle?

25 A. Yes.

1 Q. And this is the board of directors
2 presentation that you put together in August of 2012;
3 correct?

4 A. Correct.

5 Q. And I believe, in response to questions from
6 Mr. Hassi regarding the calculations you did of the
7 Endo credit, you said that you did those calculations
8 in August of 2012. Is that right?

9 A. I believe so.

10 Q. And by "calculations," just so I'm clear, I'm
11 referring to the calculations of the Endo credit that
12 we see on CX 3438-023.

13 That's a calculation where you determined --
14 or you estimated that it would be \$110 million;
15 correct?

16 A. Correct.

17 Q. And you calculated that in August of 2012.

18 A. Correct.

19 Q. Okay. Can I ask you to turn to RX 364. And
20 specifically RX 364-005.

21 And Ms. Clark, can you highlight or make bigger
22 the section on Pre-Impax Amount.

23 Are you there, Mr. Engle?

24 A. Yes, I am.

25 Q. And this is the portion of the settlement

1 agreement between Impax and Endo that we looked at
2 earlier in your testimony. Do you recall that?

3 A. Yes.

4 Q. And we looked at the fact that "Pre-Impax
5 Amount" talks about the three months from
6 October 1, 2012 through December 31, 2012.

7 Do you see that?

8 A. Yes, I see that.

9 Q. So in August of 2012, you didn't have
10 information about the prescription sales of Opana ER
11 from October 1, 2012 through December 31, 2012; right?

12 A. Correct.

13 Q. So you had to make an assumption about that?

14 A. Yes.

15 Q. Do you know what number you assumed?

16 A. No.

17 Q. But you were -- with that -- but you were able
18 to make an assumption and use that for your calculation
19 in August of 2012; correct?

20 A. I was probably estimating off of the existing
21 Wolters Kluwer trend.

22 Q. I'm sorry. What do you mean by that?

23 A. If I didn't have the actual data because this
24 time period did not occur yet, I'd have to look at the
25 Wolters Kluwer data and extrapolate.

1 Q. I see.

2 So you used the Wolters Kluwer data that you
3 had in August of 2012 and extrapolated what the sales
4 would be from October 1, 2012 through December 31,
5 2012; is that right?

6 A. That's the only way I can think about doing it
7 I think.

8 Q. Okay. Now, looking down at the bottom of
9 RX 364.0004 and onto RX 364.0006, the Quarterly Peak
10 definition, do you see that?

11 A. Yes, I do.

12 Q. And we looked at this earlier today. Do you
13 recall that?

14 A. Yes.

15 Q. And this Quarterly Peak definition discusses
16 the highest prescription sales of Opana ER during any
17 calendar quarter from July 1, 2010 through
18 September 30, 2012.

19 Do you see that?

20 A. I do see that.

21 Q. So in August of 2012 you didn't have
22 information all the way through September 30, 2012;
23 correct?

24 A. Correct.

25 Q. So you had to make an assumption about that

1 information as well; correct?

2 A. I think it would be possible that there may
3 have been a peak already, so that data might show that
4 there was already a peak at that point. It's
5 possible.

6 Q. Well, as of August of 2012, would you have
7 already known that there would have been a peak earlier
8 than all the way through September 30, 2012 without
9 knowing the sales?

10 A. No. It's theoretically possible. It's
11 theoretically possible you could have already had the
12 peak. The peak may have already occurred.

13 Q. You think it's possible that the peak would
14 have already occurred even though you didn't have all
15 the sales information through September 30, 2012; is
16 that right?

17 A. That's an approximately 26-month time period
18 between July 1, 2010 and September 30, 2012, so it's
19 possible there was a peak in there somewhere.

20 Q. But you wouldn't have actually known whether
21 that peak was higher than what it would have ended up
22 at as of September 30, 2012; right? That date hadn't
23 come yet.

24 A. It's theoretically possible that in August of
25 2012 the trend was already downward, so it's possible.

1 Q. I see.

2 So you would have looked at the trend and made
3 an assumption about what sales would have been through
4 September 30, 2012; is that right?

5 A. Yes.

6 Q. You would have extrapolated in the same way you
7 did for the sales between October and December of 2012;
8 is that right?

9 A. Correct.

10 Q. So even though you hadn't yet gotten all the
11 way through the actual sales information, with the
12 assumptions about the sales in the fourth quarter of
13 2012 and the assumptions about sales, the peak sales,
14 you were able to do an estimate of the Endo credit;
15 correct?

16 A. Yes.

17 Q. You were able to plug those -- that information
18 into the Endo credit formula and get an estimated
19 payment; correct?

20 A. Correct.

21 Q. And based on information that you got on a
22 quarterly basis between 2010 and 2012, you had the
23 capability to plug numbers from those sales figures
24 into the Endo credit formula and get an estimate of the
25 Endo credit formula -- Endo credit payment as of that

1 date in time; correct?

2 A. Yeah. I think that capability existed.

3 MR. LOUGHLIN: I have nothing further,
4 Your Honor.

5 JUDGE CHAPPELL: Anything else?

6 MR. HASSI: A few brief questions. Yes,
7 Your Honor.

8 JUDGE CHAPPELL: Go ahead.

9 - - - - -

10 RE-CROSS-EXAMINATION

11 BY MR. HASSI:

12 Q. Mr. Engle, you were asked a number of questions
13 about calculating the Endo credit in 2012 just now.

14 Do you recall when Endo switched from Opana ER
15 to reformulated Opana ER?

16 A. No. I don't recall the date.

17 Q. Do you recall whether it was in 2012?

18 A. No, I don't.

19 Q. Do you recall whether at the end of the first
20 quarter in 2012 Endo made an announcement with its
21 financial release that it was reserving \$110 million to
22 pay Impax? Do you recall that?

23 A. I do remember that and you're refreshing my
24 recollection of that.

25 Q. Tell us what you remember about that.

1 A. Actually, I believe I was surprised at the time
2 that the number was close to the number we had
3 estimated.

4 Q. You were asked some questions about wanting a
5 200 percent of your intended launch build with respect
6 to the quarterly launch planning meeting. Do you
7 recall that?

8 A. Yes, I do.

9 Q. Did you get 200 percent of your launch build in
10 2010 built?

11 A. No.

12 Q. And you were asked some -- a question or two
13 about letters of intent.

14 Can you explain to the judge what a letter of
15 intent is and what its purpose is?

16 A. The letter is to request -- it's a form letter
17 listing the different strengths and the packages size,
18 and it asks the customer for their good-faith estimate,
19 is if Impax were to have this product, how much of the
20 product would you be likely to buy, based on their own
21 forecast of how much they need or how much they sell,
22 with the -- the idea is that it's a good-faith estimate
23 to secure additional quota from DEA.

24 However, this form letter does not have pricing
25 on it, and there's no official agreement of sale. It's

1 just a statement of intent.

2 Q. And you said this form letter is to secure
3 quota from the DEA.

4 Quota for what?

5 A. It's actually a quota for all C-II products
6 such as this -- in this particular case, it's
7 oxymorphone ER.

8 Q. And quota for oxymorphone ER or for something
9 used to make oxymorphone ER with?

10 A. Well, it's actually the raw material for the
11 active pharmaceutical ingredient. When we have a C-II
12 product, our kind of nomenclature for it is quota, but
13 it is actually getting the permission to buy the raw
14 materials.

15 MR. HASSI: Thank you, Mr. Engle.

16 Nothing further, Your Honor.

17 JUDGE CHAPPELL: I saw earlier on one of the
18 documents -- and they weren't in camera -- I saw a cost
19 of like \$6.34 maybe. Was that per hundred? Do you
20 have any idea of what that amount was?

21 THE WITNESS: That --

22 JUDGE CHAPPELL: It's the one where you had
23 base and, you know, that chart.

24 THE WITNESS: Right. Right. I -- may I look
25 at it again, sir?

1 JUDGE CHAPPELL: Well, I'm just wondering --
2 and if it's proprietary, don't tell me -- but what's
3 the cost per pill? What did it end up being?

4 THE WITNESS: It vary -- the cost of our
5 products range anywhere from pennies per tablet to
6 multiple dollars per tablet.

7 So some products are relatively expensive to
8 make, and oxymorphone is a relatively expensive product
9 for us to make.

10 JUDGE CHAPPELL: So \$6.00 a pill wouldn't be
11 unreasonable?

12 THE WITNESS: No.

13 JUDGE CHAPPELL: Just wondering.

14 THE WITNESS: Yeah.

15 JUDGE CHAPPELL: Not that important.

16 Anything further?

17 MR. LOUGHLIN: No, Your Honor.

18 JUDGE CHAPPELL: Thank you. You may stand
19 down.

20 Next witness.

21 MR. LOUGHLIN: Your Honor, we have a rebuttal
22 expert, but other than that, complaint counsel rests,
23 Your Honor.

24 JUDGE CHAPPELL: All right. Are you prepared
25 to tell me how many witnesses you're calling?

1 MR. HASSI: Your Honor, we anticipate calling
2 three experts and three, possibly four fact witnesses.

3 You may recall two of those fact witnesses
4 we'd like to call on Tuesday, the 14th, so next week
5 we intend to call our three experts in the following --
6 I think in the following order: Mr. Figg, Dr. Michna,
7 Dr. Dr. Addanki, and then we have an Endo witness,
8 Mr. Cobuzzi.

9 And there's a possibility we may have -- I
10 don't think so, but we may have Ted Smolenski who you
11 heard about, a little bit about today.

12 That would be it for next week subject to
13 Mr. Hoxie appearing in counsel's rebuttal case.

14 And then on Tuesday, the 14th, we would have
15 Michael Nestor and Larry Hsu, and that will complete
16 our case.

17 JUDGE CHAPPELL: And someone on your staff will
18 be sending my office the e-mail?

19 MR. HASSI: Yes, Your Honor.

20 JUDGE CHAPPELL: With that detail?

21 MR. HASSI: Yes, Your Honor.

22 JUDGE CHAPPELL: Anything else before we close
23 for the day?

24 MR. LOUGHLIN: Not from complaint counsel,
25 Your Honor.

1 MR. HASSI: Not for respondents, Your Honor.

2 JUDGE CHAPPELL: Anything, Lawman?

3 THE BAILIFF: No, Your Honor.

4 JUDGE CHAPPELL: Josett?

5 THE REPORTER: No.

6 JUDGE CHAPPELL: Give everybody a chance.

7 We'll reconvene Monday at 9:45 a.m.

8 Until then we're in recess.

9 (Whereupon, the foregoing hearing was adjourned
10 at 5:10 p.m.)

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1 CERTIFICATE OF REPORTER

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3

4 I, JOSETT F. WHALEN, do hereby certify that the
5 foregoing proceedings were taken by me in stenotype and
6 thereafter reduced to typewriting under my supervision;
7 that I am neither counsel for, related to, nor employed
8 by any of the parties to the action in which these
9 proceedings were taken; and further, that I am not a
10 relative or employee of any attorney or counsel
11 employed by the parties hereto, nor financially or
12 otherwise interested in the outcome of the action.

13

14

15

s/Josett F. Whalen

16

JOSETT F. WHALEN

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Court Reporter

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